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Title 42
Public Health

Parts 414 to 429

Revised as of October 1, 2025

Containing a codification of documents
of general applicability and future effect

As of October 1, 2025

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Title 1 through Title 16.....as of January 1
Title 17 through Title 27.....as of April 1
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OLIVER A. POTTS,
Director,
Office of the Federal Register
October 1, 2025.

THIS TITLE

Title 42—PUBLIC HEALTH is composed of five volumes. The parts in these volumes are arranged in the following order: Parts 1–399, parts 400–413, parts 414–429, parts 430–481, and part 482 to end. The first volume (parts 1–399) contains current regulations issued under chapter I—Public Health Service (HHS). The second, third, and fourth volumes (parts 400–413, parts 414–429, and parts 430–481) include regulations issued under chapter IV—Centers for Medicare & Medicaid Services (HHS) and the fifth volume (part 482 to end) contains the remaining regulations in chapter IV and the regulations issued under chapter V by the Office of Inspector General-Health Care (HHS). The contents of these volumes represent all current regulations codified under this title of the CFR as of October 1, 2025.

For this volume, Gabrielle E. Burns was Chief Editor. The Code of Federal Regulations publication program is under the direction of John Hyrum Martinez, assisted by Stephen J. Frattini.

Title 42—Public Health

(This book contains parts 414 to 429)

Part

CHAPTER IV—Centers for Medicare & Medicaid Services, Department of Health and Human Services (Continued) 414

CHAPTER IV—CENTERS FOR MEDICARE & MEDICAID SERVICES, DEPARTMENT OF HEALTH AND HUMAN SERVICES (CONTINUED)

EDITORIAL NOTE: Nomenclature changes to chapter IV appear at 62 FR 46037, Aug. 29, 1997; 66 FR 39452, July 31, 2001; and 67 FR 36540, May 24, 2002.

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AUTHORITY: 42 U.S.C. 1302, 1395hh, and 1395rr(b)(1).

SOURCE: 55 FR 23441, June 8, 1990, unless otherwise noted.

EDITORIAL NOTE: Nomenclature changes to part 414 appear at 60 FR 50442, Sept. 29, 1995, and 60 FR 53877, Oct. 18, 1995.

Subpart A—General Provisions

§ 414.1 Basis and scope.

This part implements the following provisions of the Act:

1802—Rules for private contracts by Medicare beneficiaries.

1833—Rules for payment for most Part B services.

1834(a) and (h)—Amounts and frequency of payments for durable medical equipment and for prosthetic devices and orthotics and prosthetics.

1834(l)—Establishment of a fee schedule for ambulance services.

1834(m)—Rules for Medicare reimbursement for telehealth services.

1834A—Improving policies for clinical diagnostic laboratory tests

1842(o)—Rules for payment of certain drugs and biologicals.

1847(a) and (b)—Competitive bidding for certain durable medical equipment, prosthetics, orthotics, and supplies (DMEPOS).

1848—Fee schedule for physician services.

1881(b)—Rules for payment for services to ESRD beneficiaries.

1887—Payment of charges for physician services to patients in providers.

[67 FR 9132, Feb. 27, 2002, as amended at 69 FR 1116, Jan. 7, 2004; 71 FR 48409, Aug. 18, 2006; 81 FR 41098, June 23, 2016; 90 FR 20808, May 16, 2025]

§ 414.2 Definitions.

As used in this part, unless the context indicates otherwise—

AA stands for anesthesiologist assistant.

AHPB stands for adjusted historical payment basis.

CF stands for conversion factor.

CRNA stands for certified registered nurse anesthetist.

CY stands for calendar year.

FY stands for fiscal year.

GAF stands for geographic adjustment factor.

GPCI stands for geographic practice cost index.

HCPCS stands for CMS Common Procedure Coding System.

Health Professional Shortage Area (HPSA) means an area designated under section 332(a)(1)(A) of the Public Health Service Act as identified by the Secretary prior to the beginning of such year.

Major surgical procedure means a surgical procedure for which a 10-day or 90-day global period is used for payment under the physician fee schedule and section 1848(b) of the Act.

Physician services means the following services to the extent that they are covered by Medicare:

(1) Professional services of doctors of medicine and osteopathy (including osteopathic practitioners), doctors of optometry, doctors of podiatry, doctors of dental surgery and dental medicine, and chiropractors.

(2) Supplies and services covered ''incident to'' physician services (excluding drugs as specified in § 414.36).

(3) Outpatient physical and occupational therapy services if furnished by a person or an entity that is not a

Medicare provider of services as defined in §400.202 of this chapter.

(4) Diagnostic x-ray tests and other diagnostic tests (excluding diagnostic laboratory tests paid under the fee schedule established under section 1833(h) of the Act).

(5) X-ray, radium, and radioactive isotope therapy, including materials and services of technicians.

(6) Antigens, as described in section 1861(s)(2)(G) of the Act.

(7) Bone mass measurement.

RVU stands for relative value unit.

(8) Screening mammography services.

[56 FR 59624, Nov. 25, 1991, as amended at 57 FR 42492, Sept. 15, 1992; 58 FR 63686, Dec. 2, 1993; 59 FR 63463, Dec. 8, 1994; 60 FR 63177, Dec. 8, 1995; 63 FR 34328, June 24, 1998; 66 FR 55322, Nov. 1, 2001; 75 FR 73616, Nov. 29, 2010]

§414.4 Fee schedule areas.

(a) *General.* CMS establishes physician fee schedule areas that generally conform to the geographic localities in existence before January 1, 1992.

(b) *Changes.* CMS announces proposed changes to fee schedule areas in the FEDERAL REGISTER and provides an opportunity for public comment. After considering public comments, CMS publishes the final changes in the FEDERAL REGISTER.

[59 FR 63463, Dec. 8, 1994]

§414.5 Hospital services paid under Medicare Part B when a Part A hospital inpatient claim is denied because the inpatient admission was not reasonable and necessary, but hospital outpatient services would have been reasonable and necessary in treating the beneficiary.

(a) If a Medicare Part A claim for inpatient hospital services is denied because the inpatient admission was not reasonable and necessary, or if a hospital determines under §482.30(d) of this chapter or §485.641 of this chapter after a beneficiary is discharged that the beneficiary's inpatient admission was not reasonable and necessary, the hospital may be paid for any of the following Part B inpatient services that would have been reasonable and necessary if the beneficiary had been treated as a hospital outpatient rather than admitted as an inpatient, provided the beneficiary is enrolled in Medicare Part B:

(1) Services described in §419.21(a) of this chapter that do not require an outpatient status.

(2) Physical therapy services, speech-language pathology services, and occupational therapy services.

(3) Ambulance services, as described in section 1861(v)(1)(U) of the Act, or, if applicable, the fee schedule established under section 1834(l) of Act.

(4) Except as provided in §419.2(b)(11) of this chapter, prosthetic devices, prosthetics, prosthetic supplies, and orthotic devices.

(5) Except as provided in §419.2(b)(10) of this chapter, durable medical equipment supplied by the hospital for the patient to take home.

(6) Clinical diagnostic laboratory services.

(7)(i) Effective December 8, 2003, screening mammography services; and

(ii) Effective January 1, 2005, diagnostic mammography services.

(8) Effective January 1, 2011, annual wellness visit providing personalized prevention plan services as defined in §410.15 of this chapter.

(b) If a Medicare Part A claim for inpatient hospital services is denied because the inpatient admission was not reasonable and necessary, or if a hospital determines under §482.30(d) of this chapter or §485.641 of this chapter after a beneficiary is discharged that the beneficiary's inpatient admission was not reasonable and necessary, the hospital may be paid for hospital outpatient services described in §412.2(c)(5), §412.405, §412.540, or §412.604(f) of this chapter or §413.40(c)(2) of this chapter that are furnished to the beneficiary prior to the point of inpatient admission (that is, the inpatient admission order).

(c) The claims for the Part B services filed under the circumstances described in this section must be filed in accordance with the time limits for filing claims specified in §424.44(a) of this chapter.

[78 FR 50968, Aug. 19, 2013]

Subpart B—Physicians and Other Practitioners

SOURCE: 56 FR 59624, Nov. 25, 1991; 57 FR 42492, Sept. 15, 1992, unless otherwise noted.

§ 414.20 Formula for computing fee schedule amounts.

(a) *Participating supplier.* The fee schedule amount for a participating supplier for a physician service as defined in § 414.2 is computed as the product of the following amounts:

(1) The RVUs for the service.

(2) The GAF for the fee schedule area.

(3) The CF.

(b) *Nonparticipating supplier.* The fee schedule amount for a nonparticipating supplier for a physician service as defined in § 414.2 is 95 percent of the fee schedule amount as calculated in paragraph (a) of this section.

[62 FR 59101, Oct. 31, 1997]

§ 414.21 Medicare payment basis.

Medicare payment is based on the lesser of the actual charge or the applicable fee schedule amount.

[62 FR 59101, Oct. 31, 1997]

§ 414.22 Relative value units (RVUs).

CMS establishes RVUs for physicians' work, practice expense, and malpractice insurance.

(a) *Physician work RVUs*—(1) *General rule.* Physician work RVUs are established using a relative value scale in which the value of physician work for a particular service is rated relative to the value of work for other physician services.

(2) *Special RVUs for anesthesia and radiology services)*—(i) *Anesthesia services.* The rules for determining RVUs for anesthesia services are set forth in § 414.46.

(ii) *Radiology services.* CMS bases the RVUs for all radiology services on the relative value scale developed under section 1834(b)(1)(A) of the Act, with appropriate modifications to ensure that the RVUs established for radiology services that are similar or related to other physician services are consistent with the RVUs established for those similar or related services.

(b) *Practice expense RVUs.* (1) Practice expense RVUs are computed for each service or class of service by applying average historical practice cost percentages to the estimated average allowed charge during the 1991 base period.

(2) The average practice expense percentage for a service or class of services is computed as follows:

(i) Multiply the average practice expense percentage for each specialty by the proportion of a particular service or class of service performed by that specialty.

(ii) Add the products for all specialties.

(3) For services furnished beginning calendar year (CY) 1994, for which 1994 practice expense RVUs exceed 1994 work RVUs and that are performed in office settings less than 75 percent of the time, the 1994, 1995, and 1996 practice expense RVUs are reduced by 25 percent of the amount by which they exceed the number of 1994 work RVUs. Practice expense RVUs are not reduced to less than 128 percent of 1994 work RVUs.

(4) For services furnished beginning January 1, 1998, practice expense RVUs for certain services are reduced to 110 percent of the work RVUs for those services. The following two categories of services are excluded from this limitation:

(i) The service is provided more than 75 percent of the time in an office setting; or

(ii) The service is one described in section 1848(c)(2)(G)(v) of the Act, codified at 42 U.S.C. 1395w–4(c)(2)(G). Section 1848(c)(2)(G)(v) of the Act refers to the 1998 proposed resource-based practice expense RVUs (as specified in the June 18, 1997 physician fee schedule proposed rule (62 FR 33158)) for the specific site, either in-office or out-of-office, increased from its 1997 practice expense RVUs.)

(5) For services furnished in 2002 and subsequent years, the practice expense RVUs are based entirely on relative practice expense resources.

(i) Usually there are two levels of practice expense RVUs that correspond to each code.

(A) *Facility practice expense RVUs.* The facility practice expense RVUs apply to services furnished to patients in a hospital, a skilled nursing facility,

a community mental health center, a hospice, or an ambulatory surgical center, or in a wholly owned or wholly operated entity providing preadmission services under § 412.2(c)(5) of this chapter, or via telehealth under § 410.78 of this chapter.

(B) *Nonfacility practice expense RVUs.* The nonfacility practice expense RVUs apply to services furnished to patients in all locations other than those listed in paragraph (b)(5)(i)(A) of this section, but not limited to, a physician's office, the patient's home, a nursing facility, or a comprehensive outpatient rehabilitation facility (CORF).

(C) *Outpatient therapy and CORF services.* Outpatient therapy services (including physical therapy, occupational therapy, and speech-language pathology services) and CORF services billed under the physician fee schedule are paid using the nonfacility practice expense RVUs.

(ii) [Reserved]

(6)(i) CMS establishes criteria for supplemental surveys regarding specialty practice expenses submitted to CMS that may be used in determining practice expense RVUs.

(ii) Any CMS-designated specialty group may submit a supplemental survey.

(iii) CMS will consider for use in determining practice expense RVUs for the physician fee schedule survey data and related materials submitted to CMS by March 1, 2004 to determine CY 2005 practice expense RVUs and by March 1, 2005 to determine CY 2006 practice expense RVUs.

(c) *Malpractice insurance RVUs.* (1) Malpractice insurance RVUs are computed for each service or class of services by applying average malpractice insurance historical practice cost percentages to the estimated average allowed charge during the 1991 base period.

(2) The average historical malpractice insurance percentage for a service or class of services is computed as follows:

(i) Multiply the average malpractice insurance percentage for each specialty by the proportion of a particular service or class of services performed by that specialty.

(ii) Add all the products for all the specialties.

(3) For services furnished in the year 2000 and subsequent years, the malpractice RVUs are based on the relative malpractice insurance resources.

[56 FR 59624, Nov. 25, 1991, as amended at 57 FR 42493, Sept. 15, 1992; 58 FR 63687, Dec. 2, 1993; 62 FR 59102, Oct. 31, 1997; 63 FR 58910, Nov. 2, 1998; 64 FR 59441, Nov. 2, 1999; 65 FR 25668, May 3, 2000; 65 FR 65440, Nov. 1, 2000; 67 FR 43558, June 28, 2002; 68 FR 63261, Nov. 7, 2003; 72 FR 66932, Nov. 27, 2007; 73 FR 69935, Nov. 19, 2008; 76 FR 73471, Nov. 28, 2011; 81 FR 79879, Nov. 14, 2016; 81 FR 80553, Nov. 15, 2016]

§ 414.24 Publication of RVUs and direct PE inputs.

(a) *Definitions.* For purposes of this section, the following definitions apply:

Existing code means a code that is not a new code under paragraph (c)(2) of this section, and includes codes for which the descriptor is revised and codes that are combinations or subdivisions of previously existing codes.

New code means a code that describes a service that was not previously described or valued under the PFS using any other code or combination of codes.

(b) *Revisions of RVUs and Direct PE Inputs.* For valuations for calendar year 2017 and beyond, CMS publishes, through notice and comment rulemaking in the FEDERAL REGISTER (including proposals in a proposed rule), changes in RVUs or direct PE inputs for existing codes.

(c) *Establishing RVUs and Direct PE inputs for new codes*—(1) *General rule.* CMS establishes RVUs and direct PE inputs for new codes in the manner described in paragraph (b) of this section.

(2) *Exception for new codes for which CMS does not have sufficient information.* When CMS determines for a new code that it does not have sufficient information to include proposed RVUs or direct PE inputs in the proposed rule, but that it is in the public interest for Medicare to use a new code during a payment year, CMS will publish in the FEDERAL REGISTER RVUs and direct PE inputs that are applicable on an interim basis subject to public comment. After considering public comments and other information on interim RVUs and PE inputs for the new code, CMS

publishes in the FEDERAL REGISTER the final RVUs and PE inputs for the code.

(d) *Values for local codes (HCPCS Level 3).* (1) Carriers establish relative values for local codes for services not included in HCPCS levels 1 or 2.

(2) Carriers must obtain prior approval from CMS to establish local codes for services that meet the definition of ''physician services'' in § 414.2.

[56 FR 59624, Nov. 25, 1991, as amended at 57 FR 42492, Sept. 15, 1992; 79 FR 68003, Nov. 13, 2014]

§ 414.26 Determining the GAF.

CMS establishes a GAF for each service in each fee schedule area.

(a) *Geographic indices.* CMS uses the following indices to establish the GAF:

(1) An index that reflects one-fourth of the difference between the relative value of physicians' work effort in each of the different fee schedule areas as determined under § 414.22(a) and the national average of that work effort.

(2) An index that reflects the relative costs of the mix of goods and services comprising practice expenses (other than malpractice expenses) in each of the different fee schedule areas as determined under § 414.22(b) compared to the national average of those costs.

(3) An index that reflects the relative costs of malpractice expenses in each of the different fee schedule areas as determined under § 414.22(c) compared to the national average of those costs.

(b) *Class-specific practice cost indices.* If the application of a single index to different classes of services would be substantially inequitable because of differences in the mix of goods and services comprising practice expenses for the different classes of services, more than one index may be established under paragraph (a)(2) of this section.

(c) *Adjusting the practice expense index to account for the Frontier State floor—* (1) *General criteria.* Effective on or after January 1, 2011, CMS will adjust the practice expense index for physicians' services furnished in qualifying States to recognize the practice expense index floor established for Frontier States. A qualifying State must meet the following criteria:

(i) At least 50 percent of counties located within the State have a population density less than 6 persons per square mile.

(ii) The State does not receive a nonlabor related share adjustment determined by the Secretary to take into account the unique circumstances of hospitals located in Alaska and Hawaii.

(2) *Amount of adjustment.* The practice expense value applied for physicians' services furnished in a qualifying State will be not less than 1.00.

(3) *Process for determining adjustment.* (i) CMS will use the most recent population estimate data published by the U.S. Census Bureau to determine county definitions and population density. This analysis will be periodically revised, such as for updates to the decennial census data.

(ii) CMS will publish annually a listing of qualifying Frontier States receiving a practice expense index floor attributable to this provision.

(d) *Computation of GAF.* The GAF for each fee schedule area is the sum of the physicians' work adjustment factor, the practice expense adjustment factor, and the malpractice cost adjustment factor, as defined in this section:

(1) The geographic physicians' work adjustment factor for a service is the product of the proportion of the total relative value for the service that reflects the RVUs for the work component and the geographic physicians' work index value established under paragraph (a)(1) of this section.

(2) The geographic practice expense adjustment factor for a service is the product of the proportion of the total relative value for the service that reflects the RVUs for the practice expense component, multiplied by the geographic practice cost index (GPCI) value established under paragraph (a)(2) of this section.

(3) The geographic malpractice adjustment factor for a service is the product of the proportion of the total relative value for the service that reflects the RVUs for the malpractice component, multiplied by the GPCI value established under paragraph (a)(3) of this section.

[56 FR 59624, Nov. 25, 1991, as amended at 57 FR 42492, Sept. 15, 1992; 75 FR 73616, Nov. 29, 2010]

§ 414.28 Conversion factors.

CMS establishes CFs in accordance with section 1848(d) of the Act.

(a) *Base-year CFs.* CMS established the CF for 1992 so that had section 1848 of the Act applied during 1991, it would have resulted in the same aggregate amount of payments for physician services as the estimated aggregate amount of these payments in 1991, adjusted by the update for 1992 computed as specified in § 414.30.

(b) *Subsequent CFs.* For calendar years 1993 through 1995, the CF for each year is equal to the CF for the previous year, adjusted in accordance with § 414.30. Beginning January 1, 1996, the CF for each calendar year may be further adjusted so that adjustments to the fee schedule in accordance with section 1848(c)(2)(B)(ii) of the Act do not cause total expenditures under the fee schedule to differ by more than $20 million from the amount that would have been spent if these adjustments had not been made.

[56 FR 59624, Nov. 25, 1991, as amended at 57 FR 42492, Sept. 15, 1992; 60 FR 53877, Oct. 18, 1995; 60 FR 63177, Dec. 8, 1995]

§ 414.30 Conversion factor update.

Unless Congress acts in accordance with section 1848(d)(3) of the Act—

(a) *General rule.* The CF update for a CY equals the Medicare Economic Index increased or decreased by the number of percentage points by which the percentage increase in expenditures for physician services (or for a particular category of physician services, such as surgical services) in the second preceding FY over the third preceding FY exceeds the performance standard rate of increase established for the second preceding FY.

(b) *Downward adjustment.* The downward adjustment may not exceed the following:

(1) For CYs 1992 and 1993, 2 percentage points.

(2) For CY 1994, 2.5 percentage points.

(3) For CYs 1995 and thereafter, 5 percentage points.

[55 FR 23441, June 8, 1990, as amended at 60 FR 63177, Dec. 8, 1995; 61 FR 42385, Aug. 15, 1996]

§ 414.34 Payment for services and supplies incident to a physician's service.

(a) *Medical supplies.* (1) Except as otherwise specified in this paragraph, office medical supplies are considered to be part of a physician's practice expense, and payment for them is included in the practice expense portion of the payment to the physician for the medical or surgical service to which they are incidental.

(2) If physician services of the type routinely furnished in provider settings are furnished in a physician's office, separate payment may be made for certain supplies furnished incident to that physician service if the following requirements are met:

(i) It is a procedure that can safely be furnished in the office setting in appropriate circumstances.

(ii) It requires specialized supplies that are not routinely available in physicians' offices and that are generally disposable.

(iii) It is furnished before January 1, 1999.

(3) For the purpose of paragraph (a)(2) of this section, provider settings include only the following settings:

(i) Hospital inpatient and outpatient departments.

(ii) Ambulatory surgical centers.

(4) For the purpose of paragraph (a)(2) of this section, ''routinely furnished in provider settings'' means furnished in inpatient or outpatient hospital settings or ambulatory surgical centers more than 50 percent of the time.

(5) CMS establishes a list of services for which a separate supply payment may be made under this section.

(6) The fee schedule amount for supplies billed separately is not subject to a GPCI adjustment.

(b) *Services of nonphysicians that are incident to a physician's service.* Services of nonphysicians that are covered as incident to a physician's service are paid as if the physician had personally furnished the service.

[56 FR 59624, Nov. 25, 1991; 57 FR 42492, Sept. 15, 1992, as amended at 63 FR 58911, Nov. 2, 1998]

§ 414.36 Payment for drugs incident to a physician's service.

Payment for drugs incident to a physician's service is made in accordance with § 405.517 of this chapter.

§ 414.39 Special rules for payment of care plan oversight.

(a) *General.* Except as specified in paragraphs (b) and (c) of this section, payment for care plan oversight is included in the payment for visits and other services under the physician fee schedule. For purposes of this section a nonphysician practitioner (NPP) is a nurse practitioner, clinical nurse specialist or physician assistant.

(b) *Exception.* Separate payment is made under the following conditions for physician care plan oversight services furnished to beneficiaries who receive HHA and hospice services that are covered by Medicare:

(1) The care plan oversight services require recurrent physician supervision of therapy involving 30 or more minutes of the physician's time per month.

(2) Payment is made to only one physician per patient for services furnished during a calendar month period. The physician must have furnished a service requiring a face-to-face encounter with the patient at least once during the 6-month period before the month for which care plan oversight payment is first billed. The physician may not have a significant ownership interest in, or financial or contractual relationship with, the HHA in accordance with § 424.22(d) of this chapter. The physician may not be the medical director or employee of the hospice and may not furnish services under an arrangement with the hospice.

(3) If a physician furnishes care plan oversight services during a postoperative period, payment for care plan oversight services is made if the services are documented in the patient's medical record as unrelated to the surgery.

(c) *Special rules for payment of care plan oversight provided by nonphysician practitioners for beneficiaries who receive HHA services covered by Medicare.* (1) An NPP can furnish physician care plan oversight (but may not certify a patient as needing home health services) only if the physician who signs the plan of care provides regular ongoing care under the same plan of care as does the NPP billing for care plan oversight and either—

(i) The physician and NPP are part of the same group practice; or

(ii) If the NPP is a nurse practitioner or clinical nurse specialist, the physician signing the plan of care also has a collaborative agreement with the NPP; or

(iii) If the NPP is a physician assistant, the physician signing the plan of care is also the physician who provides general supervision of physician assistant services for the practice.

(2) Payment may be made for care plan oversight services furnished by an NPP when:

(i) The NPP providing the care plan oversight has seen and examined the patient;

(ii) The NPP providing care plan oversight is not functioning as a consultant whose participation is limited to a single medical condition rather than multi-disciplinary coordination of care; and

(iii) The NPP providing care plan oversight integrates his or her care with that of the physician who signed the plan of care.

[59 FR 63463, Dec. 8, 1994; 60 FR 49, Jan. 3, 1995; 60 FR 36733, July 18, 1995, as amended at 69 FR 66423, Nov. 15, 2004; 70 FR 16722, Apr. 1, 2005]

§ 414.40 Coding and ancillary policies.

(a) *General rule.* CMS establishes uniform national definitions of services, codes to represent services, and payment modifiers to the codes.

(b) *Specific types of policies.* CMS establishes uniform national ancillary policies necessary to implement the fee schedule for physician services. These include, but are not limited to, the following policies:

(1) Global surgery policy (for example, post- and pre-operative periods and services, and intra-operative services).

(2) Professional and technical components (for example, payment for services, such as an EEG, which typically comprise a technical component (the taking of the test) and a professional component (the interpretation)).

(3) Payment modifiers (for example, assistant-at-surgery, multiple surgery,

bilateral surgery, split surgical global services, team surgery, and unusual services).

§ 414.42 Adjustment for first 4 years of practice.

(a) *General rule.* For services furnished during CYs 1992 and 1993, except as specified in paragraph (b) of this section, the fee schedule payment amount or prevailing charge must be phased in as specified in paragraph (d) of this section for physicians, physical therapists (PTs), occupational therapists (OTs), and all other health care practitioners who are in their first through fourth years of practice.

(b) *Exception.* The reduction required in paragraph (d) of this section does not apply to primary care services or to services furnished in a rural area as defined in section 1886(d)(2)(D) of the Act that is designated under section 332(a)(1)(A) of the Public Health Service Act as a Health Professional Shortage Area.

(c) *Definition of years of practice.* (1) The ''first year of practice'' is the first full CY during the first 6 months of which the physician, PT, OT, or other health care practitioner furnishes professional services for which payment may be made under Medicare Part B, plus any portion of the prior CY if that prior year does not meet the first 6 months test.

(2) The ''second, third, and fourth years of practice'' are the first, second, and third CYs following the first year of practice, respectively.

(d) *Amounts of adjustment.* The fee schedule payment for the service of a new physician, PT, OT, or other health care practitioner is limited to the following percentages for each of the indicated years:

(1) First year—80 percent
(2) Second year—85 percent
(3) Third year—90 percent
(4) Fourth year—95 percent

[57 FR 42493, Sept. 15, 1992, as amended at 58 FR 63687, Dec. 2, 1993]

§ 414.44 Transition rules.

(a) *Adjusted historical payment basis—*(1) *All services other than radiology and nuclear medicine services.* For all physician services other than radiology services, furnished in a fee schedule area, the adjusted historical payment basis (AHPB) is the estimated weighted average prevailing charge applied in the fee schedule area for the service in CY 1991, as determined by CMS without regard to physician specialty and as adjusted to reflect payments for services below the prevailing charge, adjusted by the update established for CY 1992.

(2) *Radiology services.* For radiology services, the AHPB is the amount paid for the service in the fee schedule area in CY 1991 under the fee schedule established under section 1834(b), adjusted by the update established for CY 1992.

(3) *Nuclear medicine services.* For nuclear medicine services, the AHPB is the amount paid for the service in the fee schedule area in CY 1991 under the fee schedule established under section 6105(b) of Public Law 101–239 and section 4102(g) of Public Law 101–508, adjusted by the update established for CY 1992.

(4) *Transition adjustment.* CMS adjusts the AHPB for all services by 5.5 percent to produce budget-neutral payments for 1992.

(b) *Adjustment of 1992 payments for physician services other than radiology services.* For physician services furnished during CY 1992 the following rules apply:

(1) If the AHPB determined under paragraph (a) of this section is from 85 percent to 115 percent of the fee schedule amount for the area for services furnished in 1992, payment is at the fee schedule amount.

(2) If the AHPB determined under paragraph (a) of this section is less than 85 percent of the fee schedule amount for the area for services furnished in 1992, an amount equal to the AHPB plus 15 percent of the fee schedule amount is substituted for the fee schedule amount.

(3) If the AHPB determined under paragraph (a) of this section is greater than 115 percent of the fee schedule amount for the area for services furnished in 1992, an amount equal to the AHPB minus 15 percent of the fee schedule amount is substituted for the fee schedule amount.

(c) *Adjustment of 1992 payments for radiology services.* For radiology services furnished during CY 1992 the following rules apply:

(1) If the AHPB determined under paragraph (a) of this section is from 85 percent to 109 percent of the fee schedule amount for the area for services furnished in 1992, payment is at the fee schedule amount.

(2) If the AHPB determined under paragraph (a) of this section is less than 85 percent of the fee schedule amount for the area for services furnished in 1992, an amount equal to the AHPB plus 15 percent of the fee schedule amount is substituted for the fee schedule amount.

(3) If the AHPB determined under paragraph (a) of this section is greater than 109 percent of the fee schedule amount for the area for services furnished in 1992, an amount equal to the AHPB minus 9 percent of the fee schedule amount is substituted for the fee schedule amount.

(d) *Computation of payments for CY 1993.* For physician services subject to the transition rules in CY 1992 and furnished during CY 1993, the fee schedule is equal to 75 percent of the amount that would have been paid in the fee schedule area under the 1992 transition rules, adjusted by the amount of the 1993 update, plus 25 percent of the 1993 fee schedule amount.

(e) *Computation of payments for CY 1994.* For physician services subject to the transition rules in CY 1993, and furnished during CY 1994, the fee schedule is equal to 67 percent of the amount that would have been paid in the fee schedule area under the 1993 transition rules, adjusted by the amount of the 1994 update, plus 33 percent of the 1994 fee schedule amount.

(f) *Computation of payments for CY 1995.* For physician services subject to the transition rules in CY 1994 and furnished during CY 1995, the fee schedule is equal to 50 percent of the amount that would have been paid in the fee schedule area under the 1994 transition rules, adjusted by the amount of the 1995 update, plus 50 percent of the 1995 fee schedule amount.

§ 414.46 Additional rules for payment of anesthesia services.

(a) *Definitions.* For purposes of this section, the following definitions apply:

(1) *Base unit* means the value for each anesthesia code that reflects all activities other than anesthesia time. These activities include usual preoperative and postoperative visits, the administration of fluids and blood incident to anesthesia care, and monitoring services.

(2) *Anesthesia practitioner,* for the purpose of anesthesia time, means a physician who performs the anesthesia service alone, a CRNA who is not medically directed who performs the anesthesia service alone, or a medically directed CRNA.

(3) *Anesthesia time* means the time during which an anesthesia practitioner is present with the patient. It starts when the anesthesia practitioner begins to prepare the patient for anesthesia services and ends when the anesthesia practitioner is no longer furnishing anesthesia services to the beneficiary, that is, when the beneficiary may be placed safely under postoperative care. Anesthesia time is a continuous time period from the start of anesthesia to the end of an anesthesia service. In counting anesthesia time, the anesthesia practitioner can add blocks of anesthesia time around an interruption in anesthesia time as long as the anesthesia practitioner is furnishing continuous anesthesia care within the time periods around the interruption.

(b) *Determinations of payment amount—Basic rule.* For anesthesia services performed, medically directed, or medically supervised by a physician, CMS pays the lesser of the actual charge or the anesthesia fee schedule amount.

(1) The carrier bases the fee schedule amount for an anesthesia service on the product of the sum of allowable base and time units and an anesthesia-specific CF. The carrier calculates the time units from the anesthesia time reported by the anesthesia practitioner for the anesthesia procedure. The physician who fulfills the conditions for medical direction in § 415.110 (Conditions for payment: Anesthesiology services) reports the same anesthesia time as the medically-directed CRNA.

(2) CMS furnishes the carrier with the base units for each anesthesia procedure code. The base units are derived

from the 1988 American Society of Anesthesiologists' Relative Value Guide except that the number of base units recognized for anesthesia services furnished during cataract or iridectomy surgery is four units.

(3) Modifier units are not allowed. Modifier units include additional units charged by a physician or a CRNA for patient health status, risk, age, or unusual circumstances.

(c) *Physician personally performs the anesthesia procedure.* (1) CMS considers an anesthesia service to be personally performed under any of the following circumstances:

(i) The physician performs the entire anesthesia service alone.

(ii) The physician establishes an attending physician relationship in one or two concurrent cases involving an intern or resident and the service was furnished before January 1, 1994.

(iii) The physician establishes an attending physician relationship in one case involving an intern or resident and the service was furnished on or after January 1, 1994 but prior to January 1, 1996. For services on or after January 1, 1996, the physician must be the teaching physician as defined in §§ 415.170 through 415.184 of this chapter.

(iv) The physician and the CRNA or AA are involved in a single case and the services of each are found to be medically necessary.

(v) The physician is continuously involved in a single case involving a student nurse anesthetist.

(vi) The physician is continuously involved in a single case involving a CRNA or AA and the service was furnished prior to January 1, 1998.

(2) CMS determines the fee schedule amount for an anesthesia service personally performed by a physician on the basis of an anesthesia-specific fee schedule CF and unreduced base units and anesthesia time units. One anesthesia time unit is equivalent to 15 minutes of anesthesia time, and fractions of a 15-minute period are recognized as fractions of an anesthesia time unit.

(d) *Anesthesia services medically directed by a physician.* (1) CMS considers an anesthesia service to be medically directed by a physician if:

(i) The physician performs the activities described in § 415.110 of this chapter.

(ii) The physician directs qualified individuals involved in two, three, or four concurrent cases.

(iii) Medical direction can occur for a single case furnished on or after January 1, 1998 if the physician performs the activities described in § 415.110 of this chapter and medically directs a single CRNA or AA.

(2) The rules for medical direction differ for certain time periods depending on the nature of the qualified individual who is directed by the physician.

(i) If more than two procedures are directed on or after January 1, 1994, the qualified individuals could be AAs, CRNAs, interns, or residents. The medical direction rules apply to student nurse anesthetists only if the physician directs two concurrent cases, each of which involves a student nurse anesthetist or the physician directs one case involving a student nurse anesthetist and the other involving a CRNA, AA, intern, or resident.

(ii) For services furnished on or after January 1, 2010, the medical direction rules do not apply to a single anesthesia resident case that is concurrent to another case which is paid under the medical direction payment rules as specified in paragraph (e) of this section.

(3) Payment for medical direction is based on a specific percentage of the payment allowance recognized for the anesthesia service personally performed by a physician alone. The following percentages apply for the years specified:

(i) CY 1994—60 percent of the payment allowance for personally performed procedures.

(ii) CY 1995—57.5 percent of the payment allowance for personally performed services.

(iii) CY 1996—55 percent of the payment allowance for personally performed services.

(iv) CY 1997—52.5 percent of the payment allowance for personally performed services.

(v) CY 1998 and thereafter—50 percent of the payment allowance for personally performed services.

(e) *Special payment rule for teaching anesthesiologist involved in a single resident case or two concurrent cases.* For physicians' services furnished on or after January 1, 2010, if the teaching anesthesiologist is involved in the training of physician residents in a single anesthesia case or two concurrent anesthesia cases, the fee schedule amount must be 100 percent of the fee schedule amount otherwise applicable if the anesthesia services were personally performed by the teaching anesthesiologist and the teaching anesthesiologist fulfilled the criteria in §415.178 of this chapter. This special payment rule also applies if the teaching anesthesiologist is involved in one resident case that is concurrent to another case paid under the medical direction payment rules.

(f) *Physician medically supervises anesthesia services.* If the physician medically supervises more than four concurrent anesthesia services, CMS bases the fee schedule amount on an anesthesia-specific CF and three base units. This represents payment for the physician's involvement in the pre-surgical anesthesia services.

(g) *Payment for medical or surgical services furnished by a physician while furnishing anesthesia services.* (1) CMS allows separate payment under the fee schedule for certain reasonable and medically necessary medical or surgical services furnished by a physician while furnishing anesthesia services to the patient. CMS makes payment for these services in accordance with the general physician fee schedule rules in §414.20. These services are described in program operating instructions.

(2) CMS makes no separate payment for other medical or surgical services, such as the pre-anesthetic examination of the patient, pre- or post-operative visits, or usual monitoring functions, that are ordinarily included in the anesthesia service.

(h) *Physician involved in multiple anesthesia services.* If the physician is involved in multiple anesthesia services for the same patient during the same operative session, the carrier makes payment according to the base unit associated with the anesthesia service having the highest base unit value and anesthesia time that encompasses the multiple services. The carrier makes payment for add-on anesthesia codes according to program operating instructions.

[56 FR 59624, Nov. 25, 1991, as amended at 57 FR 42492, Sept. 15, 1992; 58 FR 63687, Dec. 2, 1993; 60 FR 63177, Dec. 8, 1995; 64 FR 59441, Nov. 2, 1999; 67 FR 80041, Dec. 31, 2002; 68 FR 63261, Nov. 7, 2003; 74 FR 62006, Nov. 25, 2009]

§ 414.48 Limits on actual charges of nonparticipating suppliers.

(a) *General rule.* A supplier, as defined in §400.202 of this chapter, who is nonparticipating and does not accept assignment may charge a beneficiary an amount up to the limiting charge described in paragraph (b) of this section.

(b) *Specific limits.* For items or services paid under the physician fee schedule, the limiting charge is 115 percent of the fee schedule amount for nonparticipating suppliers. For items or services CMS excludes from payment under the physician fee schedule (in accordance with section 1848 (j)(3) of the Act), the limiting charge is 115 percent of 95 percent of the payment basis applicable to participating suppliers as calculated in §414.20(b).

[58 FR 63687, Dec. 2, 1993, as amended at 62 FR 59102, Oct. 31, 1997]

§ 414.50 Physician or other supplier billing for diagnostic tests performed or interpreted by a physician who does not share a practice with the billing physician or other supplier.

(a) *General rules.* (1) For services covered under section 1861(s)(3) of the Act and paid for under part 414 of this chapter (other than clinical diagnostic laboratory tests paid under section 1833(a)(2)(D) of the Act, which are subject to the special billing rules set forth in section 1833(h)(5)(A) of the Act), if a physician or other supplier bills for the technical component (TC) or professional component (PC) of a diagnostic test that was ordered by the physician or other supplier (or ordered by a party related to such physician or other supplier through common ownership or control as described in §413.17 of this chapter) and the diagnostic test is performed by a physician who does not share a practice with the billing

physician or other supplier, the payment to the billing physician or other supplier (less the applicable deductibles and coinsurance paid by the beneficiary or on behalf of the beneficiary) for the TC or PC of the diagnostic test may not exceed the lowest of the following amounts:

(i) The performing supplier's net charge to the billing physician or other supplier. For purposes of this paragraph (a)(1) only, with respect to the TC, the performing supplier is the physician who supervised the TC, and with respect to the PC, the performing supplier is the physician who performed the PC.

(ii) The billing physician or other supplier's actual charge.

(iii) The fee schedule amount for the test that would be allowed if the performing supplier billed directly.

(2) The following requirements are applicable for purposes of paragraph (a)(1) of this section:

(i) The net charge must be determined without regard to any charge that is intended to reflect the cost of equipment or space leased to the performing supplier by or through the billing physician or other supplier.

(ii) A performing physician shares a practice with the billing physician or other supplier if he or she furnishes substantially all (which, for purposes of this section, means ''at least 75 percent'') of his or her professional services through such billing physician or other supplier. The ''substantially all'' requirement will be satisfied if, at the time the billing physician or other supplier submits a claim for a service furnished by the performing physician, the billing physician or other supplier has a reasonable belief that:

(A) For the 12 months prior to and including the month in which the service was performed, the performing physician furnished substantially all of his or her professional services through the billing physician or other supplier; or

(B) The performing physician will furnish substantially all of his or her professional services through the billing physician or other supplier for the next 12 months (including the month in which the service is performed).

(iii) A physician will be deemed to share a practice with the billing physician or other supplier with respect to the performance of the TC or PC of a diagnostic test if the physician is an owner, employee or independent contractor of the billing physician or other supplier and the TC or PC is performed in the office of the billing physician or other supplier. The ''office of the billing physician or other supplier'' is any medical office space, regardless of number of locations, in which the ordering physician or other ordering supplier regularly furnishes patient care, and includes space where the billing physician or other supplier furnishes diagnostic testing, if the space is located in the same building (as defined in § 411.351) in which the ordering physician or other ordering supplier regularly furnishes patient care. With respect to a billing physician or other supplier that is a physician organization (as defined in § 411.351 of this chapter), the ''office of the billing physician or other supplier'' is space in which the ordering physician provides substantially the full range of patient care services that the ordering physician provides generally. The performance of the TC includes both the conducting of the TC as well as the supervision of the TC.

(b) *Restriction on payment.* (1) The billing physician or other supplier must identify the performing supplier and indicate the performing supplier's net charge for the test. If the billing physician or other supplier fails to provide this information, CMS makes no payment to the billing physician or other supplier and the billing physician or other supplier may not bill the beneficiary.

(2) Physicians and other suppliers that accept Medicare assignment may bill beneficiaries for only the applicable deductibles and coinsurance.

(3) Physicians and other suppliers that do not accept Medicare assignment may not bill the beneficiary more than the payment amount described in paragraph (a) of this section.

[72 FR 66400, Nov. 27, 2007, as amended at 73 FR 2432, Jan. 15, 2008; 73 FR 69935, Nov. 19, 2008]

§ 414.52 Payment for physician assistants' services.

Allowed amounts for the services of a physician assistant furnished beginning January 1, 1992 and ending December 31, 1997, may not exceed the limits specified in paragraphs (a) through (c) of this section. Allowed amounts for the services of a physician assistant furnished beginning January 1, 1998, may not exceed the limits specified in paragraph (d) of this section.

(a) For assistant-at-surgery services, 65 percent of the amount that would be allowed under the physician fee schedule if the assistant-at-surgery service was furnished by a physician.

(b) For services (other than assistant-at-surgery services) furnished in a hospital, 75 percent of the physician fee schedule amount for the service.

(c) For all other services, 85 percent of the physician fee schedule amount for the service.

(d) For services (other than assistant-at-surgery services) furnished beginning January 1, 1998, 85 percent of the physician fee schedule amount for the service. For assistant-at-surgery services, 85 percent of the physician fee schedule amount that would be allowed under the physician fee schedule if the assistant-at-surgery service were furnished by a physician.

[56 FR 59624, Nov. 25, 1991; 57 FR 42492, Sept. 15, 1992, as amended at 63 FR 58911, Nov. 2, 1998]

§ 414.53 Fee schedule for clinical social worker, marriage and family therapist, and mental health counselor services.

The fee schedule for clinical social worker, marriage and family therapist, and mental health counselor services is set at 75 percent of the amount determined for clinical psychologist services under the physician fee schedule.

[88 FR 79530, Nov. 16, 2023]

§ 414.54 Payment for certified nurse-midwives' services.

(a) For services furnished after December 31, 1991, allowed amounts under the fee schedule established under section 1833(a)(1)(K) of the Act for the payment of certified nurse-midwife services may not exceed 65 percent of the physician fee schedule amount for the service.

(b) For certified nurse-midwife services furnished on or after January 1, 2011, allowed amounts may not exceed 100 percent of the physician fee schedule amount that would be paid to a physician for the services.

[75 FR 73616, Nov. 29, 2010]

§ 414.56 Payment for nurse practitioners' and clinical nurse specialists' services.

(a) *Rural areas.* For services furnished beginning January 1, 1992 and ending December 31, 1997, allowed amounts for the services of a nurse practitioner or a clinical nurse specialist in a rural area (as described in section 1861(s)(2)(K)(iii) of the Act) may not exceed the following limits:

(1) For services furnished in a hospital (including assistant-at-surgery services), 75 percent of the physician fee schedule amount for the service.

(2) For all other services, 85 percent of the physician fee schedule amount for the service.

(b) *Non-rural areas.* For services furnished beginning January 1, 1992 and ending December 31, 1997, allowed amounts for the services of a nurse practitioner or a clinical nurse specialist in a nursing facility may not exceed 85 percent of the physician fee schedule amount for the service.

(c) *Beginning January 1, 1998.* For services (other than assistant-at-surgery services) furnished beginning January 1, 1998, allowed amounts for the services of a nurse practitioner or clinical nurse specialist may not exceed 85 percent of the physician fee schedule amount for the service. For assistant-at-surgery services, allowed amounts for the services of a nurse practitioner or clinical nurse specialist may not exceed 85 percent of the physician fee schedule amount that would be allowed under the physician fee schedule if the assistant-at-surgery service were furnished by a physician.

[63 FR 58911, Nov. 2, 1998]

§ 414.58 Payment of charges for physician services to patients in providers.

(a) *Payment under the physician fee schedule.* In addition to the special conditions for payment in §§ 415.100 through 415.130, and § 415.190 of this chapter, CMS establishes payment for physician services to patients in providers under the physician fee schedule in accordance with §§ 414.1 through 414.48.

(b) *Teaching hospitals.* Services furnished by physicians in teaching hospitals may be made on a reasonable cost basis set forth in § 415.162 of this chapter if the hospital exercises the election described in § 415.160 of this chapter.

[56 FR 59624, Nov. 25, 1991, as amended at 57 FR 42492, Sept. 15, 1992; 60 FR 63189, Dec. 8, 1995]

§ 414.60 Payment for the services of CRNAs.

(a) *Basis for payment.* The allowance for the anesthesia service furnished by a CRNA, medically directed or not medically directed, is based on allowable base and time units as defined in § 414.46(a). Beginning with CY 1994—

(1) The allowance for an anesthesia service furnished by a medically directed CRNA is based on a fixed percentage of the allowance recognized for the anesthesia service personally performed by the physician alone, as specified in § 414.46(d)(3); and

(2) The CF for an anesthesia service furnished by a CRNA not directed by a physician may not exceed the CF for a service personally performed by a physician.

(b) *To whom payment may be made.* Payment for an anesthesia service furnished by a CRNA may be made to the CRNA or to any individual or entity (such as a hospital, critical access hospital, physician, group practice, or ambulatory surgical center) with which the CRNA has an employment or contract relationship that provides for payment to be made to the individual or entity.

(c) *Condition for payment.* Payment for the services of a CRNA may be made only on an assignment related basis, and any assignment accepted by a CRNA is binding on any other person presenting a claim or request for payment for the service.

[60 FR 63178, Dec. 8, 1995, as amended at 62 FR 46037, Aug. 29, 1997; 64 FR 59441, Nov. 2, 1999; 77 FR 69363, Nov. 16, 2012]

§ 414.61 Payment for anesthesia services furnished by a teaching CRNA.

(a) *Basis for payment.* Beginning January 1, 2010, anesthesia services furnished by a teaching CRNA may be paid under one of the following conditions:

(1) The teaching CRNA, who is not under medical direction of a physician, is present with the student nurse anesthetist for the pre and post anesthesia services included in the anesthesia base units payment and is continuously present during anesthesia time in a single case with a student nurse anesthetist.

(2) The teaching CRNA, who is not under the medical direction of a physician, is involved with two concurrent anesthesia cases with student nurse anesthetists. The teaching CRNA must be present with the student nurse anesthetist for the pre and post anesthesia services included in the anesthesia base unit. For the anesthesia time of the two concurrent cases, the teaching CRNA can only be involved with those two concurrent cases and may not perform services for other patients.

(b) *Level of payment.* The allowance for the service of the teaching CRNA, furnished under paragraph (a) of this section, is determined in the same way as for a physician who personally performs the anesthesia service alone as specified in § 414.46(c) of this subpart.

[74 FR 62006, Nov. 25, 2009]

§ 414.62 Fee schedule for clinical psychologist services.

The fee schedule for clinical psychologist services is set at 100 percent of the amount determined for corresponding services under the physician fee schedule.

[62 FR 59102, Oct. 31, 1997]

§ 414.63 Payment for outpatient diabetes self-management training.

(a) Payment under the physician fee schedule. Except as provided in paragraph (d) of this section, payment for

outpatient diabetes self-management training is made under the physician fee schedule in accordance with §§ 414.1 through 414.48.

(b) To whom payment may be made. Payment may be made to an entity approved by CMS to furnish outpatient diabetes self-management training in accordance with part 410, subpart H of this chapter.

(c) Limitation on payment. Payment may be made for training sessions actually attended by the beneficiary and documented on attendance sheets.

(d) Payments made to those not paid under the physician fee schedule. Payments may be made to other entities not routinely paid under the physician fee schedule, such as hospital outpatient departments, ESRD facilities, and DME suppliers. The payment equals the amounts paid under the physician fee schedule.

(e) Other conditions for fee-for-service payment. The beneficiary must meet the following conditions:

(1) Has not previously received initial training for which Medicare payment was made under this benefit.

(2) Is not receiving services as an inpatient in a hospital, SNF, hospice, or nursing home.

(3) Is not receiving services as an outpatient in an RHC or FQHC.

[65 FR 83153, Dec. 29, 2000]

§ 414.64 Payment for medical nutrition therapy.

(a) *Payment under the physician fee schedule.* Medicare payment for medical nutrition therapy is made under the physician fee schedule in accordance with subpart B of this part. Payment to nonphysician professionals, as specified in paragraph (b) of this section, is 80 percent (or 100 percent if such services are recommended with a grade of A or B by the United States Preventive Services Task Force for any indication or population and are appropriate for the individual) of the lesser of the actual charges or 85 percent of the physician fee schedule amount.

(b) *To whom payment may be made.* Payment may be made to a registered dietician or nutrition professional qualified to furnish medical nutrition therapy in accordance with part 410, subpart G of this chapter.

(c) *Effective date of payment.* Medicare pays suppliers of medical nutrition therapy on or after the effective date of enrollment of the supplier at the carrier.

(d) *Limitation on payment.* Payment is made only for documented nutritional therapy sessions actually attended by the beneficiary.

(e) *Other conditions for fee-for-service payment.* Payment is made only if the beneficiary:

(1) Is not an inpatient of a hospital, SNF, nursing home, or hospice.

(2) Is not receiving services in an RHC, FQHC or ESRD dialysis facility.

[66 FR 55332, Nov. 1, 2001, as amended at 86 FR 65668, Nov. 19, 2021]

§ 414.65 Payment for telehealth services.

(a) *Professional service.* The Medicare payment amount for telehealth services described under § 410.78 of this chapter is equal to the current fee schedule amount applicable for the service of the physician or practitioner, subject to paragraphs (a)(1) and (2) of this section, but must be made in accordance with the following limitations:

(1) Only the physician or practitioner at the distant site may bill and receive payment for the professional service via an interactive telecommunications system.

(2) Payments made to the physician or practitioner at the distant site, including deductible and coinsurance, for the professional service may not be shared with the referring practitioner or telepresenter.

(b) *Originating site facility fee.* For telehealth services furnished on or after October 1, 2001:

(1) For services furnished on or after October 1, 2001 through December 31, 2002, the payment amount to the originating site is the lesser of the actual charge or the originating site facility fee of $20. For services furnished on or after January 1 of each subsequent year, the facility fee for the originating site will be updated by the Medicare Economic Index (MEI) as defined in section 1842(i)(3) of the Act.

(2) Only the originating site may bill for the originating site facility fee and only on an assignment-related basis.

The distant site physician or practitioner may not bill for or receive payment for facility fees associated with the professional service furnished via an interactive telecommunications system.

(3) No originating site facility fee payment is made to an originating site described in § 410.78(b)(3)(x), (xi), or (xii); or to an originating site for services furnished under the exception at § 410.78(b)(4)(iv)(A) or (B) of this chapter.

(c) *Deductible and coinsurance apply.* The payment for the professional service and originating site facility fee is subject to the coinsurance and deductible requirements of sections 1833(a)(1) and (b) of the Act.

(d) *Assignment required for physicians, practitioners, and originating sites.* Payment to physicians, practitioners, and originating sites is made only on an assignment-related basis.

(e) *Sanctions.* A distant site practitioner or originating site facility may be subject to the applicable sanctions provided for in chapter IV, part 402 and chapter V, parts 1001, 1002, and 1003 of this title if he or she does any of the following:

(1) Knowingly and willfully bills or collects for services in violation of the limitation of this section.

(2) Fails to timely correct excess charges by reducing the actual charge billed for the service in an amount that does not exceed the limiting charge for the service or fails to timely refund excess collections.

(3) Fails to submit a claim on a standard form for services provided for which payment is made on a fee schedule basis.

(4) Imposes a charge for completing and submitting the standard claims form.

[66 FR 55332, Nov. 1, 2001, as amended at 67 FR 80041, Dec. 31, 2003; 69 FR 66424, Nov. 15, 2004; 70 FR 70332, Nov. 21, 2005; 72 FR 66401, Nov. 27, 2007; 73 FR 69936, Nov. 19, 2008; 74 FR 62006, Nov. 25, 2009; 75 FR 73617, Nov. 29, 2010; 76 FR 73471, Nov. 28, 2011; 77 FR 69363, Nov. 16, 2012; 78 FR 74812, Dec. 10, 2013; 83 FR 60074, Nov. 23, 2018]

§ 414.66 Incentive payments for physician scarcity areas.

(a) *Definition.* As used in this section, the following definitions apply.

Physician scarcity area is defined as an area with a shortage of primary care physicians or specialty physicians to the Medicare population in that area.

Primary care physician is defined as a general practitioner, family practice practitioner, general internist, obstetrician or gynecologist.

(b) Physicians' services furnished to a beneficiary in a Physician Scarcity Area (PSA) for primary or specialist care are eligible for a 5 percent incentive payment.

(c) Primary care physicians furnishing services in primary care PSAs are entitled to an additional 5 percent incentive payment above the amount paid under the physician fee schedule for their professional services furnished on or after January 1, 2005 and before January 1, 2008.

(d) Physicians, as defined in section 1861(r)(1) of the Act, furnishing services in specialist care PSAs are entitled to an additional 5 percent payment above the amount paid under the physician fee schedule for their professional services furnished on or after January 1, 2005 and before January 1, 2008.

[69 FR 66424, Nov. 15, 2004]

§ 414.67 Incentive payments for services furnished in Health Professional Shortage Areas.

(a) *Health Professional Shortage Area (HPSA) physician bonus program.* A HPSA physician incentive payment will be made subject to the following:

(1) HPSA bonuses are payable for services furnished by physicians as defined in section 1861(r) of the Act in areas designated as of December 31 of the prior year as geographic primary medical care HPSAs as defined in section 332(a)(1)(A) of the Public Health Service Act.

(2) HPSA bonuses are payable for services furnished by psychiatrists in areas designated as of December 31 of the prior year as geographic mental health HPSAs if the services are not already eligible for the bonus based on being in a geographic primary care HPSA.

(3) Physicians eligible for the HPSA physician bonus are entitled to a 10 percent incentive payment above the amount paid for their professional

services under the physician fee schedule.

(4) Physicians furnishing services in areas that are designated as geographic HPSAs prior to the beginning of the year but not included on the published list of zip codes for which automated HPSA bonus payments are made must use the AQ modifier to receive the HPSA physician bonus payment.

(b) *HPSA surgical incentive payment program.* A HPSA surgical incentive payment will be made subject to the following:

(1) A major surgical procedure as defined in §414.2 of this part is furnished by a general surgeon on or after January 1, 2011 and before January 1, 2016 in an area recognized for the HPSA physician bonus program under paragraph (a)(1) of this section.

(2) Payment will be made on a quarterly basis in an amount equal to 10 percent of the Part B payment amount for major surgical procedures furnished as described in paragraph (b)(1) of this section, in addition to the amount the physician would otherwise be paid.

(3) Physicians furnishing services in areas that are designated as geographic HPSAs eligible for the HPSA physician bonus program under paragraph (a)(1) of this section prior to the beginning of the year but not included on the published list of zip codes for which automated HPSA surgical incentive payments are made should report HCPCS modifier -AQ to receive the HPSA surgical incentive payment.

(4) The payment described in paragraph (b)(2) of this section is made to the surgeon or, where the surgeon has reassigned his or her benefits to a critical access hospital (CAH) paid under the optional method, to the CAH based on an institutional claim.

[75 FR 73617, Nov. 29, 2010]

§414.68 Imaging accreditation.

(a) *Scope and purpose.* Section 1834(e) of the Act requires the Secretary to designate and approve independent accreditation organizations for purposes of accrediting suppliers furnishing the technical component (TC) of advanced diagnostic imaging services and establish procedures to ensure that the criteria used by an accreditation organization is specific to each imaging modality. Suppliers of the TC of advanced diagnostic imaging services for which payment is made under the fee schedule established in section 1848(b) of the Act must become accredited by an accreditation organization designated by the Secretary beginning January 1, 2012.

(b) *Definitions.* As used in this section, the following definitions are applicable:

Accredited supplier means a supplier that has been accredited by a CMS-designated accreditation organization as specified in this part.

Advanced diagnostic imaging service means any of the following diagnostic services:

(i) Magnetic resonance imaging.

(ii) Computed tomography.

(iii) Nuclear medicine.

(iv) Positron emission tomography.

CMS-approved accreditation organization means an accreditation organization designated by CMS to perform the accreditation functions specified in section 1834(e) of the Act.

(c) *Application and reapplication procedures for accreditation organizations.* An independent accreditation organization applying for approval or reapproval of authority to survey suppliers for purposes of accrediting suppliers furnishing the TC of advanced diagnostic imaging services is required to furnish CMS with all of the following:

(1) A detailed description of how the organization's accreditation criteria satisfy the statutory standards authorized by section 1834(e)(3) of the Act, specifically—

(i) Qualifications of medical personnel who are not physicians and who furnish the TC of advanced diagnostic imaging services;

(ii) Qualifications and responsibilities of medical directors and supervising physicians (who may be the same person), such as their training in advanced diagnostic imaging services in a residency program, expertise obtained through experience, or continuing medical education courses;

(iii) Procedures to ensure the reliability, clarity, and accuracy of the technical quality of diagnostic images produced by the supplier, including a thorough evaluation of equipment performance and safety;

(iv) Procedures to ensure the safety of persons who furnish the TC of advanced diagnostic imaging services and individuals to whom such services are furnished;

(v) Procedures to assist the beneficiary in obtaining the beneficiary's imaging records on request; and

(vi) Procedures to notify the accreditation organization of any changes to the modalities subsequent to the organization's accreditation decision.

(2) An agreement to conform accreditation requirements to any changes in Medicare statutory requirements authorized by section 1834(e) of the Act. The accreditation organization must maintain or adopt standards that are equal to, or more stringent than, those of Medicare.

(3) Information that demonstrates the accreditation organization's knowledge and experience in the advanced diagnostic imaging arena.

(4) The organization's proposed fees for accreditation for each modality in which the organization intends to offer accreditation, including any plans for reducing the burden and cost of accreditation to small and rural suppliers.

(5) Any specific documentation requirements and attestations requested by CMS as a condition of designation under this part.

(6) A detailed description of the organization's survey process, including the following:

(i) Type and frequency of the surveys performed.

(ii) The ability of the organization to conduct timely reviews of accreditation applications, to include the organizations national capacity.

(iii) Description of the organization's audit procedures, including random site visits, site audits, or other strategies for ensuring suppliers maintain compliance for the duration of accreditation.

(iv) Procedures for performing unannounced site surveys.

(v) Copies of the organization's survey forms.

(vi) A description of the accreditation survey review process and the accreditation status decision-making process, including the process for addressing deficiencies identified with the accreditation requirements, and the procedures used to monitor the correction of deficiencies found during an accreditation survey.

(vii) Procedures for coordinating surveys with another accrediting organization if the organization does not accredit all products the supplier provides.

(viii) Detailed information about the individuals who perform evaluations for the accreditation organization, including all of the following information:

(A) The number of professional and technical staff that are available for surveys.

(B) The education, employment, and experience requirements surveyors must meet.

(C) The content and length of the orientation program.

(ix) The frequency and types of in-service training provided to survey personnel.

(x) The evaluation systems used to monitor the performance of individual surveyors and survey teams.

(xi) The policies and procedures regarding an individual's participation in the survey or accreditation decision process of any organization with which the individual is professionally or financially affiliated.

(xii) The policies and procedures used when an organization has a dispute regarding survey findings or an adverse decision.

(7) Detailed information about the size and composition of survey teams for each category of advanced medical imaging service supplier accredited.

(8) A description of the organization's data management and analysis system for its surveys and accreditation decisions, including the kinds of reports, tables, and other displays generated by that system.

(9) The organization's procedures for responding to and for the investigation of complaints against accredited facilities, including policies and procedures regarding coordination of these activities with appropriate licensing bodies and CMS.

(10) The organization's policies and procedures for the withholding or removal of accreditation status for facilities that fail to meet the accreditation

organization's standards or requirements, and other actions taken by the organization in response to noncompliance with its standards and requirements. These policies and procedures must include notifying CMS of Medicare facilities that fail to meet the requirements of the accrediting organization.

(11) A list of all currently accredited suppliers, the type and category of accreditation currently held by each supplier, and the expiration date of each supplier's current accreditation.

(12) A written presentation that demonstrates the organization's ability to furnish CMS with electronic data in ASCII comparable code.

(13) A resource analysis that demonstrates that the organization's staffing, funding, and other resources are adequate to perform the required surveys and related activities.

(14) A statement acknowledging that, as a condition for approval of designation, the organization agrees to carry out the following activities:

(i) Prioritize surveys for those suppliers needing to be accredited by January 1, 2012.

(ii) Notify CMS, in writing, of any Medicare supplier that had its accreditation revoked, withdrawn, revised, or any other remedial or adverse action taken against it by the accreditation organization within 30 calendar days of any such action taken.

(iii) Notify all accredited suppliers within 10 calendar days of the organization's removal from the list of designated accreditation organizations.

(iv) Notify CMS, in writing, at least 30 calendar days in advance of the effective date of any significant proposed changes in its accreditation requirements.

(v) Permit its surveyors to serve as witnesses if CMS takes an adverse action based on accreditation findings.

(vi) Notify CMS, in writing (electronically or hard copy), within 2 business days of a deficiency identified in any accreditation supplier from any source where the deficiency poses an immediate jeopardy to the supplier's beneficiaries or a hazard to the general public.

(vii) Provide, on an annual basis, summary data specified by CMS that relates to the past year's accreditations and trends.

(viii) Attest that the organization will not perform any accreditation surveys of Medicare-participating suppliers with which it has a financial relationship in which it has an interest.

(ix) Conform accreditation requirements to changes in Medicare requirements.

(x) If CMS withdraws an accreditation organization's approved status, work collaboratively with CMS to direct suppliers to the remaining accreditation organizations within a reasonable period of time.

(d) *Determination of whether additional information is needed.* If CMS determines that additional information is necessary to make a determination for approval or denial of the accreditation organization's application for designation, the organization must be notified and afforded an opportunity to provide the additional information.

(e) *Visits to the organization's office.* CMS may visit the organization's offices to verify representations made by the organization in its application, including, but not limited to, reviewing documents and interviewing the organization's staff.

(f) *Formal notice from CMS.* The accreditation organization will receive a formal notice from CMS stating whether the request for designation has been approved or denied. If approval was denied the notice includes the basis for denial and reconsideration and reapplication procedures.

(g) *Ongoing responsibilities of a CMS-approved accreditation organization.* An accreditation organization approved by CMS must carry out the following activities on an ongoing basis:

(1) Provide CMS with all of the following in written format (either electronic or hard copy):

(i) Copies of all accreditation surveys, together with any survey-related information that CMS may require (including corrective action plans and summaries of findings with respect to unmet CMS requirements).

(ii) Notice of all accreditation decisions.

(iii) Notice of all complaints related to suppliers.

(iv) Information about all accredited suppliers against which the accreditation organization has taken remedial or adverse action, including revocation, withdrawal, or revision of the supplier's accreditation.

(v) Notice of any proposed changes in its accreditation standards or requirements or survey process. If the organization implements the changes before or without CMS' approval, CMS may withdraw its approval of the accreditation organization.

(2) Within 30 calendar days after a change in CMS requirements, the accreditation organization must submit an acknowledgment of receipt of CMS' notification to CMS.

(3) The accreditation organization must permit its surveyors to serve as witnesses if CMS takes an adverse action based on accreditation findings.

(4) Within 2 business days of identifying a deficiency of an accredited supplier that poses immediate jeopardy to a beneficiary or to the general public, the accreditation organization must provide CMS with written notice of the deficiency and any adverse action implemented by the accreditation organization.

(5) Within 10 calendar days after CMS' notice to a CMS-approved accreditation organization that CMS intends to withdraw approval of the accreditation organization, the accreditation organization must provide written notice of the withdrawal to all of the organization's accredited suppliers.

(6) The organization must provide, on an annual basis, summary data specified by CMS that relate to the past year's accreditation activities and trends.

(h) *Continuing Federal oversight of approved accreditation organizations.* This paragraph establishes specific criteria and procedures for continuing oversight and for withdrawing approval of a CMS-approved accreditation organization.

(1) *Validation audits.* (i) CMS or its contractor may conduct an audit of an accredited supplier to validate the survey accreditation process of approved accreditation organizations for the TC of advanced diagnostic imaging services.

(ii) The audits must be conducted on a representative sample of suppliers who have been accredited by a particular accrediting organization or in response to allegations of supplier noncompliance with the standards.

(A) When conducted on a representative sample basis, the audit is comprehensive and addresses all of the standards, or may focus on a specific standard in issue.

(B) When conducted in response to an allegation, CMS audits any standards that CMS determines are related to the allegations.

(2) *Notice of intent to withdraw approval.* (i) If, during the audit specified in paragraph (h)(1) of this section, CMS identifies any accreditation programs for which validation audit results indicate—

(A) A 10 percent or greater rate of disparity between findings by the accreditation organization and findings by CMS on standards that do not constitute immediate jeopardy to patient health and safety if unmet; or

(B) Any disparity between findings by the accreditation organization and findings by CMS on standards that constitute immediate jeopardy to patient health and safety if unmet; or,

(C) Irrespective of the rate of disparity, widespread or systemic problems in an organization's accreditation process such that accreditation by that accreditation organization no longer provides CMS with adequate assurance that suppliers meet or exceed the Medicare requirements; then CMS will give the organization written notice of its intent to withdraw approval as specified in paragraph (h)(3) of this section.

(ii) CMS may also provide the organization written notice of its intent to withdraw approval if an equivalency review, onsite observation, or CMS' daily experience with the accreditation organization suggests that the accreditation organization is not meeting the requirements of this section.

(3) *Withdrawal of approval.* CMS may withdraw its approval of an accreditation organization at any time if CMS determines that—

(i) Accreditation by the organization no longer adequately assures that the suppliers furnishing the technical component of advanced diagnostic imaging

service are meeting the established industry standards for each modality and that failure to meet those requirements could jeopardize the health or safety of Medicare beneficiaries and could constitute a significant hazard to the public health; or

(ii) The accreditation organization has failed to meet its obligations with respect to application or reapplication procedures.

(i) *Reconsideration.* An accreditation organization dissatisfied with a determination that its accreditation requirements do not provide or do not continue to provide reasonable assurance that the suppliers accredited by the accreditation organization meet the applicable quality standards is entitled to a reconsideration. CMS reconsiders any determination to deny, remove, or not renew the approval of designation to accreditation organizations if the accreditation organization files a written request for reconsideration by its authorized officials or through its legal representative.

(1) *Filing requirements.* (i) The request must be filed within 30 calendar days of the receipt of CMS notice of an adverse determination or non-renewal.

(ii) The request for reconsideration must specify the findings or issues with which the accreditation organization disagrees and the reasons for the disagreement.

(iii) A requestor may withdraw its request for reconsideration at any time before the issuance of a reconsideration determination.

(2) *CMS response to a filing request.* In response to a request for reconsideration, CMS provides the accreditation organization with—

(i) The opportunity for an informal hearing to be conducted by a hearing officer appointed by the Administrator of CMS and provide the accreditation organization the opportunity to present, in writing and in person, evidence or documentation to refute the determination to deny approval, or to withdraw or not renew designation; and

(ii) Written notice of the time and place of the informal hearing at least 10 business days before the scheduled date.

(3) *Hearing requirements and rules.* (i) The informal reconsideration hearing is open to all of the following:

(A) CMS.

(B) The organization requesting the reconsideration including—

(*1*) Authorized representatives;

(*2*) Technical advisors (individuals with knowledge of the facts of the case or presenting interpretation of the facts); and

(*3*) Legal counsel.

(ii) The hearing is conducted by the hearing officer who receives testimony and documents related to the proposed action.

(iii) Testimony and other evidence may be accepted by the hearing officer even though such evidence may be inadmissible under the Federal Rules of Civil Procedure.

(iv) The hearing officer does not have the authority to compel by subpoena the production of witnesses, papers, or other evidence.

(v) Within 45 calendar days of the close of the hearing, the hearing officer presents the findings and recommendations to the accreditation organization that requested the reconsideration.

(vi) The written report of the hearing officer includes separate numbered findings of fact and the legal conclusions of the hearing officer.

(vii) The hearing officer's decision is final.

(j) *Change of ownership.* An accreditation organization whose accreditation program(s) is (are) approved and recognized by CMS that wishes to undergo a change of ownership are subject to the requirements set out at § 488.5(f) of this chapter.

[74 FR 62006, Nov. 25, 2009, as amended at 87 FR 25427, Apr. 29, 2022]

§ 414.80 Incentive payment for primary care services.

(a) *Definitions.* As defined in this section—

Eligible primary care practitioner means one of the following:

(i) A physician (as defined in section 1861(r)(1) of the Act) who meets all of the following criteria:

(A) Enrolled in Medicare with a primary specialty designation of 08-family practice, 11-internal medicine, 37-pediatrics, or 38-geriatrics.

(B) At least 60 percent of the physician's allowed charges under the physician fee schedule (excluding hospital inpatient care and emergency department visits) during a reference period specified by the Secretary are for primary care services.

(ii) A nurse practitioner, clinical nurse specialist, or physician assistant (as defined in section 1861(aa)(5) of the Act) who meets all of the following criteria:

(A) Enrolled in Medicare with a primary specialty designation of 50-nurse practitioner, 89-certified clinical nurse, or 97-physician assistant.

(B) At least 60 percent of the practitioner's allowed charges under the physician fee schedule (excluding hospital inpatient care and emergency department visits) during a reference period specified by the Secretary are for primary care services.

Primary care services means—

(i) New and established patient office or other outpatient evaluation and management (E/M) visits;

(ii) Initial, subsequent, discharge, and other nursing facility E/M services;

(iii) New and established patient domiciliary, rest home (for example, boarding home), or custodial care E/M services;

(iv) Domiciliary, rest home (for example, assisted living facility), or home care plan oversight services; and

(v) New and established patient home E/M visits.

(b) *Payment.* (1) For primary care services furnished by an eligible primary care practitioner on or after January 1, 2011 and before January 1, 2016, payment is made on a quarterly basis in an amount equal to 10 percent of the payment amount for the primary care services under Part B, in addition to the amount the primary care practitioner would otherwise be paid for the primary care services under Part B.

(2) The payment described in paragraph (b)(1) of this section is made to the eligible primary care practitioner or, where the physician has reassigned his or her benefits to a critical access hospital (CAH) paid under the optional method, to the CAH based on an institutional claim.

[75 FR 73617, Nov. 29, 2010]

§ 414.84 Payment for MDPP services.

(a) *Definitions.* In addition to the definitions specified at § 410.79(b) and § 424.205(a) of this chapter, the following definitions apply to this section.

Attendance payment means a payment that is made to an MDPP supplier for furnishing services to an MDPP beneficiary when the MDPP beneficiary attends an MDPP core or core maintenance session. CMS will allow up to 22 sessions (alone or in combination with other codes, not to exceed 22 sessions in a 12- month timeframe).

Performance goal means a weight loss goal that an MDPP beneficiary must achieve during the MDPP services period for an MDPP supplier to be paid a performance payment.

Performance payment means a payment made to an MDPP supplier for furnishing certain MDPP services to an MDPP beneficiary when the MDPP beneficiary achieves the applicable performance goal.

(b) *Performance payment.* CMS makes one or more types of performance payments to an MDPP supplier as specified in this paragraph (b). Each type of performance payment is made only if the beneficiary achieves the applicable performance goal. Certain performance goals are allowed only once per MDPP beneficiary and include the performance goals in paragraphs (b)(1)(i) and (b)(2)(i) of this section. A performance payment is made only on an assignment-related basis in accordance with § 424.55 of this chapter, and MDPP suppliers must accept the Medicare allowed charge as payment in full and may not bill or collect from the beneficiary any amount. CMS will make a performance payment only to an MDPP supplier that complies with all applicable enrollment and program requirements and only for MDPP services that are furnished by an eligible coach, on or after his or her coach eligibility start date and, if applicable, before his or her coach eligibility end date. As a condition of payment, the MDPP supplier must report the NPI of the coach who furnished the session on the claim for the MDPP session. The two types of performance payments are as follows:

(1) *Performance Goal 1: Achieves the required minimum 5-percent weight loss.*

CMS makes a performance payment to an MDPP supplier for an MDPP beneficiary who achieves the required minimum weight loss as measured in-person or during a distance learning session during a core session or core maintenance session furnished by that supplier. The amount of this performance payment is determined as follows:

(i) For a core session or core maintenance session, as applicable, furnished January 1, 2024 through December 31, 2024 the amount is $145.

(ii) For a core session or core maintenance session, as applicable, furnished during a calendar year subsequent to CY 2018. The performance payment amount specified in this paragraph for the prior year, adjusted as specified in paragraph (d) of this section.

(iii) If the beneficiary maintains the required minimum weight loss during a core maintenance session, as measured in-person or described in § 410.79(e)(3)(iii) the amount is $8.

(2) *Performance Goal 2: Achieves 9-percent weight loss.* CMS makes a performance payment to an MDPP supplier for an MDPP beneficiary who achieves at least a 9-percent weight loss as measured in-person or in a distance learning session during a core session or core maintenance session furnished by that supplier. The amount of this performance payment is determined as follows:

(i) For a core session or core maintenance session, as applicable, furnished January 1, 2024 through December 31, 2024. $25.

(ii) For a core session or core maintenance session, as applicable, furnished during a calendar year subsequent to CY 2018. The performance payment amount specified in this paragraph, adjusted as specified in paragraph (d) of this section.

(c) *Attendance payment: Attends a core session or core maintenance session.* CMS makes a payment to an MDPP supplier if an MDPP beneficiary attends a core session or core maintenance session. An attendance payment is made only on an assignment-related basis in accordance with § 424.55 of this chapter, and MDPP suppliers must accept the Medicare allowed charge as payment in full and may not bill or collect from the beneficiary any amount. CMS will make an attendance payment only to an MDPP supplier that complies with all applicable enrollment and program requirements and only for MDPP services that are furnished by an eligible coach, on or after his or her coach eligibility start date and, if applicable, before his or her coach eligibility end date. As a condition of payment, the MDPP supplier must report the NPI of the coach who furnished the session on the claim for the MDPP session.

(1) The first core session attended, which initiates the MDPP services period, and that first core session was furnished by that supplier.

(2) For the Extended flexibilities period described in § 410.79(e)(2)(iii), the distance learning HCPCS G-code applies for any Set of MDPP services that are delivered by distance learning, as described in § 410.79(b).

(3) Medicare pays for up to 22 sessions in a 12-month period. The amount of this payment is determined as follows:

(i) For a core session or core maintenance session furnished January 1, 2024 through December 31, 2024. $25.

(ii) [Reserved]

(4) Current Procedural Terminology (CPT) Modifier 76 (repeat services by same physician) must be appended to any claim for G9886 or G9887 to identify a MDPP make-up session that was held on the same day as a regularly scheduled MDPP session.

(d) *Updating performance payments and attendance payments.* The performance payments and attendance payments will be adjusted each calendar year by the percent change in the Consumer Price Index for All Urban Consumers (CPI–U) (U.S. city average) for the 12-month period ending June 30th of the year preceding the update year. The percent change update will be calculated based on the level of precision of the index as published by the Bureau of Labor Statistics (BLS) and applied based on one decimal place of precision. The annual MDPP services payment update will be published by CMS transmittal.

[82 FR 53360, Nov. 15, 2017, as amended at 86 FR 65668, Nov. 19, 2021; 86 FR 73159, Dec. 27, 2021; 88 FR 79530, Nov. 16, 2023; 89 FR 98558, Dec. 9, 2024]

§ 414.90 Physician Quality Reporting System (PQRS).

(a) *Basis and scope.* This section implements the following provisions of the Act:

(1) 1848(a)—Payment Based on Fee Schedule.

(2) 1848(k)—Quality Reporting System.

(3) 1848(m)—Incentive Payments for Quality Reporting.

(b) *Definitions.* As used in this section, unless otherwise indicated—

Administrative claims means a reporting mechanism under which an eligible professional or group practice uses claims to report data on PQRS quality measures. Under this reporting mechanism, CMS analyzes claims data to determine which measures an eligible professional or group practice reports.

Certified survey vendor means a vendor that is certified by CMS for a particular program year to transmit survey measures data to CMS.

Covered professional services means services for which payment is made under, or is based on, the Medicare physician fee schedule as provided under section 1848(k)(3) of the Act and which are furnished by an eligible professional.

Direct electronic health record (EHR) product means an electronic health record vendor's product and version that submits data on PQRS measures directly to CMS.

Electronic health record (EHR) data submission vendor product means an entity that receives and transmits data on PQRS measures from an EHR product to CMS.

Eligible professional means any of the following:

(i) A physician.

(ii) A practitioner described in section 1842(b)(18)(C) of the Act.

(iii) A physical or occupational therapist or a qualified speech-language pathologist.

(iv) A qualified audiologist (as defined in section 1861(ll)(3)(B) of the Act).

Group practice means a physician group practice that is defined by a TIN, with 2 or more individual eligible professionals (or, as identified by NPIs) that has reassigned their billing rights to the TIN.

Group practice reporting option (GPRO) web interface means a web product developed by CMS that is used by group practices that are selected to participate in the group practice reporting option (GPRO) to submit data on PQRS quality measures.

Maintenance of Certification Program means a continuous assessment program, such as qualified American Board of Medical Specialties Maintenance of Certification Program or an equivalent program (as determined by the Secretary), that advances quality and the lifelong learning and self-assessment of board certified specialty physicians by focusing on the competencies of patient care, medical knowledge, practice-based learning, interpersonal and communication skills, and professionalism. Such a program must include the following:

(i) The program requires the physician to maintain a valid unrestricted license in the United States.

(ii) The program requires a physician to participate in educational and self-assessment programs that require an assessment of what was learned.

(iii) The program requires a physician to demonstrate, through a formalized secure examination, that the physician has the fundamental diagnostic skills, medical knowledge, and clinical judgment to provide quality care in their respective specialty.

(iv) The program requires successful completion of a qualified maintenance of certification program practice assessment.

Maintenance of Certification Program Practice Assessment means an assessment of a physician's practice that—

(i) Includes an initial assessment of an eligible professional's practice that is designed to demonstrate the physician's use of evidence-based medicine.

(ii) Includes a survey of patient experience with care.

(iii) Requires a physician to implement a quality improvement intervention to address a practice weakness identified in the initial assessment under paragraph (h) of this section and then to remeasure to assess performance improvement after such intervention.

Measures group means a subset of six or more PQRS measures that have a

particular clinical condition or focus in common. The denominator definition and coding of the measures group identifies the condition or focus that is shared across the measures within a particular measures group.

Physician Quality Reporting System (PQRS) means the physician reporting system under section 1848(k) of the Act for the reporting by eligible professionals of data on quality measures and the incentive payment associated with this physician reporting system.

Performance rate means the percentage of a defined population who receives a particular process of care or achieve a particular outcome for a particular quality measure.

Qualified clinical data registry means a CMS-approved entity that has self-nominated and successfully completed a qualification process that collects medical and/or clinical data for the purpose of patient and disease tracking to foster improvement in the quality of care provided to patients. A qualified clinical data registry must perform the following functions:

(i) Submit quality measures data or results to CMS for purposes of demonstrating that, for a reporting period, its eligible professionals have satisfactorily participated in PQRS. A qualified clinical data registry must have in place mechanisms for the transparency of data elements and specifications, risk models, and measures.

(ii) Submit to CMS, for purposes of demonstrating satisfactory participation, quality measures data on multiple payers, not just Medicare patients.

(iii) Provide timely feedback, at least four times a year, on the measures at the individual participant level for which the qualified clinical data registry reports on the eligible professional's behalf for purposes of the individual eligible professional's satisfactory participation in the clinical quality data registry.

(iv) Possess benchmarking capacity that measures the quality of care an eligible professional provides with other eligible professionals performing the same or similar functions.

Qualified registry means a medical registry or a maintenance of certification program operated by a specialty body of the American Board of Medical Specialties that, with respect to a particular program year, has self-nominated and successfully completed a vetting process (as specified by CMS) to demonstrate its compliance with the PQRS qualification requirements specified by CMS for that program year. The registry may act as a data submission vendor, which has the requisite legal authority to provide PQRS data (as specified by CMS) on behalf of an eligible professional to CMS. If CMS finds that a qualified registry submits grossly inaccurate data for reporting periods occurring in a particular year, CMS reserves the right to disqualify a registry for reporting periods occurring in the subsequent year.

Reporting rate means the percentage of patients that the eligible professional indicated a quality action was or was not performed divided by the total number of patients in the denominator of the measure.

(c) *Incentive payments.* For 2007 to 2014, with respect to covered professional services furnished during a reporting period by an eligible professional, an eligible professional (or in the case of a group practice under paragraph (i) of this section, a group practice) may receive an incentive if—

(1) There are any quality measures that have been established under the PQRS that are applicable to any such services furnished by such professional (or in the case of a group practice under paragraph (i) of this section, such group practice) for such reporting period; and

(2) If the eligible professional (or in the case of a group practice under paragraph (j) of this section, the group practice) satisfactorily submits (as determined under paragraph (g) of this section for the eligible professional and paragraph (i) of this section for the group practice) to the Secretary data on such quality measures in accordance with the PQRS for such reporting period, in addition to the amount otherwise paid under section 1848 of the Act, there also must be paid to the eligible professional (or to an employer or facility in the cases described in section 1842(b)(6)(A) of the Act or, in the case of a group practice under paragraph (i) of this section, to the group

practice) from the Federal Supplementary Medical Insurance Trust Fund established under section 1841 of the Act an amount equal to the applicable quality percent (as specified in paragraph (c)(3) of this section) of the eligible professional's (or, in the case of a group practice under paragraph (i) of this section, the group practice's) total estimated allowed charges for all covered professional services furnished by the eligible professional (or, in the case of a group practice under paragraph (i) of this section, by the group practice) during the reporting period.

(3) The applicable quality percent is as follows:

(i) For 2007 and 2008, 1.5 percent.

(ii) For 2009 and 2010, 2.0 percent.

(iii) For 2011, 1.0 percent.

(iv) For 2012, 2013, and 2014, 0.5 percent.

(4) For purposes of this paragraph (c)—

(i) The eligible professional's (or, in the case of a group practice under paragraph (i) of this section, the group practice's) total estimated allowed charges for covered professional services furnished during a reporting period are determined based on claims processed in the National Claims History (NCH) no later than 2 months after the end of the applicable reporting period;

(ii) In the case of the eligible professional who furnishes covered professional services in more than one practice, incentive payments are separately determined for each practice based on claims submitted for the eligible professional for each practice;

(iii) Incentive payments to a group practice under this paragraph must be in lieu of the payments that would otherwise be made under the PQRS to eligible professionals in the group practice for meeting the criteria for satisfactory reporting for individual eligible professionals. For any program year in which the group practice (as identified by the TIN) is selected to participate in the PQRS group practice reporting option, the eligible professional cannot individually qualify for a PQRS incentive payment by meeting the requirements specified in paragraph (g) of this section.

(iv) Incentive payments earned by the eligible professional (or in the case of a group practice under paragraph (i) of this section, by the group practice) for a particular program year will be paid as a single consolidated payment to the TIN holder of record.

(5) The Secretary must treat an individual eligible professional, as identified by a unique TIN/NPI combination, as satisfactorily submitting data on quality measures (as determined under paragraph (g) of this section), if the eligible professional is satisfactorily participating (as determined under paragraph (h) of this section), in a qualified clinical data registry.

(d) *Additional incentive payment.* Through 2014, if an eligible professional meets the requirements described in paragraph (d)(2) of this section, the applicable percent for such year, as described in paragraphs (c)(3)(iii) and (iv) of this section, must be increased by 0.5 percentage points.

(1) In order to qualify for the additional incentive payment described in paragraph (d) of this section, an eligible professional must meet all of the following requirements:

(i) Satisfactorily submits data on quality measures, or, for 2014, in lieu of satisfactory reporting, satisfactorily participates in a qualified clinical data registry for purposes of this section for the applicable incentive year.

(ii) Have such data submitted on their behalf through a Maintenance of Certification program that meets:

(A) The criteria for a registry (as specified by CMS); or

(B) An alternative form and manner determined appropriate by the Secretary.

(iii) The eligible professional, more frequently than is required to qualify for or maintain board certification status—

(A) Participates in a maintenance of certification program for a year; and

(B) Successfully completes a qualified maintenance of certification program practice assessment for such year.

(2) In order for an eligible professional to receive the additional incentive payment, a Maintenance of Certification Program must submit to the Secretary, on behalf of the eligible professional, information—

(i) In a form and manner specified by the Secretary, that the eligible professional has successfully met the requirements of paragraph (d)(1)(iii) of this section, which may be in the form of a structural measure.

(ii) If requested by the Secretary, on the survey of patient experience with care.

(iii) As the Secretary may require, on the methods, measures, and data used under the Maintenance of Certification Program and the qualified Maintenance of Certification Program practice assessment.

(e) *Payment adjustments.* For 2015 through 2018, with respect to covered professional services furnished by an eligible professional, if the eligible professional does not satisfactorily submit data on quality measures for covered professional services for the quality reporting period for the year (as determined under section 1848(m)(3)(A) of the Act), the fee schedule amount for such services furnished by such professional during the year (including the fee schedule amount for purposes for determining a payment based on such amount) must be equal to the applicable percent of the fee schedule amount that would otherwise apply to such services under this paragraph (e).

(1) The applicable percent is as follows:

(i) For 2015, 98.5 percent.

(ii) For 2016 through 2018, 98 percent.

(2) The Secretary must treat an individual eligible professional, as identified by a unique TIN/NPI combination, as satisfactorily submitting data on quality measures (as determined under paragraph (h) of this section), if the eligible professional is satisfactorily participating, in a qualified clinical data registry.

(f) *Use of appropriate and consensus-based quality measures.* For measures selected for inclusion in the PQRS quality measure set, CMS will use group practice measures determined appropriate by CMS and consensus-based quality measures that meet one of the following criteria:

(1) Be such measures selected by the Secretary from measures that have been endorsed by the entity with a contract with the Secretary under section 1890(a) of the Act. In the case of a specified area or medical topic determined appropriate by the Secretary for which a feasible and practical measure has not been endorsed by the entity with a contract under section 1890(a) of the Act, the Secretary may specify a measure that is not so endorsed as long as due consideration is given to measures that have been endorsed or adopted by a consensus organization identified by the Secretary.

(2) For each quality measure adopted by the Secretary under this paragraph, the Secretary ensures that eligible professionals have the opportunity to provide input during the development, endorsement, or selection of quality measures applicable to services they furnish.

(g) *Use of quality measures for satisfactory participation in a qualified clinical data registry.* For measures selected for reporting to meet the criteria for satisfactory participation in a qualified clinical data registry, CMS will use measures selected by qualified clinical data registries based on parameters set by CMS.

(h) *Satisfactory reporting requirements for the incentive payments.* In order to qualify to earn a PQRS incentive payment for a particular program year, an individual eligible professional, as identified by a unique TIN/NPI combination, must meet the criteria for satisfactory reporting specified by CMS under paragraph (h)(3) of (h)(5) of this section for such year by reporting on either individual PQRS quality measures or PQRS measures groups identified by CMS during a reporting period specified in paragraph (h)(1) of this section, using one of the reporting mechanisms specified in paragraph (h)(2) or (4) of this section, and using one of the reporting criteria specified in paragraph (h)(3) or (5) of this section.

(1) *Reporting periods.* For purposes of this paragraph, the reporting period is—

(i) The 12-month period from January 1 through December 31 of such program year.

(ii) A 6-month period from July 1 through December 31 of such program year.

(A) For 2011, such 6-month reporting period is not available for EHR–based

reporting of individual PQRS quality measures.

(B) For 2012 and subsequent program years, such 6-month reporting period from July 1 through December 31 of such program year is only available for registry-based reporting of PQRS measures groups by eligible professionals.

(2) *Reporting mechanisms for individual eligible professionals.* An individual eligible professional who wishes to participate in the PQRS must report information on PQRS quality measures identified by CMS in one of the following manners:

(i) *Claims.* Reporting PQRS quality measures or PQRS measures groups to CMS, by no later than 2 months after the end of the applicable reporting period, on the eligible professional's Medicare Part B claims for covered professional services furnished during the applicable reporting period.

(A) If an eligible professional re-submits a Medicare Part B claim for reprocessing, the eligible professional may not attach a G–code at that time for reporting on individual PQRS measures or measures groups.

(B) [Reserved]

(ii) *Registry.* Reporting PQRS quality measures or PQRS measures groups to a qualified registry in the form and manner and by the deadline specified by the qualified registry selected by the eligible professional. The selected registry must submit information, as required by CMS, for covered professional services furnished by the eligible professional during the applicable reporting period to CMS on the eligible professional's behalf.

(iii) *Direct EHR product.* Reporting PQRS quality measures to CMS by extracting clinical data using a secure data submission method, as required by CMS, from a direct EHR product by the deadline specified by CMS for covered professional services furnished by the eligible professional during the applicable reporting period.

(iv) *EHR data submission vendor.* Reporting PQRS quality measures to CMS by extracting clinical data using a secure data submission method, as required by CMS, from an EHR data submission vendor product by the deadline specified by CMS for covered professional services furnished by the eligible professional during the applicable reporting period.

(v) Although an eligible professional may attempt to qualify for the PQRS incentive payment by reporting on both individual PQRS quality measures and measures groups, using more than one reporting mechanism (as specified in paragraph (g)(2) of this section), or reporting for more than one reporting period, he or she will receive only one PQRS incentive payment per TIN/NPI combination for a program year.

(3) *Satisfactory reporting criteria for individual eligible professionals for the 2014 PQRS incentive.* An individual eligible professional who wishes to qualify for the 2014 PQRS incentive must report information on PQRS quality measures data in one of the following manners:

(i) *Via Claims.* For the 12-month 2014 PQRS incentive reporting period—

(A) Report at least 9 measures covering at least 3 National Quality Strategy domains, and report each measure for at least 50 percent of the Medicare Part B FFS patients seen during the reporting period to which the measure applies; or if less than 9 measures covering at least 3 National Quality Strategy domains apply to the eligible professional, report 1 to 8 measures covering 1 to 3 National Quality Strategy domains and report each measure for at least 50 percent of the Medicare Part B FFS patients seen during the reporting period to which the measure applies. For an eligible professional who reports fewer than 9 measures covering at least 3 NQS domains via the claims-based reporting mechanism, the eligible professional would be subject to the Measures Applicability Validation process, which would allow us to determine whether an eligible professional should have reported quality data codes for additional measures and/or covering additional National Quality Strategy domains. Measures with a 0 percent performance rate would not be counted.

(B) [Reserved]

(ii) *Via Qualified Registry.* (A) For the 12-month 2014 PQRS incentive reporting period—

(1) Report at least 9 measures covering at least 3 of the National Quality Strategy domains report each measure

for at least 50 percent of the eligible professional's Medicare Part B FFS patients seen during the reporting period to which the measure applies; or, if less than 9 measures covering at least 3 NQS domains apply to the eligible professional, report 1 to 8 measures covering 1 to 3 National Quality Strategy domains for which there is Medicare patient data and report each measure for at least 50 percent of the eligible professional's Medicare Part B FFS patients seen during the reporting period to which the measure applies. For an eligible professional who reports fewer than 9 measures covering at least 3 NQS domains via the qualified registry-based reporting mechanism, the eligible professional will be subject to the Measures Applicability Validation process, which would allow us to determine whether an eligible professional should have reported on additional measures and/or measures covering additional National Quality Strategy domains. Measures with a 0 percent performance rate would not be counted.

(*2*) Report at least 1 measures group and report each measures group for at least 20 patients, a majority of which much be Medicare Part B FFS patients. Measures with a 0 percent performance rate or measures groups containing a measure with a 0 percent performance rate will not be counted.

(B) For the 6-month 2014 PQRS incentive reporting period, report at least 1 measures group and report each measures group for at least 20 patients, a majority of which much be Medicare Part B FFS patients. Measures groups containing a measure with a 0 percent performance rate will not be counted.

(iii) *Via EHR Direct Product.* For the 12-month 2014 PQRS incentive reporting period, report 9 measures covering at least 3 of the National Quality Strategy domains. If an eligible professional's CEHRT does not contain patient data for at least 9 measures covering at least 3 domains, then the eligible professional must report the measures for which there is Medicare patient data. An eligible professional must report on at least 1 measure for which there is Medicare patient data.

(iv) *Via EHR Data Submission Vendor.* For the 12-month 2014 PQRS incentive reporting period, report 9 measures covering at least 3 of the National Quality Strategy domains. If an eligible professional's CEHRT does not contain patient data for at least 9 measures covering at least 3 domains, then the eligible professional must report the measures for which there is Medicare patient data. An eligible professional must report on at least 1 measure for which there is Medicare patient data.

(4) *Reporting mechanisms for group practices.* With the exception of a group practice who wishes to participate in the PQRS using the certified survey vendor mechanism (as specified in paragraph (h)(4)(v) of this section), a group practice must report information on PQRS quality measures identified by CMS in one of the following reporting mechanisms:

(i) *Web interface.* For 2013 and subsequent years, reporting PQRS quality measures to CMS using a CMS web interface in the form and manner and by the deadline specified by CMS.

(ii) *Registry.* For 2013 and subsequent years, reporting on PQRS quality measures to a qualified registry in the form and manner and by the deadline specified by the qualified registry selected by the eligible professional. The selected registry must submit information, as required by CMS, for covered professional services furnished by the eligible professional during the applicable reporting period to CMS on the eligible professional's behalf.

(iii) *Direct EHR product.* For 2014 and subsequent years, reporting PQRS quality measures to CMS by extracting clinical data using a secure data submission method, as required by CMS, from a direct EHR product by the deadline specified by CMS for covered professional services furnished by the eligible professional during the applicable reporting period.

(iv) *EHR data submission vendor.* For 2014 and subsequent years, reporting PQRS quality measures to CMS by extracting clinical data using a secure data submission method, as required by CMS, from an EHR data submission vendor product by the deadline specified by CMS for covered professional services furnished by the eligible professional during the applicable reporting period.

(v) *Certified survey vendors.* For 2014 and subsequent years, reporting CAHPS for PQRS survey measures to CMS using a vendor that is certified by CMS for a particular program year to transmit survey measures data to CMS. Group practices that elect this reporting mechanism must select an additional group practice reporting mechanism in order to meet the criteria for satisfactory reporting for the incentive payments.

(vi) Although a group practice may attempt to qualify for the PQRS incentive payment by using more than one reporting mechanism (as specified in paragraph (g)(3) of this section), or reporting for more than one reporting period, the group practice will receive only one PQRS incentive payment for a program year.

(5) *Satisfactory reporting criteria for group practices for the 2014 PQRS incentive.* A group practice who wishes to qualify for the 2014 PQRS incentive must report information on PQRS quality measures identified by CMS in one of the following manners:

(i) *Via the GPRO web interface.* (A) For the 12-month 2014 PQRS incentive reporting period, for a group practice of 25 to 99 eligible professionals, report on all measures included in the web interface and populate data fields for the first 218 consecutively ranked and assigned beneficiaries in the order in which they appear in the group's sample for each module or preventive care measure. If the pool of eligible assigned beneficiaries is less than 218, then report on 100 percent of assigned beneficiaries.

(B) For the 12-month 2014 PQRS incentive reporting period, for a group practice of 100 or more eligible professionals, report on all measures included in the web interface and populate data fields for the first 411 consecutively ranked and assigned beneficiaries in the order in which they appear in the group's sample for each module or preventive care measure. If the pool of eligible assigned beneficiaries is less than 411, then report on 100 percent of assigned beneficiaries. In addition, for the 12-month 2014 PQRS incentive reporting period, the group practice must report all CAHPS for PQRS survey measures via a CMS-certified survey vendor, and report at least 6 measures covering at least 2 of the National Quality Strategy domains using a qualified registry, direct EHR product, or EHR data submission vendor.

(ii) *Via Qualified Registry.* For the 12-month 2014 PQRS incentive reporting period, for a group practice of 2 or more eligible professionals, report at least 9 measures, covering at least 3 of the National Quality Strategy domains and report each measure for at least 50 percent of the group practice's Medicare Part B FFS patients seen during the reporting period to which the measure applies; or, if less than 9 measures covering at least 3 NQS domains apply to the group practice, then the group practice must report 1–8 measures for which there is Medicare patient data and report each measure for at least 50 percent of the group practice's Medicare Part B FFS patients seen during the reporting period to which the measure applies. For a group practice who reports fewer than 9 measures covering at least 3 NQS domains via the qualified registry-based reporting mechanism, the group practice would be subject to the Measures Applicability Validation process, which would allow us to determine whether a group practice should have reported on additional measures and/or measures covering additional National Quality Strategy domains. Measures with a 0 percent performance rate would not be counted.

(iii) *Via EHR Direct Product.* For the 12-month 2014 PQRS incentive reporting period, for a group practice of 2 or more eligible professionals, report 9 measures covering at least 3 of the National Quality Strategy domains. If a group practice's CEHRT does not contain patient data for at least 9 measures covering at least 3 domains, then the group practice must report the measures for which there is Medicare patient data. A group practice must report on at least 1 measure for which there is Medicare patient data.

(iv) *Via EHR Data Submission Vendor.* For the 12-month 2014 PQRS incentive reporting period, for a group practice of 2 or more eligible professionals, report 9 measures covering at least 3 of

the National Quality Strategy domains. If a group practice's CEHRT does not contain patient data for at least 9 measures covering at least 3 domains, then the group practice must report the measures for which there is Medicare patient data. A group practice must report on at least 1 measure for which there is Medicare patient data.

(v) *Via a Certified survey vendor, in addition to the GPRO web interface, qualified registry, direct EHR product, or EHR data submission vendor reporting mechanisms.* For the 12-month 2014 PQRS incentive reporting period, for a group practice of 25 or more eligible professionals, report all CAHPS for PQRS survey measures via a CMS-certified survey vendor, and report at least 6 measures covering at least 2 of the National Quality Strategy domains using a qualified registry, direct EHR product, EHR data submission vendor, or GPRO web interface.

(i) *Satisfactory participation requirements for the incentive payments for individual eligible professionals.* To qualify for the 2014 PQRS incentive using a qualified clinical data registry, an individual eligible professional, as identified by a unique TIN/NPI combination, must meet the criteria for satisfactory participation as specified under paragraph (i)(3) of this section by reporting on quality measures identified by a qualified clinical data registry during a reporting period specified in paragraph (i)(1) of this section, and using the reporting mechanism specified in paragraph (i)(2) of this section.

(1) *Reporting period.* For purposes of this paragraph, the reporting period is the 12–month period from January 1 through December 31.

(2) *Reporting Mechanism.* An individual eligible professional who wishes to meet the criteria for satisfactory participation in a qualified clinical data registry must use a qualified clinical data registry to report information on quality measures identified by the qualified clinical data registry.

(3) *Satisfactory participation criteria for individual eligible professionals for the 2014 PQRS incentive.* An individual eligible professional who wishes to qualify for the 2014 PQRS incentive through satisfactory participation in a qualified clinical data registry must report information on quality measures identified by the qualified clinical data registry in the following manner:

(i) For the 12-month 2014 PQRS incentive reporting period, report at least 9 measures designated for reporting under a qualified clinical data registry covering at least 3 of the National Quality Strategy domains and report each measure for at least 50 percent of the eligible professional's patients. Of the measures reported via a qualified clinical data registry, the eligible professional must report on at least 1 outcome measure.

(ii) [Reserved]

(j) *Satisfactory reporting requirements for the payment adjustments.* In order to satisfy the requirements for the PQRS payment adjustment for a particular program year, an individual eligible professional, as identified by a unique TIN/NPI combination, or a group practice must meet the criteria for satisfactory reporting specified by CMS for such year by reporting on either individual PQRS measures or PQRS measures groups identified by CMS during a reporting period specified in paragraph (j)(1) of this section, using one of the reporting mechanisms specified in paragraph (j)(2) or (4) of this section, and using one of the reporting criteria specified in section (j)(3) or (5) of this section.

(1) For purposes of this paragraph (j), the reporting period for the payment adjustment, with respect to a payment adjustment year, is the 12-month period from January 1 through December 31 that falls 2 years prior to the year in which the payment adjustment is applied.

(i) For the 2015 and 2016 PQRS payment adjustments only, an alternative 6-month reporting period, from July 1–December 31 that fall 2 years prior to the year in which the payment adjustment is applied, is also available.

(ii) Secondary Reporting Period for the 2017 PQRS payment adjustment for certain eligible professionals or group practices– Individual eligible professionals or group practices, who bill under the TIN of an ACO participant if the ACO failed to report data on behalf of such EPs or group practices during the previously established reporting

period for the 2017 PQRS payment adjustment, may separately report during a secondary reporting period for the 2017 PQRS payment adjustment. The secondary reporting period for the 2017 PQRS payment adjustment for the affected individual eligible professionals or group practices is January 1, 2016 through December 31, 2016.

(2) *Reporting mechanisms for individual eligible professionals.* An individual eligible professional participating in the PQRS must report information on PQRS quality measures identified by CMS in one of the following manners:

(i) *Claims.* Reporting PQRS quality measures or PQRS measures groups to CMS, by no later than 2 months after the end of the applicable reporting period, on the eligible professional's Medicare Part B claims for covered professional services furnished during the applicable reporting period.

(A) If an eligible professional re-submits a Medicare Part B claim for reprocessing, the eligible professional may not attach a G-code at that time for reporting on individual PQRS measures or measures groups.

(B) [Reserved]

(ii) *Registry.* Reporting PQRS quality measures or PQRS measures groups to a qualified registry in the form and manner and by the deadline specified by the qualified registry selected by the eligible professional. The selected registry must submit information, as required by CMS, for covered professional services furnished by the eligible professional during the applicable reporting period to CMS on the eligible professional's behalf.

(iii) *Direct EHR product.* Reporting PQRS quality measures to CMS by extracting clinical data using a secure data submission method, as required by CMS, from a direct EHR product by the deadline specified by CMS for covered professional services furnished by the eligible professional during the applicable reporting period.

(iv) *EHR data submission vendor.* Reporting PQRS quality measures to CMS by extracting clinical data using a secure data submission method, as required by CMS, from an EHR data submission vendor product by the deadline specified by CMS for covered professional services furnished by the eligible professional during the applicable reporting period.

(v) *Administrative claims.* For 2015, reporting data on PQRS quality measures via administrative claims during the applicable reporting period. Eligible professionals that are administrative claims reporters must meet the following requirement for the payment adjustment:

(A) Elect to participate in the PQRS using the administrative claims reporting option.

(B) Reporting Medicare Part B claims data for CMS to determine whether the eligible professional has performed services applicable to certain individual PQRS quality measures.

(3) *Satisfactory reporting criteria for individual eligible professionals for the 2016 PQRS payment adjustment.* An individual eligible professional who wishes to meet the criteria for satisfactory reporting for the 2016 PQRS payment adjustment must report information on PQRS quality measures identified by CMS in one of the following manners:

(i) *Via Claims.* (A) For the 12-month 2016 PQRS payment adjustment reporting period—

(*1*)(*i*) Report at least 9 measures covering at least 3 National Quality Strategy domains and report each measure for at least 50 percent of the Medicare Part B FFS patients seen during the reporting period to which the measure applies; or if less than 9 measures covering at least 3 NQS domains apply to the eligible professional, report 1–8 measures covering 1–3 National Quality Strategy domains, and report each measure for at least 50 percent of the Medicare Part B FFS patients seen during the reporting period to which the measure applies. For an eligible professional who reports fewer than 9 measures covering at least 3 NQS domains via the claims-based reporting mechanism, the eligible professional would be subject to the Measures Applicability Validation process, which would allow us to determine whether an eligible professional should have reported quality data codes for additional measures and/or covering additional National Quality Strategy domains; or

(*ii*) Report at least 3 measures covering at least 1 NQS domain, or, if less than 3 measures covering at least 1 NQS domain apply to the eligible professional, report 1–2 measures covering at least 1 NQS domain; and report each measure for at least 50 percent of the eligible professional's Medicare Part B FFS patients seen during the reporting period to which the measure applies.

(*2*) Measures with a 0 percent performance rate would not be counted.

(ii) *Via Qualified Registry*. (A) For the 12-month 2016 PQRS payment adjustment reporting period—

(*1*)(*i*) Report at least 9 measures covering at least 3 of the National Quality Strategy domains; or if less than 9 measures covering at least 3 NQS domains apply to the eligible professional, report 1 to 8 measures covering 1 to 3 National Quality Strategy domains for which there is Medicare patient data, and report each measure for at least 50 percent of the eligible professional's Medicare Part B FFS patients seen during the reporting period to which the measure applies. For an eligible professional who reports fewer than 9 measures covering at least 3 NQS domains via the qualified registry-based reporting mechanism, the eligible professional would be subject to the Measures Applicability Validation process, which would allow us to determine whether an eligible professional should have reported on additional measures and/or measures covering additional National Quality Strategy domains; or

(*ii*) Report at least 3 measures covering at least 1 of the NQS domains; or if less than 3 measures covering at least 1 NQS domain apply to the eligible professional, report 1 to 2 measures covering 1 National Quality Strategy domain for which there is Medicare patient data, and report each measure for at least 50 percent of the eligible professional's Medicare Part B FFS patients seen during the reporting period to which the measure applies. For an eligible professional who reports fewer than 3 measures covering 1 NQS domain via the registry-based reporting mechanism, the eligible professional would be subject to the Measures Applicability Validation process, which would allow us to determine whether an eligible professional should have reported on additional measures; or

(*iii*) Report at least 1 measures group and report each measures group for at least 20 patients, a majority of which much be Medicare Part B FFS patients.

(*2*) Measures with a 0 percent performance rate or measures groups containing a measure with a 0 percent performance rate will not be counted.

(B) For the 6-month 2016 PQRS payment adjustment reporting period—

(*1*) Report at least 1 measures group and report each measures group for at least 20 patients, a majority of which much be Medicare Part B FFS patients. Measures groups containing a measure with a 0 percent performance rate will not be counted.

(iii) *Via EHR Direct Product*. For the 12-month 2016 PQRS payment adjustment reporting period, report 9 measures covering at least 3 of the National Quality Strategy domains. If an eligible professional's CEHRT does not contain patient data for at least 9 measures covering at least 3 domains, then the eligible professional must report the measures for which there is Medicare patient data. An eligible professional must report on at least 1 measure for which there is Medicare patient data.

(iv) *Via EHR Data Submission Vendor*. For the 12-month 2016 PQRS payment adjustment reporting period, report 9 measures covering at least 3 of the National Quality Strategy domains. If an eligible professional's CEHRT does not contain patient data for at least 9 measures covering at least 3 domains, then the eligible professional must report the measures for which there is Medicare patient data. An eligible professional must report on at least 1 measure for which there is Medicare patient data.

(4) *Satisfactory Reporting Criteria for Individual Eligible Professionals for the 2017 PQRS Payment Adjustment*. An individual eligible professional who wishes to meet the criteria for satisfactory reporting for the 2017 PQRS payment adjustment must report information on PQRS quality measures identified by CMS in one of the following manners:

(i) *Via Claims.* (A) For the 12-month 2017 PQRS payment adjustment reporting period—

(*1*)(*i*) Report at least 9 measures, covering at least 3 of the NQS domains and report each measure for at least 50 percent of the eligible professional's Medicare Part B FFS patients seen during the reporting period to which the measure applies. Of the 9 measures reported, if the eligible professional sees at least 1 Medicare patient in a face-to-face encounter, the eligible professional must report on at least 1 measure contained in the cross-cutting measure set specified by CMS. If less than 9 measures apply to the eligible professional, report up to 8 measures and report each measure for at least 50 percent of the Medicare Part B FFS patients seen during the reporting period to which the measure applies. Measures with a 0 percent performance rate would not be counted.

(*ii*) [Reserved]

(ii) *Via Qualified Registry.* (A) For the 12-month 2017 PQRS payment adjustment reporting period—

(*1*)(*i*) Report at least 9 measures, covering at least 3 of the NQS domains and report each measure for at least 50 percent of the eligible professional's Medicare Part B FFS patients seen during the reporting period to which the measure applies. Of the 9 measures reported, if the eligible professional sees at least 1 Medicare patient in a face-to-face encounter, the eligible professional must report on at least 1 measure contained in the cross-cutting measure set specified by CMS. If less than 9 measures apply to the eligible professional, report up to 8 measures and report each measure for at least 50 percent of the Medicare Part B FFS patients seen during the reporting period to which the measure applies.

(*ii*) Report at least 1 measures group and report each measures group for at least 20 patients, a majority of which much be Medicare Part B FFS patients.

(*2*) Measures with a 0 percent performance rate or measures groups containing a measure with a 0 percent performance rate will not be counted.

(iii) *Via EHR Direct Product.* For the 12-month 2017 PQRS payment adjustment reporting period, report 9 measures covering at least 3 of the NQS domains. If an eligible professional's direct EHR product does not contain patient data for at least 9 measures covering at least 3 domains, then the eligible professional must report the measures for which there is Medicare patient data. An eligible professional must report on at least 1 measure for which there is Medicare patient data.

(iv) *Via EHR Data Submission Vendor.* For the 12-month 2017 PQRS payment adjustment reporting period, report 9 measures covering at least 3 of the NQS domains. If an eligible professional's EHR data submission vendor product does not contain patient data for at least 9 measures covering at least 3 domains, then the eligible professional must report the measures for which there is Medicare patient data. An eligible professional must report on at least 1 measure for which there is Medicare patient data.

(v) Paragraphs (j)(8)(ii), (iii), and (iv) of this section apply to individuals reporting using the secondary reporting period established under paragraph (j)(1)(ii) of this section for the 2017 PQRS payment adjustment.

(5) *Reporting mechanisms for group practices.* With the exception of a group practice who wishes to participate in the PQRS using the certified survey vendor mechanism, a group practice participating in the PQRS must report information on PQRS quality measures identified by CMS in one of the following reporting mechanisms:

(i) *Web interface.* For the 2015 payment adjustment and subsequent payment adjustments, reporting PQRS quality measures to CMS using a CMS web interface in the form and manner and by the deadline specified by CMS.

(ii) *Registry.* For the 2015 subsequent adjustment and subsequent payment adjustments, reporting on PQRS quality measures to a qualified registry in the form and manner and by the deadline specified by the qualified registry selected by the eligible professional. The selected registry will submit information, as required by CMS, for covered professional services furnished by the eligible professional during the applicable reporting period to CMS on the eligible professional's behalf.

(iii) *Direct EHR product.* For the 2016 subsequent adjustment and subsequent payment adjustments, reporting PQRS quality measures to CMS by extracting clinical data using a secure data submission method, as required by CMS, from a direct EHR product by the deadline specified by CMS for covered professional services furnished by the eligible professional during the applicable reporting period.

(iv) *EHR data submission vendor.* For the 2016 subsequent adjustment and subsequent payment adjustments, reporting PQRS quality measures to CMS by extracting clinical data using a secure data submission method, as required by CMS, from an EHR data submission vendor product by the deadline specified by CMS for covered professional services furnished by the group practice during the applicable reporting period.

(v) *Administrative claims.* For 2015, reporting data on PQRS quality measures via administrative claims during the applicable reporting period. Group practices that are administrative claims reporters must meet the following requirement for the payment adjustment:

(A) Elect to participate in the PQRS using the administrative claims reporting option.

(B) Reporting Medicare Part B claims data for CMS to determine whether the group practice has performed services applicable to certain individual PQRS quality measures.

(vi) *Certified Survey Vendors.* For 2016 and subsequent years, reporting CAHPS for PQRS survey measures to CMS using a vendor that is certified by CMS for a particular program year to transmit survey measures data to CMS. Group practices that elect this reporting mechanism must select an additional group practice reporting mechanism in order to meet the criteria for satisfactory reporting for the payment adjustment.

(6) *Satisfactory reporting criteria for group practices for the 2016 PQRS payment adjustment.* A group practice who wishes to meet the criteria for satisfactory reporting for the 2016 PQRS payment adjustment must report information on PQRS quality measures identified by CMS in one of the following manners:

(i) *Via the GPRO web interface.* (A) For the 12-month 2016 PQRS payment adjustment reporting period, for a group practice of 25 to 99 eligible professionals, report on all measures included in the web interface and populate data fields for the first 218 consecutively ranked and assigned beneficiaries in the order in which they appear in the group's sample for each module or preventive care measure. If the pool of eligible assigned beneficiaries is less than 218, then report on 100 percent of assigned beneficiaries.

(B) For the 12-month 2016 PQRS payment adjustment reporting period, for a group practice of 100 or more eligible professionals, report on all measures included in the Web interface and populate data fields for the first 411 consecutively ranked and assigned beneficiaries in the order in which they appear in the group's sample for each module or preventive care measure. If the pool of eligible assigned beneficiaries is less than 411, then report on 100 percent of assigned beneficiaries. In addition, the group practice must also report all CAHPS for PQRS survey measures via certified survey vendor.

(ii) *Via Qualified Registry.* (A) For the 12-month 2016 PQRS payment adjustment reporting period, for a group practice of 2 or more eligible professionals—

(*1*) Report at least 9 measures, covering at least 3 of the National Quality Strategy domains and report each measure for at least 50 percent of the group practice's Medicare Part B FFS patients seen during the reporting period to which the measure applies; or If less than 9 measures covering at least 3 NQS domains apply to the eligible professional, then the group practices must report 1–8 measures for which there is Medicare patient data and report each measure for at least 50 percent of the group practice's Medicare Part B FFS patients seen during the reporting period to which the measure applies. For a group practice who reports fewer than 9 measures covering at least 3 NQS domains via the registry-based reporting mechanism, the group practice would be subject to the Measures Applicability Validation

process, which would allow us to determine whether a group practice should have reported on additional measures. Measures with a 0 percent performance rate would not be counted; or

(*2*) Report at least 3 measures, covering at least 1 of the National Quality Strategy domains and report each measure for at least 50 percent of the group practice's Medicare Part B FFS patients seen during the reporting period to which the measure applies; or if less than 3 measures covering at least 1 NQS domain apply to the group practice, then the group practice must report 1–2 measures for which there is Medicare patient data and report each measure for at least 50 percent of the group practice's Medicare Part B FFS patients seen during the reporting period to which the measure applies. For a group practice who reports fewer than 3 measures covering at least 1 NQS domain via the registry-based reporting mechanism, the group practice would be subject to the Measures Applicability Validation process, which would allow us to determine whether a group practice should have reported on additional measures. Measures with a 0 percent performance rate would not be counted.

(iii) *Via EHR Direct Product*. For a group practice of 2 or more eligible professionals, for the 12-month 2016 PQRS payment adjustment reporting period, report 9 measures covering at least 3 of the National Quality Strategy domains. If a group practice's CEHRT does not contain patient data for at least 9 measures covering at least 3 domains, then the group practice must report the measures for which there is Medicare patient data. A group practice must report on at least 1 measure for which there is Medicare patient data.

(iv) *Via EHR Data Submission Vendor*. For a group practice of 2 or more eligible professionals, for the 12-month 2016 PQRS payment adjustment reporting period, report 9 measures covering at least 3 of the National Quality Strategy domains. If a group practice's CEHRT does not contain patient data for at least 9 measures covering at least 3 domains, then the group practice must report the measures for which there is Medicare patient data. A group practice must report on at least 1 measure for which there is Medicare patient data.

(v) *Via a Certified survey vendor, in addition to the GPRO Web interface, qualified registry, direct EHR product, or EHR data submission vendor reporting mechanisms*. For a group practice of 25 or more eligible professionals, for the 12-month 2016 PQRS payment adjustment reporting period, report all CAHPS for PQRS survey measures via a CMS-certified survey vendor and report at least 6 measures covering at least 2 of the National Quality Strategy domains using a qualified registry, direct EHR product, EHR data submission vendor, or GPRO Web interface.

(7) *Satisfactory reporting criteria for group practices for the 2017 PQRS payment adjustment*. A group practice who wishes to meet the criteria for satisfactory reporting for the 2017 PQRS payment adjustment must report information on PQRS quality measures identified by CMS in one of the following manners:

(i) *Via the GPRO web interface*. For the 12-month 2017 PQRS payment adjustment reporting period, for a group practice of 25 to 99 eligible professionals, report on all measures included in the web interface and populate data fields for the first 248 consecutively ranked and assigned beneficiaries in the order in which they appear in the group's sample for each module or preventive care measure. If the pool of eligible assigned beneficiaries is less than 248, then report on 100 percent of assigned beneficiaries. A group practice must report on at least 1 measure for which there is Medicare patient data.

(ii) *Via Qualified Registry*. For a group practice of 2 to 99 eligible professionals, for the 12-month 2017 PQRS payment adjustment reporting period, report at least 9 measures, covering at least 3 of the NQS domains and report each measure for at least 50 percent of the group practice's Medicare Part B FFS patients seen during the reporting period to which the measure applies; or if less than 9 measures covering at least 3 NQS domains apply to the eligible professional, then the group practice must report up to 8 measures for which there is Medicare patient data

and report each measure for at least 50 percent of the group practice's Medicare Part B FFS patients seen during the reporting period to which the measure applies. Of the measures reported, if any eligible professional in the group practice sees at least 1 Medicare patient in a face-to-face encounter, the group practice must report on at least 1 measure contained in the cross-cutting measure set specified by CMS. Measures with a 0 percent performance rate would not be counted; or

(iii) *Via EHR Direct Product.* For a group practice of 2 to 99 eligible professionals, for the 12-month 2017 PQRS payment adjustment reporting period, report 9 measures covering at least 3 of the NQS domains. If a group practice's direct EHR product does not contain patient data for at least 9 measures covering at least 3 domains, then the group practice must report the measures for which there is Medicare patient data. A group practice must report on at least 1 measure for which there is Medicare patient data.

(iv) *Via EHR Data Submission Vendor.* For a group practice of 2 to 99 eligible professionals, for the 12-month 2017 PQRS payment adjustment reporting period, report 9 measures covering at least 3 of the NQS domains. If a group practice's EHR data submission vendor product does not contain patient data for at least 9 measures covering at least 3 domains, then the group practice must report the measures for which there is Medicare patient data. A group practice must report on at least 1 measure for which there is Medicare patient data.

(v) *Via a Certified Survey Vendor in addition to a Qualified Registry.* For a group practice of 2 or more eligible professionals, for the 12-month 2017 PQRS payment adjustment reporting period, report all CAHPS for PQRS survey measures via a CMS-certified survey vendor and report at least 6 additional measures covering at least 2 of the NQS domains using a qualified registry. If less than 6 measures apply to the group practice, the group practice must report up to 5 measures. Of the additional measures that must be reported in conjunction with reporting the CAHPS for PQRS survey measures, if any eligible professional in the group practice sees at least 1 Medicare patient in a face-to-face encounter, the group practice must report on at least 1 measure in the cross-cutting measure set specified by CMS.

(vi) *Via a Certified Survey Vendor in addition a Direct EHR Product or EHR Data Submission Vendor.* For a group practice of 2 or more eligible professionals, for the 12-month 2017 PQRS payment adjustment reporting period, report all CAHPS for PQRS survey measures via a CMS-certified survey vendor and report at least 6 additional measures, outside of CAHPS for PQRS, covering at least 2 of the NQS domains using the direct EHR product that is CEHRT or EHR data submission vendor product that is CEHRT. If less than 6 measures apply to the group practice, the group practice must report up to 5 measures. Of the additional measures that must be reported in conjunction with reporting the CAHPS for PQRS survey measures, the group practice must report on at least 1 measure for which there is Medicare patient data.

(vii) *Via a Certified Survey Vendor in addition to the GPRO Web interface.* (A) For a group practice of 25 or more eligible professionals, for the 12-month 2017 PQRS payment adjustment reporting period, report all CAHPS for PQRS survey measures via a CMS-certified survey vendor and report on all measures included in the GPRO web interface; AND populate data fields for the first 248 consecutively ranked and assigned beneficiaries in the order in which they appear in the group's sample for each module or preventive care measure. If the pool of eligible assigned beneficiaries is less than 248, then the group practice would report on 100 percent of assigned beneficiaries. A group practice must report on at least 1 measure for which there is Medicare patient data.

(B) [Reserved]

(viii) Paragraphs (j)(9)(ii), (iii), and (iv) of this section apply to group practices reporting using the secondary reporting period established under paragraph (j)(1)(ii) of this section for the 2017 PQRS payment adjustment.

(8) *Satisfactory reporting criteria for individual eligible professionals for the 2018 PQRS payment adjustment.* An individual eligible professional who wishes

to meet the criteria for satisfactory reporting for the 2018 PQRS payment adjustment must report information on PQRS quality measures identified by CMS in one of the following manners:

(i) *Via claims.* (A) For the 12-month 2018 PQRS payment adjustment reporting period—

(*1*)(*i*) Report at least 6 measures and report each measure for at least 50 percent of the eligible professional's Medicare Part B Fee-for-Service patients seen during the reporting period to which the measure applies. If less than 6 measures apply to the eligible professional, the eligible professional must report on each measure that is applicable, and report each measure for at least 50 percent of the Medicare Part B Fee-for-Service patients seen during the reporting period to which the measure applies. Measures with a 0 percent performance rate will not be counted (unless they are inverse measures where a lower rate reflects better performance).

(*ii*) [Reserved]

(*2*) [Reserved]

(B) [Reserved]

(ii) *Via qualified registry.* (A) For the 12-month 2018 PQRS payment adjustment reporting period—

(*1*)(*i*) Report at least 6 measures and report each measure for at least 50 percent of the eligible professional's Medicare Part B Fee-for-Service patients seen during the reporting period to which the measure applies. If less than 6 measures apply to the eligible professional, the eligible professional must report on each measure that is applicable, and report each measure for at least 50 percent of the Medicare Part B Fee-for-Service patients seen during the reporting period to which the measure applies.

(*ii*) Report at least 1 measures group and report each measures group for at least 20 patients, a majority of which must be Medicare Part B FFS patients.

(*2*) Measures with a 0 percent performance rate or measures groups containing a measure with a 0 percent performance rate will not be counted (unless they are inverse measures where a lower rate reflects better performance).

(B) [Reserved]

(iii) *Via EHR direct product.* For the 12-month 2018 PQRS payment adjustment reporting period, report 6 measures. If an eligible professional's direct EHR product or EHR data submission vendor product does not contain patient data for at least 6 measures, then the eligible professional must report all of the measures for which there is Medicare patient data. An eligible professional must report on at least 1 measure for which there is Medicare patient data.

(iv) *Via EHR data submission vendor.* For the 12-month 2018 PQRS payment adjustment reporting period, report at least 6 measures. If an eligible professional's direct EHR product or EHR data submission vendor product does not contain patient data for at least 6 measures, then the eligible professional must report all of the measures for which there is Medicare patient data. An eligible professional must report on at least 1 measure for which there is Medicare patient data.

(9) *Satisfactory reporting criteria for group practices for the 2018 PQRS payment adjustment.* A group practice who wishes to meet the criteria for satisfactory reporting for the 2018 PQRS payment adjustment must report information on PQRS quality measures identified by CMS in one of the following manners:

(i) *Via the GPRO web interface.* For the 12-month 2018 PQRS payment adjustment reporting period, for a group practice of 25 or more eligible professionals, report on all measures included in the web interface; AND populate data fields for the first 248 consecutively ranked and assigned beneficiaries in the order in which they appear in the group's sample for each module or preventive care measure. If the pool of eligible assigned beneficiaries is less than 248, then the group practice must report on 100 percent of assigned beneficiaries. In some instances, the sampling methodology will not be able to assign at least 248 patients on which a group practice may report, particularly those group practices on the smaller end of the range of 25–99 eligible professionals. If the group practice is assigned less than 248 Medicare beneficiaries, then the group practice must report on 100 percent of its assigned beneficiaries. A group practice must report on at least 1 measure

for which there is Medicare patient data.

(ii) *Via qualified registry.* For a group practice of 2 or more eligible professionals, for the 12-month 2018 PQRS payment adjustment reporting period, report at least 6 measures and report each measure for at least 50 percent of the group practice's Medicare Part B Fee-for-Service patients seen during the reporting period to which the measure applies. If less than 6 measures apply to the group practice, the group practice must report on each measure that is applicable, and report each measure for at least 50 percent of the Medicare Part B Fee-for-Service patients seen during the reporting period to which the measure applies. Measures with a 0 percent performance rate would not be counted (unless they are inverse measures where a lower rate reflects better performance).

(iii) *Via EHR direct product.* For a group practice of 2 or more eligible professionals, for the 12-month 2018 PQRS payment adjustment reporting period, report 6 measures. If the group practice's direct EHR product or EHR data submission vendor product does not contain patient data for at least 6 measures, then the group practice must report all of the measures for which there is Medicare patient data. A group practice must report on at least 1 measure for which there is Medicare patient data.

(iv) *Via EHR data submission vendor.* For a group practice of 2 or more eligible professionals, for the 12-month 2018 PQRS payment adjustment reporting period, report 6 measures. If the group practice's direct EHR product or EHR data submission vendor product does not contain patient data for at least 6 measures, then the group practice must report all of the measures for which there is Medicare patient data. A group practice must report on at least 1 measure for which there is Medicare patient data.

(v) *Via a certified survey vendor in addition to a qualified registry.* For a group practice of 2 or more eligible professionals that elects to report via a certified survey vendor in addition to a qualified registry for the 12-month 2018 PQRS payment adjustment reporting period, the group practice must have all CAHPS for PQRS survey measures reported on its behalf via a CMS-certified survey vendor. In addition, the group practice must report at least 3 additional measures using the qualified registry and report each measure for at least 50 percent of the group practice's Medicare Part B Fee-for-Service patients seen during the reporting period to which the measure applies. If less than 3 measures apply to the group practice, the group practice must report on each measure that is applicable, and report each measure for at least 50 percent of the Medicare Part B Fee-for-Service patients seen during the reporting period to which the measure applies. Measures with a 0 percent performance rate would not be counted (unless they are inverse measures where a lower rate reflects better performance).

(vi) *Via a certified survey vendor in addition to a direct EHR product or EHR data submission vendor.* For a group practice of 2 or more eligible professionals that elects to report via a certified survey vendor in addition to a direct EHR product or EHR data submission vendor for the 12-month 2018 PQRS payment adjustment reporting period, the group practice must have all CAHPS for PQRS survey measures reported on its behalf via a CMS-certified survey vendor. In addition, the group practice must report at least 3 additional measures using the direct EHR product or EHR data submission vendor product. If less than 3 measures apply to the group practice, the group practice must report all of the measures for which there is patient data. Of the additional 3 measures that must be reported in conjunction with reporting the CAHPS for PQRS survey measures, a group practice must report on at least 1 measure for which there is Medicare patient data.

(vii) *Via a certified survey vendor in addition to the GPRO web interface.* (A) For a group practice of 25 or more eligible professionals, for the 12-month 2018 PQRS payment adjustment reporting period, the group practice must have all CAHPS for PQRS survey measures reported on its behalf via a CMS-certified survey vendor. In addition, the group practice must report on all measures included in the GPRO web

interface; AND populate data fields for the first 248 consecutively ranked and assigned beneficiaries in the order in which they appear in the group's sample for each module or preventive care measure. If the pool of eligible assigned beneficiaries is less than 248, then the group practice must report on 100 percent of assigned beneficiaries. A group practice will be required to report on at least 1 measure for which there is Medicare patient data.

(B) [Reserved]

(viii) If the CAHPS for PQRS survey is applicable to the practice, group practices comprised of 100 or more eligible professionals that register to participate in the GPRO may administer the CAHPS for PQRS survey, regardless of the GPRO reporting mechanism selected.

(k) *Satisfactory participation requirements for the payment adjustments for individual eligible professionals and group practices.* In order to satisfy the requirements for the PQRS payment adjustment for a particular program year through participation in a qualified clinical data registry, an individual eligible professional, as identified by a unique TIN/NPI combination, or group practice must meet the criteria for satisfactory participation as specified in paragraph (k)(3) of this section for such year, by reporting on quality measures identified by a qualified clinical data registry during a reporting period specified in paragraph (k)(1) of this section, using the reporting mechanism specified in paragraph (k)(2) of this section.

(1) Reporting period. For purposes of this paragraph, the reporting period is—

(i) The 12-month period from January 1 through December 31 that falls 2 years prior to the year in which the payment adjustment is applied.

(ii) [Reserved]

(2) *Reporting mechanism.* An individual eligible professional or group practice who wishes to meet the criteria for satisfactory participation in a qualified clinical data registry must use the qualified clinical data registry to report information on quality measures identified by the qualified clinical data registry.

(3) *Satisfactory participation criteria for individual eligible professionals for the 2016 PQRS payment adjustment.* Satisfactory participation criteria for individual eligible professionals for the 2016 PQRS payment adjustment. An individual eligible professional who wishes to meet the criteria for satisfactory participation in a qualified clinical data registry for the 2016 PQRS payment adjustment must report information on quality measures identified by the qualified clinical data registry in one of the following manners:

(i) For the 12-month 2016 PQRS payment adjustment reporting period—

(A) Report at least 9 measures available for reporting under a qualified clinical data registry covering at least 3 of the National Quality Strategy domains and report each measure for at least 50 percent of the eligible professional's patients; or

(B) Report at least 3 measures available for reporting under a qualified clinical data registry covering at least 1 of the National Quality Strategy domains and report each measure for at least 50 percent of the eligible professional's patients.

(4) *Satisfactory participation criteria for individual eligible professionals for the 2017 PQRS payment adjustment.* An individual eligible professional who wishes to meet the criteria for satisfactory participation in a QCDR for the 2017 PQRS payment adjustment must report information on quality measures identified by the QCDR in one of the following manner:

(i) For the 12-month 2017 PQRS payment adjustment reporting period, report at least 9 measures available for reporting under a QCDR covering at least 3 of the NQS domains, and report each measure for at least 50 percent of the eligible professional's patients. Of these measures, report on at least 2 outcome measures, or, if 2 outcomes measures are not available, report on at least 2 outcome measures and at least 1 of the following types of measures—resource use, patient experience of care, efficiency/appropriate use or patient safety.

(ii) Section 414.90(k)(5) applies to individuals and group practices reporting using the secondary reporting period established under paragraph (j)(1)(ii) of this section for the 2017 PQRS payment adjustment.

(5) *Satisfactory participation criteria for individual eligible professionals and group practices for the 2018 PQRS payment adjustment.* An individual eligible professional or group practice who wishes to meet the criteria for satisfactory participation in a QCDR for the 2018 PQRS payment adjustment must report information on quality measures identified by the QCDR in the following manner:

(i) *Individual eligible professional.* For the applicable 12-month reporting period, report at least 6 measures available for reporting under a QCDR and report each measure for at least 50 percent of the eligible professional's patients seen during the reporting period to which the measure applies. If less than 6 measures apply to the eligible professional, the eligible professional must report on each measure that is applicable, and report each measure for at least 50 percent of the eligible professional's patients.

(ii) *Group practices.* For the applicable 12-month reporting period, report at least 6 measures available for reporting under a QCDR and report each measure for at least 50 percent of the group practice's patients seen during the reporting period to which the measure applies. If less than 6 measures apply to the group practice, the group practice must report on each measure that is applicable, and report each measure for at least 50 percent of the group practice's patients. If a group practice reports the CAHPS for PQRS survey measures, apply reduced criteria as follows: 3 measures, as applicable.

(l) *Requirements for group practices.* Under the PQRS, a group practice must meet all of the following requirements:

(1) Meet the participation requirements specified by CMS for the PQRS group practice reporting option.

(2) Report measures in the form and manner specified by CMS.

(3) Meet other requirements for satisfactory reporting specified by CMS.

(4) Meet participation requirements.

(i) If an eligible professional, as identified by an individual NPI, has reassigned his or her Medicare billing rights to a group practice (as identified by the TIN) selected to participate in the PQRS group practice reporting option for a program year, then for that program year the eligible professional must participate in the PQRS via the group practice reporting option.

(ii) If, for the program year, the eligible professional participates in the PQRS as part of a group practice (as identified by the TIN) that is not selected to participate in the PQRS group practice reporting option for that program year, then the eligible professional may individually participate and qualify for a PQRS incentive by meeting the requirements specified in paragraph (g) of this section under that TIN.

(m) *Informal review.* Eligible professionals or group practices may seek an informal review of the determination that an eligible professional or group practices did not satisfactorily submit data on quality measures under the PQRS, or, for individual eligible professionals, in lieu of satisfactory reporting, did not satisfactorily participate in a qualified clinical data registry.

(1) To request an informal review for reporting periods that occur prior to 2014, an eligible professional or group practice must submit a request to CMS within 90 days of the release of the feedback reports. To request an informal review for reporting periods that occur in 2014 and subsequent years, an eligible professional or group practice must submit a request to CMS within 60 days of the release of the feedback reports. The request must be submitted in writing and summarize the concern(s) and reasons for requesting an informal review and may also include information to assist in the review.

(2) CMS will provide a written response within 90 days of the receipt of the original request.

(i) All decisions based on the informal review will be final.

(ii) There will be no further review or appeal.

(3) If, during the informal review process, CMS finds errors in data that was submitted by a third-party vendor on behalf of an eligible professional or group practice using either the qualified registry, EHR data submission vendor, or QCDR reporting mechanisms, CMS may allow for the resubmission of data to correct these errors.

(i) CMS will not allow resubmission of data submitted via claims, direct

EHR, and the GPRO web interface reporting mechanisms.

(ii) CMS will only allow resubmission of data that was already previously submitted to CMS.

(iii) CMS will only accept data that was previously submitted for the reporting periods for which the corresponding informal review period applies.

(n) *Limitations on review.* Except as specified in paragraph (i) of this section, there is no administrative or judicial review under section 1869 or 1879 of the Act, or otherwise of—

(1) The determination of measures applicable to services furnished by eligible professionals under the PQRS;

(2) The determination of satisfactory reporting; and

(3) The determination of any Physician Quality Reporting System incentive payment and the PQRS payment adjustment.

(o) *Public reporting of an eligible professional's or group practice's PQRS data.* For each program year, CMS will post on a public Web site, in an easily understandable format, a list of the names of eligible professionals (or in the case of reporting under paragraph (g) of this section, group practices) who satisfactorily submitted PQRS quality measures.

[78 FR 74812, Dec. 10, 2013, as amended at 79 FR 68003, Nov. 13, 2014; 81 FR 34913, June 1, 2016; 81 FR 77537, Nov. 4, 2016; 81 FR 80554, Nov. 15, 2016; 82 FR 53362, Nov. 15, 2017]

§ 414.92 Electronic Prescribing Incentive Program.

(a) *Basis and scope.* This section implements the following provisions of the Act:

(1) Section 1848(a)—Payment Based on Fee Schedule.

(2) Section 1848(m)—Incentive Payments for Quality Reporting.

(b) *Definitions.* As used in this section, unless otherwise indicated—

Certified electronic health record technology means an electronic health record vendor's product and version as described in 45 CFR 170.102.

Covered professional services means services for which payment is made under, or is based on, the Medicare physician fee schedule which are furnished by an eligible professional.

Electronic Prescribing Incentive Program means the incentive payment program established under section 1848(m) of the Act for the adoption and use of electronic prescribing technology by eligible professionals.

Eligible professional means any of the following healthcare professionals who have prescribing authority:

(i) A physician.

(ii) A practitioner described in section 1842(b)(18)(C) of the Act.

(iii) A physical or occupational therapist or a qualified speech-language pathologist.

(iv) A qualified audiologist (as defined in section 1861(ll)(3)(B) of the Act).

Group practice means a group practice that is—

(i)(A) Defined at § 414.90(b), that is participating in the Physician Quality Reporting System; or

(B) In a Medicare-approved demonstration project or other Medicare program, under which Physician Quality Reporting System requirements and incentives have been incorporated; and

(ii) Has indicated its desire to participate in the electronic prescribing group practice option.

Qualified electronic health record product means an electronic health record product and version that, with respect to a particular program year, is designated by CMS as a qualified electronic health record product for the purpose of the Physician Quality Reporting System (as described in § 414.90) and the product's vendor has indicated a desire to have the product qualified for purposes of the product's users to submit information related to the electronic prescribing measure.

Qualified registry means a medical registry or a Maintenance of Certification Program operated by a specialty body of the American Board of Medical Specialties that, with respect to a particular program year, is designated by CMS as a qualified registry for the purpose of the Physician Quality Reporting System (as described in § 414.90) and that has indicated its desire to be qualified to submit the electronic prescribing measure on behalf of eligible professionals for the purposes of the

Electronic Prescribing Incentive Program.

(c) *Incentive payments and payment adjustments.* (1) *Incentive payments.* Subject to paragraph (c)(3) of this section, with respect to covered professional services furnished during a reporting period by an eligible professional, if the eligible professional is a successful electronic prescriber for such reporting period, in addition to the amount otherwise paid under section 1848 of the Act, there also must be paid to the eligible professional (or to an employer or facility in the cases described in section 1842(b)(6)(A) of the Act) or, in the case of a group practice under paragraph (e) of this section, to the group practice, from the Federal Supplementary Medical Insurance Trust Fund established under section 1841 of the Act an amount equal to the applicable electronic prescribing percent (as specified in paragraph (c)(1)(ii) of this section) of the eligible professional's (or, in the case of a group practice under paragraph (e) of this section, the group practice's) total estimated allowed charges for all covered professional services furnished by the eligible professional (or, in the case of a group practice under paragraph (e) of this section, by the group practice) during the applicable reporting period.

(i) For purposes of paragraph (c)(1) of this section,

(A) The eligible professional's (or, in the case of a group practice under paragraph (e) of this section, the group practice's) total estimated allowed charges for covered professional services furnished during a reporting period are determined based on claims processed in the National Claims History (NCH) no later than 2 months after the end of the applicable reporting period;

(B) In the case of an eligible professional who furnishes covered professional services in more than one practice, incentive payments are separately determined for each practice based on claims submitted for the eligible professional for each practice;

(C) Incentive payments earned by an eligible professional (or in the case of a group practice under paragraph (e) of this section, by a group practice) for a particular program year will be paid as a single consolidated payment to the TIN holder of record.

(ii) *Applicable electronic prescribing percent.* The applicable electronic prescribing percent is as follows:

(A) For the 2011 and 2012 program years, 1.0 percent.

(B) For the 2013 program year, 0.5 percent.

(iii) *Limitation with respect to electronic health record (EHR) incentive payments.* The provisions of this paragraph do not apply to an eligible professional (or, in the case of a group practice under paragraph (e) of this section, a group practice) if, for the electronic health record reporting period the eligible professional (or group practice) receives an incentive payment under section 1848(o)(1)(A) of the Act with respect to a certified electronic health record technology (as defined in section 1848(o)(4) of the Act) that has the capability of electronic prescribing.

(2) *Payment adjustment.* Subject to paragraphs (c)(1)(ii) and (c)(3) of this section, with respect to covered professional services furnished by an eligible professional during 2012, 2013, or 2014, if the eligible professional (or in the case of a group practice under paragraph (e) of this section, the group practice) is not a successful electronic prescriber (as specified by CMS for purposes of the payment adjustment) for an applicable reporting period (as specified by CMS) the fee schedule amount for such services furnished by such professional (or group practice) during the program year (including the fee schedule amount for purposes of determining a payment based on such amount) is equal to the applicable percent (as specified in paragraph (c)(2)(i) of this section) of the fee schedule amount that would otherwise apply to such services under section 1848 of the Act.

(i) *Applicable percent.* The applicable percent is as follows:

(A) For 2012, 99 percent;

(B) For 2013, 98.5 percent; and

(C) For 2014, 98 percent.

(ii) *Significant hardship exception.* CMS may, on a case-by-case basis, exempt an eligible professional (or in the case of a group practice under paragraph (e) of this section, a group practice) from the application of the payment adjustment under paragraph

(c)(2) of this section if, CMS determines, subject to annual renewal, that compliance with the requirement for being a successful electronic prescriber would result in a significant hardship. Eligible professionals (or, in the case of a group practice under paragraph (e) of this section, a group practice) may request consideration for a significant hardship exemption from a eRx payment adjustment if one of the following circumstances apply:

(A) From the 2012 payment adjustments by meeting one of the following:

(*1*) The practice is located in a rural area without high speed internet access.

(*2*) The practice is located in an area without sufficient available pharmacies for electronic prescribing.

(*3*) Registration to participate in the Medicare or Medicaid EHR Incentive Program and adoption of Certified EHR Technology.

(*4*) Inability to electronically prescribe due to local, State or Federal law or regulation.

(*5*) Eligible professionals who achieve meaningful use during the respective 6 or 12-month payment adjustment reporting periods.

(*6*) Eligible professionals who have registered to participate in the EHR Incentive Program and adopted Certified EHR Technology prior to application of the respective payment adjustment.

(B) From the 2013 and 2014 payment adjustments by meeting one of the following:

(*1*) The eligible professional or group practice is located in a rural area without high speed internet access.

(*2*) The eligible professional or group practice is located in an area without sufficient available pharmacies for electronic prescribing.

(*3*) The eligible professional or group practice is unable to electronically prescribe due to local, State, or Federal law or regulation.

(*4*) The eligible professional or group practice has limited prescribing activity, as defined by an eligible professional generating fewer than 100 prescriptions during a 6-month reporting period.

(iii) *Other limitations to the payment adjustment.* An eligible professional (or in the case of a group practice under paragraph (b) of this section, a group practice) is exempt from the application of the payment adjustment under paragraph (c)(2) of this section if one of the following applies:

(A) The eligible professional is not an MD, DO, podiatrist, nurse practitioner, or physician assistant.

(B) The eligible professional does not have at least 100 cases containing an encounter code that falls within the denominator of the electronic prescribing measure for dates of service during the 6-month reporting period specified in paragraph (f)(1) of this section.

(3) *Limitation with respect to electronic prescribing quality measures.* The provisions of paragraphs (c)(1) and (c)(2) of this section do not apply to an eligible professional (or, in the case of a group practice under paragraph (e) of this section, a group practice) if for the reporting period the allowed charges under section 1848 of the Act for all covered professional services furnished by the eligible professional (or group, as applicable) for the codes to which the electronic prescribing measure applies are less than 10 percent of the total of the allowed charges under section 1848 of the Act for all such covered professional services furnished by the eligible professional (or the group practice, as applicable).

(d) *Requirements for individual eligible professionals to qualify to receive an incentive payment.* In order to be considered a successful electronic prescriber and qualify to earn an electronic prescribing incentive payment (subject to paragraph (c)(3) of this section), an individual eligible professional, as identified by a unique TIN/NPI combination, must meet the criteria for being a successful electronic prescriber under section 1848(m)(3)(B) of the Act and as specified by CMS during the reporting period specified in paragraph (d)(1) of this section and using one of the reporting mechanisms specified in paragraph (d)(2) of this section. Although an eligible professional may attempt to qualify for the electronic prescribing incentive payment using more than one reporting mechanism (as specified in paragraph (d)(2) of this section), the eligible professional will receive only one electronic prescribing incentive

payment per TIN/NPI combination for a program year.

(1) *Reporting period.* For purposes of this paragraph, the reporting period with respect to a program year is the entire calendar year.

(2) *Reporting mechanisms.* An eligible professional who wishes to participate in the Electronic Prescribing Incentive Program must report information on the electronic prescribing measure identified by CMS to—

(i) CMS, by no later than 2 months after the end of the applicable reporting period, on the eligible professional's Medicare Part B claims for covered professional services furnished by the eligible professional during the reporting period specified in paragraph (d)(1) of this section;

(ii) A qualified registry (as defined in paragraph (b) of this section) in the form and manner and by the deadline specified by the qualified registry selected by the eligible professional. The selected qualified registry will submit information, as required by CMS, for covered professional services furnished by the eligible professional during the reporting period specified in paragraph (d)(1) of this section to CMS on the eligible professional's behalf; or

(iii) CMS by extracting clinical data using a secure data submission method, as required by CMS, from a qualified electronic health record product (as defined in paragraph (b) of this section) by the deadline specified by CMS for covered professional services furnished by the eligible professional during the reporting period specified in paragraph (d)(1) of this section. Prior to actual data submission for a given program year and by a date specified by CMS, the eligible professional must submit a test file containing real or dummy clinical quality data extracted from the qualified electronic health record product selected by the eligible professional using a secure data submission method, as required by CMS.

(e) *Requirements for group practices to qualify to receive an incentive payment.* (1) A group practice (as defined in paragraph (b) of this section) will be treated as a successful electronic prescriber for covered professional services for a reporting period if the group practice meets the criteria for successful electronic prescriber specified by CMS in the form and manner and at the time specified by CMS.

(2) *No double payments.* Payments to a group practice under this paragraph must be in lieu of the payments that would otherwise be made under the Electronic Prescribing Incentive Program to eligible professionals in the group practice for being a successful electronic prescriber.

(i) If an eligible professional, as identified by an individual NPI, has reassigned his or her Medicare billing rights to a TIN selected to participate in the electronic prescribing group practice reporting option for a program year, then for that program year the eligible professional must participate in the Electronic Prescribing Incentive Program via the group practice reporting option. For any program year in which the TIN is selected to participate in the Electronic Prescribing Incentive Program group practice reporting option, the eligible professional cannot individually qualify for an electronic prescribing incentive payment by meeting the requirements specified in paragraph (d) of this section.

(ii) If, for the program year, the eligible professional participates in the Electronic Prescribing Incentive Program under a TIN that is not selected to participate in the Electronic Prescribing Incentive Program group practice reporting option for that program year, then the eligible professional may individually qualify for an electronic prescribing incentive by meeting the requirements specified in paragraph (d) of this section under that TIN.

(f) *Requirements for individual eligible professionals and group practices for the payment adjustment.* In order to be considered a successful electronic prescriber for the electronic prescribing payment adjustment, an individual eligible professional (or, in the case of a group practice under paragraph (b) of this section, a group practice), as identified by a unique TIN/NPI combination, must meet the criteria for being a successful electronic prescriber specified by CMS, in the form and manner specified in paragraph (f)(2) of this section, and during the reporting period

specified in paragraph (f)(1) of this section.

(1) *Reporting periods.* (i) For purposes of this paragraph (f), the reporting period for the 2013 payment adjustment is either of the following:

(A) The 12-month period from January 1, 2011 through December 31, 2011.

(B) The 6-month period from January 1, 2012 through June 30, 2012.

(ii) For purposes of this paragraph (f), the reporting period for the 2014 payment adjustment is either of the following:

(A) The 12-month period from January 1, 2012 through December 31, 2012.

(B) The 6-month period from January 1, 2013 through June 30, 2013.

(2) *Reporting mechanisms.* An eligible professional (or, in the case of a group practice under paragraph (e) of this section, a group practice) who wishes to participate in the Electronic Prescribing Incentive Program must report information on the electronic prescribing measure identified by CMS to one of the following:

(i) For the 6- and 12-month reporting periods under paragraph (f)(1) of this section, CMS, by no later than 2 months after the end of the applicable 12-month reporting period or by no later than 1 month after the end of the applicable 6-month reporting period, on the eligible professional's Medicare Part B claims for covered professional services furnished by the eligible professional during the reporting period specified in paragraph (f)(1) of this section.

(A) If an eligible professional re-submits a Medicare Part B claim for reprocessing, the eligible professional may not attach a G-code at that time for reporting on the electronic prescribing measure.

(B) [Reserved]

(ii) For the 12-month reporting period under paragraph (f)(1) of this section, a qualified registry (as defined in paragraph (b) of this section) in the form and manner and by the deadline specified by the qualified registry selected by the eligible professional. The selected qualified registry submits information, as required by CMS, for covered professional services furnished by the eligible professional during the reporting period specified in paragraph (f)(1) of this section to CMS on the eligible professional's behalf.

(iii) For the 12-month reporting period under paragraph (f)(1) of this section, CMS by extracting clinical data using a secure data submission method, as required by CMS, from a qualified electronic health record product (as defined in paragraph (b) of this section) by the deadline specified by CMS for covered professional services furnished by the eligible professional during the reporting period specified in paragraph (f)(1) of this section. Prior to actual data submission for a given program year and by a date specified by CMS, the eligible professional must submit a test file containing dummy clinical quality data extracted from the qualified electronic health record product selected by the eligible professional using a secure data submission method, as required by CMS.

(g) *Informal review.* Eligible professionals (or in the case of reporting under paragraph (e) of this section, group practices) may seek an informal review of the determination that an eligible professional (or in the case of reporting under paragraph (e) of this section, group practices) did not meet the requirements for the 2012 and 2013 incentives or the 2013 and 2014 payment adjustments.

(1) To request an informal review for the 2012 and 2013 incentives, an eligible professional or group practice must submit a request to CMS via email within 90 days of the release of the feedback reports. The request must be submitted in writing and summarize the concern(s) and reasons for requesting an informal review and may also include information to assist in the review.

(2) To request an informal review for the 2013 and 2014 payment adjustments, an eligible professional or group practices must submit a request to CMS via email by February 28 of the year in which the eligible professional is receiving the applicable payment adjustment. The request must be submitted in writing and summarize the concern(s) and reasons for requesting an informal review and may also include information to assist in the review.

(3) CMS will provide a written response of CMS' determination.

(i) All decisions based on the informal review will be final.

(ii) There will be no further review or appeal.

(h) *Public reporting of an eligible professional's or group practice's Electronic Prescribing Incentive Program data.* For each program year, CMS will post on a public Web site, in an easily understandable format, a list of the names of eligible professionals (or in the case of reporting under paragraph (e) of this section, group practices) who are successful electronic prescribers.

[75 FR 73620, Nov. 29, 2010, as amended at 76 FR 54968, Sept. 6, 2011; 76 FR 73472, Nov. 28, 2011; 77 FR 69368, Nov. 16, 2012; 80 FR 71379, Nov. 16, 2015]

§ 414.94 [Reserved]

Subpart C—Fee Schedules for Parenteral and Enteral Nutrition (PEN) Nutrients, Equipment and Supplies, Splints, Casts, and Certain Intraocular Lenses (IOLs)

SOURCE: 66 FR 45176, Aug. 28, 2001, unless otherwise noted.

§ 414.100 Purpose.

This subpart implements fee schedules for PEN items and services, splints and casts, and IOLs inserted in a physician's office as authorized by section 1842(s) of the Act.

[78 FR 72252, Dec. 2, 2013]

§ 414.102 General payment rules.

(a) *General rule.* For PEN items and services furnished on or after January 1, 2002, and for splints and casts and IOLs inserted in a physician's office on or after April 1, 2014, Medicare pays for the items and services as described in paragraph (b) of this section on the basis of 80 percent of the lesser of—-

(1) The actual charge for the item or service; or

(2) The fee schedule amount for the item or service, as determined in accordance with §§ 414.104 thru 414.108.

(b) *Payment classification.* (1) CMS or the carrier determines fee schedules for parenteral and enteral nutrition (PEN) nutrients, equipment, and supplies, splints and casts, and IOLs inserted in a physician's office, as specified in §§ 414.104 thru 414.108.

(2) CMS designates the specific items and services in each category through program instructions.

(c) *Updating the fee schedule amounts.* For the years 2003 through 2010 for PEN items and services, the fee schedule amounts of the preceding year are updated by the percentage increase in the CPI–U for the 12-month period ending with June of the preceding year. For each year subsequent to 2010 for PEN items and services and for each year subsequent to 2014 for splints and casts, and IOLs inserted in a physician's office, the fee schedule amounts of the preceding year are updated by the percentage increase in the CPI–U for the 12-month period ending with June of the preceding year, reduced by the productivity adjustment described in section 1886(b)(3)(B)(xi)(II) of the Act.

[66 FR 45176, Aug. 28, 2001, as amended at 78 FR 72252, Dec. 2, 2013]

§ 414.104 PEN Items and Services.

(a) *Payment rules.* Payment for PEN items and services is made in a lump sum for nutrients and supplies that are purchased and on a monthly basis for equipment that is rented.

(b) *Fee schedule amount.* The fee schedule amount for payment for an item or service furnished in 2002 is the lesser of—

(i) The reasonable charge from 1995; or

(ii) The reasonable charge that would have been used in determining payment for 2002.

§ 414.105 Application of competitive bidding information.

For enteral nutrients, equipment and supplies furnished on or after January 1, 2011, the fee schedule amounts may be adjusted based on information on the payment determined as part of implementation of the programs under subpart F using the methodologies set forth at § 414.210(g).

[79 FR 66262, Nov. 6, 2014]

§ 414.106 Splints and casts.

(a) *Payment rules.* Payment is made in a lump sum for splints and casts.

(b) *Fee schedule amount.* The fee schedule amount for payment for an item or service furnished in 2014 is the reasonable charge amount for 2013, updated by the percentage increase in the CPI–U for the 12-month period ending with June of 2013.

[78 FR 72253, Dec. 2, 2013]

§414.108 IOLs inserted in a physician's office.

(a) *Payment rules.* Payment is made in a lump sum for IOLs inserted in a physician's office.

(b) *Fee schedule amount.* The fee schedule amount for payment for an IOL furnished in 2014 is the national average allowed charge for the IOL furnished from in calendar year 2012, updated by the percentage increase in the CPI–U for the 24-month period ending with June of 2013.

[78 FR 72253, Dec. 2, 2013]

§414.110 Continuity of pricing when HCPCS codes are divided or combined.

(a) *General Rule.* If a new HCPCS code is added, CMS or contractors make every effort to determine whether the item and service has a fee schedule pricing history. If there is a fee schedule pricing history, the previous fee schedule amounts for the old code(s) are mapped to the new code(s) to ensure continuity of pricing.

(b) *Mapping fee schedule amounts based on different kinds of coding changes.* When the code for an item is divided into several codes for the components of that item, the total of the separate fee schedule amounts established for the components must not be higher than the fee schedule amount for the original item. When there is a single code that describes two or more distinct complete items (for example, two different but related or similar items), and separate codes are subsequently established for each item, the fee schedule amounts that applied to the single code continue to apply to each of the items described by the new codes. When the codes for the components of a single item are combined in a single global code, the fee schedule amounts for the new code are established by totaling the fee schedule amounts used for the components (that is, use the total of the fee schedule amounts for the components as the fee schedule amount for the global code). When the codes for several different items are combined into a single code, the fee schedule amounts for the new code are established using the average (arithmetic mean), weighted by allowed services, of the fee schedule amounts for the formerly separate codes.

[84 FR 60806, Nov. 8, 2019]

§414.112 Establishing fee schedule amounts for new HCPCS codes for items and services without a fee schedule pricing history.

(a) *General rule.* If a HCPCS code is new and describes items and services that do not have a fee schedule pricing history (classified and paid for previously under a different code), the fee schedule amounts for the new code are established based on the process described in paragraphs (b) or (c) of this section.

(b) *Comparability.* Fee schedule amounts for new HCPCS codes for items and services without a fee schedule pricing history are established using existing fee schedule amounts for comparable items when items with existing fee schedule amounts are determined to be comparable to the new items and services based on a comparison of: Physical components; mechanical components; electrical components; function and intended use; and additional attributes and features. If there are no items with existing fee schedule amounts that are comparable to the items and services under the new code, the fee schedule amounts for the new code are established in accordance with paragraph (c) of this section.

(c) *Use of supplier or commercial price lists.* (1) Fee schedule amounts for items and services without a fee schedule pricing history described by new HCPCS codes that are not comparable to items and services with existing fee schedule amounts may be established using supplier price lists, including catalogs and other retail price lists (such as internet retail prices) that provide information on commercial pricing for the item. Potential appropriate sources for such commercial

pricing information can also include payments made by Medicare Advantage plans, as well as verifiable information from supplier invoices and non-Medicare payer data. If the only available price information is from a period other than the fee schedule base period, deflation factors are applied against current pricing in order to approximate the base period price.

(i) The annual deflation factors are specified in program instructions and are based on the percentage change in the consumer price index for all urban consumers (CPI–U) from the mid-point of the year the prices are in effect to the mid-point of the fee schedule base period, as calculated using the following formula: ((base CPI–U minus current CPI–U) divided by current CPI–U) plus one.

(ii) The deflated amounts are then increased by the update factors specified in § 414.102(c).

(2) If within 5 years of establishing fee schedule amounts using supplier or commercial prices, the supplier or commercial prices decrease by less than 15 percent, a one-time adjustment to the fee schedule amounts is made using the new prices. The new supplier or commercial prices would be used to establish the new fee schedule amounts in the same way that the older prices were used, including application of the deflation formula in paragraph (c)(1) of this section.

[84 FR 60806, Nov. 8, 2019]

§ 414.114 Procedures for making benefit category determinations and payment determinations for new PEN items and services covered under the prosthetic device benefit; splints and casts; and IOLs inserted in a physician's office covered under the prosthetic device benefit.

(a) *Definitions.* For the purpose of this subpart:

Benefit category determination means a national determination regarding whether an item or service meets the Medicare definition of a prosthetic device at section 1861(s)(8) of the Act or is a splint, cast, or device used for reduction of fractures or dislocations subject to section 1842(s) of the Act and the rules of this subpart and is not otherwise excluded from coverage by statute.

(b) *General rule.* The procedures for determining whether new items and services addressed in a request for a HCPCS Level II code(s) or by other means meet the definition of items and services that may be covered and paid for in accordance with this subpart are as follows:

(1) At the start of a HCPCS coding cycle, CMS performs an analysis to determine if the item or service is statutorily excluded from coverage under Medicare under section 1862 of the Act, and, if not excluded by statute, whether the item or service is parenteral or enteral nutrients, supplies, and equipment covered under the prosthetic device benefit, splints and casts or other devices used for reductions of fractures or dislocations, or IOLs inserted in a physician's office covered under the prosthetic device benefit.

(2) If a preliminary determination is made that the item or service is parenteral or enteral nutrients, supplies, and equipment covered under the prosthetic device benefit, splints and casts or other devices used for reductions of fractures or dislocations, or IOLs inserted in a physician's office covered under the prosthetic device benefit, CMS makes a preliminary payment determination for the item or service.

(3) CMS posts preliminary benefit category determinations and payment determinations on *CMS.gov* approximately 2 weeks prior to a public meeting.

(4) After consideration of public consultation provided at a public meeting on preliminary benefit category determinations and payment determinations for items and services, CMS establishes the benefit category determinations and payment determinations for items and services through program instructions.

[86 FR 73910, Dec. 28, 2021]

Subpart D—Payment for Durable Medical Equipment and Prosthetic and Orthotic Devices

§414.200 Purpose.

This subpart implements sections 1834(a), (h) and (i) of the Act by specifying how payments are made for the purchase or rental of new and used durable medical equipment, prosthetic and orthotic devices, and surgical dressings for Medicare beneficiaries.

[78 FR 72253, Dec. 2, 2013]

§414.202 Definitions.

For purposes of this subpart, the following definitions apply:

Complex rehabilitative power-driven wheelchair means a power-driven wheelchair that is classified as—

(1) Group 2 power wheelchair with power options that can accommodate rehabilitative features (for example, tilt in space); or

(2) Group 3 power wheelchair.

Covered item update means the percentage increase in the consumer price index for all urban consumers (U.S. city average) (CPI-U) for the 12-month period ending with June of the previous year.

Durable medical equipment means equipment, furnished by a supplier or a home health agency that meets the following conditions:

(1) Can withstand repeated use.

(2) Effective with respect to items classified as DME after January 1, 2012, has an expected life of at least 3 years.

(3) Is primarily and customarily used to serve a medical purpose.

(4) Generally is not useful to an individual in the absence of an illness or injury.

(5) Is appropriate for use in the home.

Prosthetic and orthotic devices means—

(1) Devices that replace all or part of an internal body organ, including ostomy bags and supplies directly related to ostomy care, and replacement of such devices and supplies;

(2) One pair of conventional eyeglasses or contact lenses furnished subsequent to each cataract surgery with insertion of an intraocular lens; and

(3) Leg, arm, back, and neck braces, and artificial legs, arms, and eyes, including replacements if required because of a change in the beneficiary's physical condition.

The following are neither prosthetic nor orthotic devices—

(1) Parenteral and enteral nutrients, supplies, and equipment;

(2) Intraocular lenses;

(3) Medical supplies such as catheters, catheter supplies, ostomy bags, and supplies related to ostomy care that are furnished by an HHA as part of home health services under §409.40(e) of this chapter;

(4) Dental prostheses.

Region means, for the purpose of implementing §414.210(g), geographic areas defined by the Bureau of Economic Analysis in the United States Department of Commerce for economic analysis purposes, and, for the purpose of implementing §414.228, those contractor service areas administered by CMS regional offices.

Rural area means, for the purpose of implementing §414.210(g), a geographic area represented by a postal zip code if at least 50 percent of the total geographic area of the area included in the zip code is estimated to be outside any metropolitan area (MSA). A rural area also includes a geographic area represented by a postal zip code that is a low population density area excluded from a competitive bidding area in accordance with the authority provided by section 1847(a)(3)(A) of the Act at the time the rules at §414.210(g) are applied.

[57 FR 57689, Dec. 7, 1992, as amended at 75 FR 73622, Nov. 29, 2010; 76 FR 70314, Nov. 10, 2011; 79 FR 66262, Nov. 6, 2014]

§414.210 General payment rules.

(a) *General rule.* For items furnished on or after January 1, 1989, except as provided in paragraphs (c), (d), and (g) of this section, Medicare pays for durable medical equipment, prosthetics and orthotics, including a separate payment for maintenance and servicing of the items as described in paragraph (e) of this section, on the basis of 80 percent of the lesser of—

(1) The actual charge for the item;

(2) The fee schedule amount for the item, as determined in accordance with the provisions of §§414.220 through 414.232

(b) *Payment classification.* (1) The carrier determines fee schedules for the following classes of equipment and devices:

(i) Inexpensive or routinely purchased items, as specified in § 414.220.

(ii) Items requiring frequent and substantial servicing, as specified in § 414.222.

(iii) Certain customized items, as specified in § 414.224.

(iv) Oxygen and oxygen equipment, as specified in § 414.226.

(v) Prosthetic and orthotic devices, as specified in § 414.228.

(vi) Other durable medical equipment (capped rental items), as specified in § 414.229.

(vii) Transcutaneous electrical nerve stimulators (TENS), as specified in § 414.232.

(2) CMS designates the items in each class of equipment or device through its program instructions.

(c) *Exception for certain HHAs.* Public HHAs and HHAs that furnish services or items free-of-charge or at nominal prices to a significant number of low-income patients, as defined in § 413.13(a) of this chapter, are paid on the basis of 80 percent of the fee schedule amount determined in accordance with the provision of §§ 414.220 through 414.230.

(d) *Prohibition on special limits.* For items furnished on or after January 1, 1989 and before January 1, 1991, neither CMS nor a carrier may establish a special reasonable charge for items covered under this subpart on the basis of inherent reasonableness as described in § 405.502(g) of this chapter.

(e) *Maintenance and servicing*—(1) *General rule.* Except as provided in paragraph (e)(3) of this section, the carrier pays the reasonable and necessary charges for maintenance and servicing of beneficiary-owned equipment. Reasonable and necessary charges are those made for parts and labor not otherwise covered under a manufacturer's or supplier's warranty. Payment is made for replacement parts in a lump sum based on the carrier's consideration of the item. The carrier establishes a reasonable fee for labor associated with repairing, maintaining, and servicing the item. Payment is not made for maintenance and servicing of a rented item other than the maintenance and servicing fee for oxygen equipment described in paragraph (e)(2) of this section or for other durable medical equipment as described in § 414.229(e).

(2) *Maintenance and servicing payment for certain oxygen equipment furnished after the 36-month rental period from January 1, 2009 through June 30, 2010.* The carrier makes a maintenance and servicing payment for oxygen equipment other than liquid and gaseous equipment (stationary and portable) as follows:

(i) For the first 6-month period following the date on which the 36-month rental period ends in accordance with § 414.226(a)(1) of this subpart, no payments are made.

(ii) For each succeeding 6-month period, payment may be made during the first month of that period for 30 minutes of labor for routine maintenance and servicing of the equipment in the beneficiary's home (including an institution used as the beneficiary's home).

(iii) The supplier must visit the beneficiary's home (including an institution used as the beneficiary's home) to inspect the equipment during the first month of the 6-month period.

(3) *Exception to maintenance and servicing payments.* For items purchased on or after June 1, 1989, no payment is made under the provisions of paragraph (e)(1) of this section for the maintenance and servicing of:

(i) Items requiring frequent and substantial servicing, as defined in § 414.222(a);

(ii) Capped rental items, as defined in § 414.229(a), that are not beneficiary-owned in accordance with § 414.229(d), § 414.229(f)(2), or § 414.229(h); and

(iii) Capped rental items, as defined in § 414.229(a), that are not beneficiary-owned in § 414.229(d), § 414.229(f)(2), or § 414.229(h); and

(iv) Oxygen equipment, as described in § 414.226.

(4) *Supplier replacement of beneficiary-owned equipment based on accumulated repair costs.* A supplier that transfers title to a capped rental item to a beneficiary in accordance with § 414.229(f)(2) is responsible for furnishing replacement equipment at no cost to the beneficiary or to the Medicare program if the carrier determines that the item

furnished by the supplier will not last for the entire reasonable useful lifetime established for the equipment in accordance with §414.210(f)(1). In making this determination, the carrier may consider whether the accumulated costs of repair exceed 60 percent of the cost to replace the item.

(5) *Maintenance and servicing payment for certain oxygen equipment furnished after the 36-month rental period and on or after July 1, 2010.* For oxygen equipment other than liquid and gaseous equipment (stationary and portable), the carrier makes payment as follows:

(i) For the first 6-month period following the date on which the 36-month rental period ends in accordance with §414.226(a)(1) of this subpart, no payments are made.

(ii) For each succeeding 6-month period, payment may be made during the first month of that period for routine maintenance and servicing of the equipment in the beneficiary's home (including an institution used as the beneficiary's home).

(iii) Payment for maintenance and servicing is made based on a reasonable fee not to exceed 10 percent of the purchase price for a stationary oxygen concentrator. This payment includes payment for maintenance and servicing of all oxygen equipment other than liquid or gaseous equipment (stationary or portable).

(iv) The supplier must visit the beneficiary's home (including an institution used as the beneficiary's home) to inspect the equipment during the first month of the 6-month period.

(f) *Payment for replacement of equipment.* If an item of DME or a prosthetic or orthotic device paid for under this subpart has been in continuous use by the patient for the equipment's reasonable useful lifetime or if the carrier determines that the item is lost, stolen, or irreparably damaged, the patient may elect to obtain a new piece of equipment.

(1) The reasonable useful lifetime of DME or prosthetic and orthotic devices is determined through program instructions. In the absence of program instructions, carriers may determine the reasonable useful lifetime of equipment but in no case can it be less than 5 years. Computation is based on when the equipment is delivered to the beneficiary, not the age of the equipment.

(2) If the beneficiary elects to obtain replacement oxygen equipment, payment is made in accordance with §414.226(a).

(3) If the beneficiary elects to obtain a replacement capped rental item, payment is made in accordance with §414.229(a)(2) or (a)(3).

(4) For all other beneficiary-owned items, if the beneficiary elects to obtain replacement equipment, payment is made on a purchase basis.

(g) *Application of Competitive Bidding Information and Limitation of Inherent Reasonableness Authority.* For items furnished on or after January 1, 2011, the fee schedule amounts may be adjusted, and for DME items furnished on or after January 1, 2016, the fee schedule amounts shall be adjusted, based on information on the payment determined as part of implementation of the programs under subpart F, of this part, excluding information on the payment determined in accordance with the special payment rules at §414.409. In the case of such adjustments, the rules at §405.502(g) and (h) of this chapter shall not be applied. The methodologies for adjusting fee schedule amounts are provided below. In any case where application of these methodologies results in an increase in the fee schedule amount, the adjustment to the fee schedule amount is not made.

(1) *Payment adjustments for areas within the contiguous United States using information from competitive bidding programs.* For an item or service subject to the programs under subpart F of this part, the fee schedule amounts for such item or service for areas within the contiguous United States shall be adjusted as follows:

(i) CMS determines a regional price for each state in the contiguous United States and the District of Columbia equal to the un-weighted average of the single payment amounts for an item or service established in accordance with §414.416 for competitive bidding areas that are fully or partially located in the same region that contains the state or District of Columbia.

(ii) CMS determines a national average price equal to the un-weighted average of the regional prices determined

under paragraph (g)(1)(i) of this section.

(iii) A regional price determined under paragraph (g)(1)(i) of this section cannot be greater than 110 percent of the national average price determined under paragraph (g)(1)(ii) of this section nor less than 90 percent of the national average price determined under paragraph (g)(1)(ii) of this section.

(iv) The fee schedule amount for all areas within a state that are not defined as rural areas for purposes of this subpart is adjusted to the regional price determined under paragraphs (g)(1)(i) and (iii) of this section.

(v) For items and services furnished before February 28, 2022, the fee schedule amount for all areas within a state that are defined as rural areas for the purposes of this subpart is adjusted to 110 percent of the national average price determined under paragraph (g)(1)(ii) of this section.

(2) Payment adjustments for areas outside the contiguous United States and for items furnished on or after February 28, 2022 in rural areas within the contiguous United States using information from competitive bidding programs.

(i) For an item or service subject to the programs under subpart F, the fee schedule amounts for areas outside the contiguous United States (Alaska, Hawaii, and U.S. territories) for items and services furnished from January 1, 2016, through December 31, 2020 are reduced to the greater of—

(A) The average of the single payment amounts for the item or service for CBAs outside the contiguous United States.

(B) 110 percent of the national average price for the item or service determined under paragraph (g)(1)(ii) of this section.

(ii) For an item or service subject to the programs under subpart F of this part, the fee schedule amounts for areas outside the contiguous United States for items and services furnished on or after February 28, 2022, or the date immediately following the duration of the emergency period described in section 1135(g)(1)(B) of the Act (42 U.S.C. 1320b–5(g)(1)(B)), or December 31, 2023, whichever is later, is adjusted to equal the sum of—

(A) Fifty percent of the greater of the average of the single payment amounts for the item or service for CBAs outside the contiguous United States or 110 percent of the national average price for the item or service determined under paragraph (g)(1)(ii) of this section; and

(B) Fifty percent of the fee schedule amount for the area in effect on December 31, 2015, increased for each subsequent year beginning in 2016 by the annual update factors specified in sections 1834(a)(14), 1834(h)(4), and 1842(s)(1)(B) of the Act, respectively, for durable medical equipment and supplies, off-the-shelf orthotics, and enteral nutrients, supplies, and equipment.

(iii) For an item or service subject to the programs under subpart F of this part, the fee schedule amounts for rural areas within the contiguous United States for items and services furnished on or after February 28, 2022, or the date immediately following the duration of the emergency period described in section 1135(g)(1)(B) of the Act (42 U.S.C. 1320b–5(g)(1)(B)), or December 31, 2023, whichever is later, is adjusted to equal the sum of—

(A) Fifty percent of 110 percent of the national average price for the item or service determined under paragraph (g)(1)(ii) of this section; and

(B) Fifty percent of the fee schedule amount for the area in effect on December 31, 2015, increased for each subsequent year beginning in 2016 by the annual update factors specified in sections 1834(a)(14), 1834(h)(4), and 1842(s)(1)(B) of the Act, respectively, for durable medical equipment and supplies, off-the-shelf orthotics, and enteral nutrients, supplies, and equipment.

(3) *Payment adjustments for items and services included in no more than ten competitive bidding programs.* Notwithstanding paragraph (g)(1) of this section, for an item or service that is included in ten or fewer competitive bidding programs as defined at § 414.402, the fee schedule amounts applied for all areas within and outside the contiguous United States are reduced to 110 percent of the un-weighted average of the single payment amounts from the

ten or fewer competitive bidding programs for the item or service in the areas where the ten or fewer competitive bidding programs are in place.

(4) *Payment adjustments using data on items and services included in competitive bidding programs no longer in effect.* In the case where adjustments to fee schedule amounts are made using any of the methodologies described, other than paragraph (g)(10) of this section, if the adjustments are based solely on single payment amounts from competitive bidding programs that are no longer in effect, the single payment amounts are updated before being used to adjust the fee schedule amounts. The single payment amounts are updated based on the percentage change in the Consumer Price Index for all Urban Consumers (CPI–U) from the mid-point of the last year the single payment amounts were in effect to the month ending 6 months prior to the date the initial fee schedule reductions go into effect. Following the initial adjustments to the fee schedule amounts, if the adjustments continue to be based solely on single payment amounts from competitive bidding programs that are no longer in effect, the single payment amounts used to reduce the fee schedule amounts are updated every 12 months using the percentage change in the CPI–U for the 12-month period ending 6 months prior to the date the updated payment adjustments would go into effect.

(5) *Adjusted payment amounts for accessories used with different types of base equipment.* In situations where a HCPCS code that describes an item used with different types of base equipment is included in more than one product category in a CBA under competitive bidding, a weighted average of the single payment amounts for the code is computed for each CBA based on the total number of allowed services for the item on a national basis for the code from each product category prior to applying the payment adjustment methodologies in this section.

(6) *Adjustments of single payment amounts resulting from price inversions under the DMEPOS Competitive Bidding Program.* (i) In situations where a price inversion defined in §414.402 occurs under the DMEPOS Competitive Bidding Program in a competitive bidding area (CBA) following a competition for a grouping of similar items identified in paragraph (g)(6)(ii) of this section, prior to adjusting the fee schedule amounts under paragraph (g) of this section the single payment amount for each item in the grouping of similar items in the CBA is adjusted to be equal to the weighted average of the single payment amounts for the items in the grouping of similar items in the CBA.

(ii) The groupings of similar items subject to this rule include—

(A) Hospital beds (HCPCS codes E0250, E0251, E0255, E0256, E0260, E0261, E0290, E0291, E0292, E0293, E0294, E0295, E0301, E0302, E0303, and E0304).

(B) Mattresses and overlays (HCPCS codes E0277, E0371, E0372, and E0373)

(C) Power wheelchairs (HCPCS codes K0813, K0814, K0815, K0816, K0820, K0821, K0822, and K0823).

(D) Seat lift mechanisms (HCPCS codes E0627 and E0629).

(E) TENS devices (HCPCS codes E0720 and E0730).

(F) Walkers (HCPCS codes E0130, E0135, E0141, and E0143).

(iii) The weight for each item (HCPCS code) used in calculating the weighted average described in paragraph (g)(6)(ii) of this section is equal to the proportion of total nationwide allowed services furnished in calendar year 2012 for the item (HCPCS code) in the grouping of similar items, relative to the total nationwide allowed services furnished in calendar year 2012 for each of the other items (HCPCS codes) in the grouping of similar items.

(7) *Payment adjustments for mail order items furnished in the Northern Mariana Islands.* The fee schedule amounts for mail order items furnished to beneficiaries in the Northern Mariana Islands are adjusted so that they are equal to 100 percent of the single payment amounts established under a national mail order competitive bidding program. Beginning on or after the date that the Northern Mariana Islands are included under a national mail order competitive bidding program, the fee schedule adjustment methodology under this paragraph no longer applies.

(8) *Updating adjusted fee schedule amounts.* The adjusted fee schedule

amounts are revised each time a single payment amount for an item or service is updated following one or more new competitions and as other items are added to programs established under Subpart F of this part.

(9) *Transition rules.* The payment adjustments described above are phased in as follows:

(i) For applicable items and services furnished with dates of service from January 1, 2016 through December 31, 2016, based on the fee schedule amount for the area is equal to 50 percent of the adjusted payment amount established under this section and 50 percent of the unadjusted fee schedule amount.

(ii) For items and services furnished with dates of service from January 1, 2017, through May 31, 2018, the fee schedule amount for the area is equal to 100 percent of the adjusted payment amount established under this section.

(iii) For items and services furnished in rural areas and non-contiguous areas (Alaska, Hawaii, and U.S. territories) with dates of service from June 1, 2018 through the duration of the emergency period described in section 1135(g)(1)(B) of the Act (42 U.S.C. 1320b–5(g)(1)(B)) or December 31, 2023 of the emergency period described in section 1135(g)(1)(B) of the Act (42 U.S.C. 1320b–5(g)(1)(B)), whichever is later, based on the fee schedule amount for the area is equal to 50 percent of the adjusted payment amount established under this section and 50 percent of the unadjusted fee schedule amount.

(iv) For items and services furnished in areas other than rural or noncontiguous areas with dates of service from June 1, 2018 through March 5, 2020, based on the fee schedule amount for the area is equal to 100 percent of the adjusted payment amount established under this section.

(v) For items and services furnished in areas other than rural or noncontiguous areas with dates of service from March 6, 2020, through the remainder of the duration of the emergency period described in section 1135(g)(1)(B) of the Act (42 U.S.C. 1320b–5(g)(1)(B)) or December 31, 2023, whichever is later, based on the fee schedule amount for the area is equal to 75 percent of the adjusted payment amount established under this section and 25 percent of the unadjusted fee schedule amount.

(vi) For items and services furnished in all areas with dates of service on or after January 1, 2024, or the date immediately following the duration of the emergency period described in section 1135(g)(1)(B) of the Act, whichever is later, based on the fee schedule amount for the area is equal to the adjusted payment amount established under paragraph (g) of this section.

(10) *Payment adjustments for items and services furnished in former competitive bidding areas during temporary gaps in the DMEPOS CBP.* During a temporary gap in the entire DMEPOS CBP and/or National Mail Order CBP, the fee schedule amounts for items and services that were competitively bid and furnished in areas that were competitive bidding areas at the time the program(s) was in effect are adjusted based on the SPAs in effect in the competitive bidding areas on the last day before the CBP contract period of performance ended, increased by the projected percentage change in the Consumer Price Index for all Urban Consumers (CPI–U) for the 12-month period ending on the date after the contract periods ended. If the gap in the CBP lasts for more than 12 months, the fee schedule amounts are increased once every 12 months on the anniversary date of the first day of the gap period based on the projected percentage change in the CPI–U for the 12-month period ending on the anniversary date.

[57 FR 57689, Dec. 7, 1992, as amended at 71 FR 65932, Nov. 9, 2006; 73 FR 69936, Nov. 19, 2008; 73 FR 80304, Dec. 31, 2008; 74 FR 62009, Nov. 25, 2009; 79 FR 66262, Nov. 6, 2013; 81 FR 77965, Nov. 4, 2016; 83 FR 21925, May 11, 2018; 83 FR 57070, Nov. 14, 2018; 85 FR 27623, May 8, 2020; 86 FR 73911, Dec. 28, 2021; 87 FR 199, Jan. 4, 2022; 88 FR 77875, Nov. 13, 2023]

§ 414.220 Inexpensive or routinely purchased items.

(a) *Definitions.* (1) *Inexpensive equipment* means equipment the average purchase price of which did not exceed $150 during the period July 1986 through June 1987.

(2) *Routinely purchased equipment* means equipment that was acquired by purchase on a national basis at least 75 percent of the time during the period July 1986 through June 1987.

(3) *Accessories.* Effective January 1, 1994, accessories used in conjunction with a nebulizer, aspirator, or ventilator excluded from §414.222 meet the definitions of ''inexpensive equipment'' and ''routinely purchased equipment'' in paragraphs (a)(1) and (a)(2) of this section, respectively.

(b) *Payment rules.* (1) Subject to the limitation in paragraph (b)(3) of this section, payment for inexpensive and routinely purchased items is made on a rental basis or in a lump sum amount for purchase of the item based on the applicable fee schedule amount.

(2) Effective January 1, 1994, payment for ostomy supplies, tracheostomy supplies, urologicals, and surgical dressings not furnished as incident to a physician's professional service or furnished by an HHA is made using the methodology for the inexpensive and routinely purchased class.

(3) The total amount of payments made for an item may not exceed the fee schedule amount recognized for the purchase of that item.

(c) *Fee schedule amount for 1989 and 1990.* The fee schedule amount for payment of purchase or rental of inexpensive or routinely purchased items furnished in 1989 and 1990 is the local payment amount determined as follows:

(1) The carrier determines the average reasonable charge for inexpensive or routinely purchased items that were furnished during the period July 1, 1986 through June 30, 1987 based on the mean of the carrier's allowed charges for the item. A separate determination of an average reasonable charge is made for rental equipment, new purchased equipment, and used purchased equipment.

(2) The carrier adjusts the amount determined under paragraph (c)(1) of this section by the change in the level of the CPI-U for the 6-month period ending December 1987.

(d) *Updating the local payment amounts for years after 1990.* For each year subsequent to 1990, the local payment amounts of the preceding year are increased or decreased by the covered item update. For 1991 and 1992, the covered item update is reduced by 1 percentage point.

(e) *Calculating the fee schedule amounts for years after 1990.* For years after 1990, the fee schedule amounts are equal to the national limited payment amount.

(f) *Calculating the national limited payment amount.* The national limited payment amount is computed as follows:

(1) The 1991 national limited payment amount is equal to:

(i) 100 percent of the local payment amount if the local payment amount is neither greater than the weighted average nor less than 85 percent of the weighted average of all local payment amounts;

(ii) The sum of 67 percent of the local payment amount plus 33 percent of the weighted average of all local payment amounts if the local payment amount exceeds the weighted average of all local payment amounts; or

(iii) The sum of 67 percent of the local payment amount plus 33 percent of 85 percent of the weighted average of all local payment amounts if the local payment amount is less than 85 percent of the weighted average of all local payment amounts.

(2) The 1992 national limited payment amount is equal to:

(i) 100 percent of the local payment amount if the local payment amount is neither greater than the weighted average nor less than 85 percent of the weighted average of all local payment amounts;

(ii) The sum of 33 percent of the local payment amount plus 67 percent of the weighted average of all local payment amounts if the local payment amount exceeds the weighted average; or

(iii) The sum of 33 percent of the local payment amount plus 67 percent of 85 percent of the weighted average of all local payment amounts if the local payment amount is less than 85 percent of the weighted average.

(3) For 1993, the national limited payment amount is equal to one of the following:

(i) 100 percent of the local payment amount if the local payment amount is neither greater than the weighted average nor less than 85 percent of the weighted average of all local payment amounts.

(ii) 100 percent of the weighted average of all local payment amounts if the local payment amount exceeds the

weighted average of all local payment amounts.

(iii) 85 percent of the weighted average of all local payment amounts if the local payment amount is less than 85 percent of the weighted average of all local payment amounts.

(4) For 1994 and subsequent years, the national limited payment amount is equal to one of the following:

(i) If the local payment amount is not in excess of the median, nor less than 85 percent of the median, of all local payment amounts—100 percent of the local payment amount.

(ii) If the local payment amount exceeds the median—100 percent of the median of all local payment amounts.

(iii) If the local payment amount is less than 85 percent of the median—85 percent of the median of all local payment amounts.

(g) *Payment for surgical dressings.* For surgical dressings furnished after December 31, 1993, the national limited payment amount is computed based on local payment amounts using average reasonable charges for the 12-month period ending December 31, 1992, increased by the covered item updates for 1993 and 1994.

[57 FR 57689, Dec. 7, 1992, as amended at 60 FR 35497, July 10, 1995]

§ 414.222 Items requiring frequent and substantial servicing.

(a) *Definition.* Items requiring frequent and substantial servicing in order to avoid risk to the beneficiary's health are the following:

(1) Ventilators (except those that are either continuous airway pressure devices or respiratory assist devices with bi-level pressure capability with or without a backup rate, previously referred to as ''intermittent assist devices with continuous airway pressure devices'').

(2) Continuous and intermittent positive pressure breathing machines.

(3) Continuous passive motion machines.

(4) Other items specified in CMS program instructions.

(5) Other items identified by the carrier.

(b) *Payment rule.* Rental payments for items requiring frequent and substantial servicing are made on a monthly basis, and continue until medical necessity ends.

(c) *Fee schedule amount for 1989 and 1990.* The fee schedule amount for items requiring frequent and substantial servicing is the local payment amount determined as follows:

(1) The carrier determines the average reasonable charge for rental of items requiring frequent and substantial servicing that were furnished during the period July 1, 1986 through June 30, 1987 based on the mean of the carrier's allowed charges for the item.

(2) The carrier adjusts the amounts determined under paragraph (c)(1) of this section by the change in the level of the CPI-U for the 6-month period ending December 1987.

(d) *Updating the fee schedule amounts for years after 1990.* For years after 1990, the fee schedules are determined using the methodology contained in paragraphs (d), (e), and (f) of § 414.220.

(e) *Transition to other payment classes.* For purposes of calculating the 15-month rental period, beginning January 1, 1994, if an item has been paid for under the frequent and substantial servicing class and is subsequently paid for under another payment class, the rental period begins with the first month of continuous rental, even if that period began before January 1, 1994. For example, if the rental period began on July 1, 1993, the carrier must use this date as beginning the first month of rental. Likewise, for purposes of calculating the 10-month purchase option, the rental period begins with the first month of continuous rental without regard to when that period started. For example, if the rental period began in August 1993, the 10-month purchase option must be offered to the beneficiary in May 1994, the tenth month of continuous rental.

(f) *Multi-function ventilators*—(1) Definition. For the purpose of this paragraph (f), a multi-function ventilator is a ventilator as defined in paragraph (a)(1) of this section that also performs medically necessary functions for the patient at the same time that would otherwise be performed by one or more different items classified under § 414.220, § 414.226, or § 414.229.

(2) *Payment rule.* Effective for dates of service on or after January 1, 2019, the

monthly rental fee schedule amount for a multi-function ventilator described in paragraph (f)(1) of this section is equal to the monthly rental fee schedule amount for the ventilator established in paragraph (c) and paragraph (d) of this section plus the average of the lowest monthly cost for one additional function determined under paragraph (f)(3) of this section and the monthly cost of all additional functions determined under paragraph (f)(3) of this section, increased by the annual covered item updates of section 1834(a)(14) of the Act.

(3) *Monthly cost for additional functions.* (i) For functions performed by items classified under this section prior to 1994, the monthly cost is equal to the monthly rental fee schedule amount established in paragraphs (c) and (d) of this section increased by the covered item update of section 1834(a)(14) of the Act.

(ii) For functions performed by items classified under §414.220, the monthly cost is equal to the fee schedule amount for purchased equipment established in §414.220(c), (d), (e), and (f), adjusted in accordance with §414.210(g), divided by 60 months or total number of months of the reasonable useful lifetime of the equipment.

(iii) For functions performed by items classified under §414.226, the monthly cost is equal to the monthly payment amount established in §414.226(e) and (f), adjusted in accordance with §414.210(g), multiplied by 36 and divided by 60 months or total number of months of the reasonable useful lifetime of the oxygen equipment.

(iv) For functions performed by items classified under §414.229, the monthly cost is equal to the purchase price established in §414.229(c), adjusted in accordance with §414.210(g), divided by 60 months or total number of months of the reasonable useful lifetime of the equipment.

[57 FR 57690, Dec. 7, 1992, as amended at 60 FR 35497, July 10, 1995; 71 FR 4525, Jan. 27, 2006; 83 FR 57071, Nov. 14, 2018]

§414.224 Customized items.

(a) *Criteria for a customized item.* To be considered a customized item for payment purposes under paragraph (b) of this section, a covered item (including a wheelchair) must be uniquely constructed or substantially modified for a specific beneficiary according to the description and orders of a physician and be so different from another item used for the same purpose that the two items cannot be grouped together for pricing purposes.

(b) *Payment rule.* Payment is made on a lump sum basis for the purchase of a customized item based on the carrier's individual consideration and judgment of a reasonable payment amount for each customized item. The carrier's individual consideration takes into account written documentation on the costs of the item including at least the cost of labor and materials used in customizing an item.

[56 FR 65998, Dec. 20, 1991, as amended at 58 FR 34919, June 30, 1993]

§414.226 Oxygen and oxygen equipment.

(a) *Payment rules*—(1) *Oxygen equipment.* Payment for rental of oxygen equipment is made based on a monthly fee schedule amount during the period of medical need, but for no longer than a period of continuous use of 36 months. A period of continuous use is determined under the provisions in §414.230.

(2) *Oxygen contents.* Payment for purchase of oxygen contents is made based on a monthly fee schedule amount until medical necessity ends.

(b) *Monthly fee schedule amount for items furnished prior to 2007.* (1) Monthly fee schedule amounts are separately calculated for the following items:

(i) Stationary oxygen equipment and oxygen contents (stationary and portable oxygen contents).

(ii) Portable oxygen equipment only.

(iii) Stationary and portable oxygen contents only.

(iv) Portable oxygen contents only.

(2) For 1989 and 1990, the monthly fee schedule amounts are the local payment amounts determined as follows:

(i) The carrier determines the base local average monthly payment rate equal to the total reasonable charges for the item for the 12-month period ending December 1986 divided by the total number of months for all beneficiaries receiving the item for the same period. In determining the local

average monthly payment rate, the following limitations apply:

(A) Purchase charges for oxygen systems are not included as items classified under paragraph (b)(1)(i) of this section.

(B) Purchase charges for portable equipment are not included as items classified under paragraph (b)(1)(ii) of this section.

(ii) The carrier determines the local monthly payment amount equal to 0.95 times the base local average monthly payment amount adjusted by the change in the CPI-U for the six-month period ending December 1987.

(3) For 1991 through 2006, the fee schedule amounts for items described in paragraphs (b)(1)(iii) and (iv) of this section are determined using the methodology contained in § 414.220(d), (e), and (f).

(4) For 1991 through 2006, the fee schedule amounts for items described in paragraphs (b)(1)(i) and (ii) of this section are determined using the methodology contained in § 414.220(d), (e), and (f).

(5) For 2005 and 2006, the fee schedule amounts determined under paragraph (b)(4) of this section are reduced using the methodology described in section 1834(a)(21)(A) of the Act.

(c) *Monthly fee schedule amount for items furnished from 2007 through 2018.* (1) For 2007, national limited monthly payment rates are calculated and paid as the monthly fee schedule amounts for the following classes of items:

(i) Stationary oxygen equipment (including stationary concentrators) and oxygen contents (stationary and portable).

(ii) Portable equipment only (gaseous or liquid tanks).

(iii) Oxygen generating portable equipment only.

(iv) Stationary oxygen contents only.

(v) Portable oxygen contents only.

(2) The national limited monthly payment rate for items described in paragraph (c)(1)(i) of this section is equal to the weighted average fee schedule amount established under paragraph (b)(5) of this section reduced by $1.44.

(3) The national limited monthly payment rate for items described in paragraph (c)(1)(ii) of this section is equal to the weighted average of the fee schedule amounts established under paragraph (b)(5) of this section.

(4) The national limited monthly payment rate for items described in paragraph (c)(1)(iii) of this section is equal to the national limited monthly payment rate established under paragraph (c)(5) of this section, multiplied by 24, and divided by 36.

(5) The national limited monthly payment rate for items described in paragraphs (c)(1)(iv) and (c)(1)(v) of this section is equal to 50 percent of the weighted average fee schedule amounts established under paragraph (b)(3) of this section for items described in paragraph (b)(1)(iii) of this section.

(6) For 2008 through 2018, CMS makes an annual adjustment to the national limited monthly payment rate for items described in paragraph (c)(1)(i) of this section to ensure that such payment rates do not result in expenditures for any year that are more or less than the expenditures that would have been made if such classes had not been established.

(d) *Application of monthly fee schedule amounts for items furnished from 2007 through 2018.* (1) The fee schedule amount for items described in paragraph (c)(1)(i) of this section is paid when the beneficiary rents stationary oxygen equipment.

(2) Subject to the limitation set forth in paragraph (g)(2) of this section, the fee schedule amount for items described in paragraphs (c)(1)(ii) and (c)(1)(iii) of this section is paid when the beneficiary rents portable oxygen equipment.

(3) The fee schedule amount for items described in paragraph (c)(1)(iv) of this section is paid when the beneficiary—

(i) Owns stationary oxygen equipment that requires delivery of gaseous or liquid oxygen contents; or

(ii) Rents stationary oxygen equipment that requires delivery of gaseous or liquid oxygen contents after the period of continuous use of 36 months described in paragraph (a)(1) of this section.

(4) The fee schedule amount for items described in paragraph (c)(1)(v) of this section is paid when the beneficiary—

(i) Owns portable oxygen equipment described in (c)(1)(ii) of this section;

(ii) Rents portable oxygen equipment described in paragraph (c)(1)(ii) of this section during the period of continuous use of 36 months described in paragraph (a)(1) of this section and does not rent stationary oxygen equipment; or

(iii) Rents portable oxygen equipment described in paragraph (c)(1)(ii) of this section after the period of continuous use of 36 months described in paragraph (a)(1) of this section.

(e) *Monthly fee schedule amount for items furnished for years after 2018.* (1) For 2019, national limited monthly payment rates are calculated and paid as the monthly fee schedule amounts for the following classes of items:

(i) Stationary oxygen equipment (including stationary concentrators) and oxygen contents (stationary and portable).

(ii) Portable gaseous equipment only.

(iii) Portable liquid equipment only.

(iv) Oxygen generating portable equipment only.

(v) Stationary oxygen contents only.

(vi) Portable oxygen contents only, except for portable liquid oxygen contents for prescribed flow rates greater than four liters per minute.

(vii) Portable liquid oxygen contents only for prescribed flow rates of more than 4 liters per minute.

(2) The monthly payment rate for items described in paragraphs (e)(1)(i), (ii), (iv), (v), and (vi) of this section are determined using the applicable methodologies contained in § 414.210(g).

(3) The monthly payment rate for items described in paragraph (e)(1)(iii) of this section is determined initially based on the monthly payment rate for items described in paragraph (e)(1)(iv) of this section and is subsequently adjusted using the applicable methodologies contained in § 414.210(g).

(4) The monthly payment rate for items described in paragraph (e)(1)(vii) of this section is determined initially based on 150 percent of the monthly payment rate for items described in paragraph (e)(1)(vi) of this section and is subsequently adjusted using the applicable methodologies contained in § 414.210(g).

(5) Beginning in 2019, CMS makes an annual adjustment to the monthly payment rate for items described in paragraphs (e)(1)(i) through (e)(1)(vii) of this section to ensure that such payment rates do not result in expenditures for any year that are more or less than the expenditures that would have been made if such classes had not been established.

(f) *Application of monthly fee schedule amounts for items furnished for years after 2018.* (1) The fee schedule amount for items described in paragraph (e)(1)(i) of this section is paid when the beneficiary rents stationary oxygen equipment.

(2) Subject to the limitation set forth in paragraph (g)(2) of this section, the fee schedule amount for items described in paragraphs (e)(1)(ii), (iii), and (iv) of this section is paid when the beneficiary rents portable oxygen equipment.

(3) The fee schedule amount for items described in paragraph (e)(1)(v) of this section is paid when the beneficiary—

(i) Owns stationary oxygen equipment that requires delivery of gaseous or liquid oxygen contents; or

(ii) Rents stationary oxygen equipment that requires delivery of gaseous or liquid oxygen contents after the period of continuous use of 36 months described in paragraph (a)(1) of this section.

(4) The fee schedule amount for items described in paragraph (e)(1)(vi) of this section is paid when the beneficiary—

(i) Owns portable oxygen equipment described in paragraphs (e)(1)(ii) or (e)(1)(iii) of this section; or Code of Federal Regulations/Title 42—Public Health/Vol. 3/2017–10–0166

(ii) Rents portable oxygen equipment described in paragraphs (e)(1)(ii) or (e)(1)(iii) of this section during the period of continuous use of 36 months described in paragraph (a)(1) of this section and does not rent stationary oxygen equipment; or

(iii) Rents portable oxygen equipment described in paragraphs (e)(1)(ii) or (e)(1)(iii) of this section after the period of continuous use of 36 months described in paragraph (a)(1) of this section.

(5) The fee schedule amount for items described in paragraph (e)(1)(vii) of this section is paid when the beneficiary has a prescribed flow rate of more than 4 liters per minute and—

(i) Owns portable liquid oxygen equipment described in paragraph (e)(1)(iii) of this section; or Code of Federal Regulations/Title 42—Public Health/Vol. 3/2017–10–0166

(ii) Rents portable liquid oxygen equipment described in paragraph (e)(1)(iii) of this section during the period of continuous use of 36 months described in paragraph (a)(1) of this section and does not rent stationary oxygen equipment; or

(iii) Rents portable liquid oxygen equipment described in paragraph (e)(1)(iii) of this section after the period of continuous use of 36 months described in paragraph (a)(1) of this section.

(g) *Volume adjustments.* (1) The fee schedule amount for an item described in paragraph (c)(1)(i) of this section is adjusted as follows:

(i) If the attending physician prescribes an oxygen flow rate exceeding four liters per minute, the fee schedule amount is increased by 50 percent, subject to the limit in paragraph (g)(2) of this section.

(ii) If the attending physician prescribes an oxygen flow rate of less than one liter per minute, the fee schedule amount is decreased by 50 percent.

(2) If portable oxygen equipment is used and the prescribed oxygen flow rate exceeds four liters per minute, the total fee schedule amount recognized for payment is limited to the higher of—

(i) The sum of the monthly fee schedule amount for the items described in paragraphs (c)(1)(i) and (c)(1)(ii) or (c)(1)(iii) of this section; or

(ii) The adjusted fee schedule amount described in paragraph (g)(1)(i) of this section.

(3) In establishing the volume adjustment for those beneficiaries whose physicians prescribe varying flow rates, the following rules apply:

(i) If the prescribed flow rate is different for stationary oxygen equipment than for portable oxygen equipment, the flow rate for the stationary equipment is used.

(ii) If the prescribed flow rate is different for the patient at rest than for the patient at exercise, the flow rate for the patient at rest is used.

(iii) If the prescribed flow rate is different for nighttime use and daytime use, the average of the two flow rates is used.

(h) *Furnishing oxygen and oxygen equipment after the 36-month rental cap.* (1) The supplier that furnishes oxygen equipment for the 36th continuous month during which payment is made under this section must—

(i) Continue to furnish the equipment during any period of medical need for the remainder of the reasonable useful lifetime established for the equipment in accordance with § 414.210(f)(1); or

(ii) Arrange for furnishing the oxygen equipment with another supplier if the beneficiary relocates to an area that is outside the normal service area of the supplier that initially furnished the equipment.

(2) The supplier that furnishes liquid or gaseous oxygen equipment (stationary or portable) for the 36th continuous month during which payment is made under this section must—

(i) Continue to furnish the oxygen contents necessary for the effective use of the liquid or gaseous equipment during any period of medical need for the remainder of the reasonable useful lifetime established for the equipment in accordance with § 414.210(f)(1); or

(ii) Arrange for furnishing the oxygen contents with another supplier if the beneficiary relocates to an area that is outside the normal service area of the supplier that initially furnished the equipment.

(i) *Additional supplier requirements for rentals that begin on or after January 1, 2007.* (1) The supplier that furnishes oxygen equipment for the first month during which payment is made under this section must continue to furnish the equipment for the entire 36-month period of continuous use, unless medical necessity ends or—

(i) The item becomes subject to a competitive acquisition program implemented in accordance with section 1847(a) of the Act;

(ii) The beneficiary relocates to an area that is outside the normal service area of the supplier that initially furnished the equipment;

(iii) The beneficiary elects to obtain oxygen equipment from a different supplier prior to the expiration of the 36-month rental period; or

(iv) CMS or the carrier determines that an exception should apply in an individual case based on the circumstances.

(2) Oxygen equipment furnished under this section may not be replaced by the supplier prior to the expiration of the reasonable useful lifetime established for the equipment in accordance with § 414.210(f)(1) unless:

(i) The supplier replaces an item with the same, or equivalent, make and model of equipment because the item initially furnished was lost, stolen, irreparably damaged, is being repaired, or no longer functions;

(ii) A physician orders different equipment for the beneficiary. If the order is based on medical necessity, then the order must indicate why the equipment initially furnished is no longer medically necessary and the supplier must retain this order in the beneficiary's medical record;

(iii) The beneficiary chooses to obtain a newer technology item or upgraded item and signs an advanced beneficiary notice (ABN); or

(iv) CMS or the carrier determines that a change in equipment is warranted.

(3) Before furnishing oxygen equipment, the supplier must disclose to the beneficiary its intentions regarding whether it will accept assignment of all monthly rental claims for the duration of the rental period. A supplier's intentions could be expressed in the form of a written agreement between the supplier and the beneficiary.

[57 FR 57690, Dec. 7, 1992, as amended at 71 FR 65933, Nov. 9, 2006; 73 FR 69936, Nov. 19, 2008; 78 FR 72253, Dec. 2, 2013; 83 FR 57071, Nov. 14, 2018]

§ 414.228 Prosthetic and orthotic devices.

(a) *Payment rule.* Payment is made on a lump-sum basis for prosthetic and orthotic devices subject to this subpart.

(b) *Fee schedule amounts.* The fee schedule amount for prosthetic and orthotic devices is determined as follows:

(1) The carrier determines a base local purchase price equal to the average reasonable charge for items purchased during the period July 1, 1986 through June 30, 1987 based on the mean of the carrier's allowed charges for the item.

(2) The carrier determines a local purchase price equal to the following:

(i) For 1989 and 1990, the base local purchase price is adjusted by the change in the level of the CPI-U for the 6-month period ending December 1987.

(ii) For 1991 through 1993, the local purchase price for the preceding year is adjusted by the applicable percentage increase for the year. The applicable percentage increase is equal to 0 percent for 1991. For 1992 and 1993, the applicable percentage increase is equal to the percentage increase in the CPI-U for the 12-month period ending with June of the previous year.

(iii) For 1994 and 1995, the applicable percentage increase is 0 percent.

(iv) For all subsequent years the applicable percentage increase is equal to the percentage increase in the CPI-U for the 12-month period ending with June of the previous year.

(3) CMS determines the regional purchase price equal to the following:

(i) For 1992, the average (weighted by the relative volume of all claims among carriers) of the local purchase prices for the carriers in the region.

(ii) For 1993 and subsequent years, the regional purchase price for the preceding year adjusted by the applicable percentage increase for the year.

(4) CMS determines a purchase price equal to the following:

(i) For 1989, 1990 and 1991, 100 percent of the local purchase price.

(ii) For 1992, 75 percent of the local purchase price plus 25 percent of the regional purchase price.

(iii) For 1993, 50 percent of the local purchase price plus 50 percent of the regional purchase price.

(iv) For 1994 and subsequent years, 100 percent of the regional purchase price.

(5) For 1992 and subsequent years, CMS determines a national average purchase price equal to the unweighted average of the purchase prices determined under paragraph (b)(4) of this section for all carriers.

(6) CMS determines the fee schedule amount equal to 100 percent of the purchase price determined under paragraph (b)(4) of this section, subject to the following limitations:

(i) For 1992, the amount cannot be greater than 125 percent nor less than 85 percent of the national average purchase price determined under paragraph (b)(5) of this section.

(ii) For 1993 and subsequent years, the amount cannot be greater than 120 percent of the national average nor less than 90 percent of the national average purchase price determined under paragraph (b)(5) of this section.

(c) *Payment for therapeutic shoes.* The payment rules specified in paragraphs (a) and (b) of this section are applicable to custom molded and extra depth shoes, modifications, and inserts (therapeutic shoes) furnished after December 31, 2004.

[57 FR 57691, Dec. 7, 1992, as amended at 60 FR 35498, July 10, 1995; 73 FR 69937, Nov. 19, 2008]

§ 414.229 Other durable medical equipment—capped rental items.

(a) *General payment rule.* Payment is made for other durable medical equipment that is not subject to the payment provisions set forth in § 414.220 through § 414.228 as follows:

(1) For items furnished prior to January 1, 2006, payment is made on a rental or purchase option basis in accordance with the rules set forth in paragraphs (b) through (e) of this section.

(2) For items other than power-driven wheelchairs furnished on or after January 1, 2006, payment is made in accordance with the rules set forth in paragraph (f) of this section.

(3) For power-driven wheelchairs furnished on or after January 1, 2006 through December 31, 2010, payment is made in accordance with the rules set forth in paragraphs (f) or (h) of this section.

(4) For power-driven wheelchairs that are not classified as complex rehabilitative power-driven wheelchairs, furnished on or after January 1, 2011, payment is made in accordance with the rules set forth in paragraph (f) of this section.

(5) For power-driven wheelchairs classified as complex rehabilitative power-driven wheelchairs, furnished on or after January 1, 2011, payment is made in accordance with the rules set forth in paragraphs (f) or (h) of this section.

(b) *Fee schedule amounts for rental.* (1) For 1989 and 1990, the monthly fee schedule amount for rental of other covered durable medical equipment equals 10 percent of the purchase price recognized as determined under paragraph (c) of this section subject to the following limitation: For 1989 and 1990, the fee schedule amount cannot be greater than 115 percent nor less than 85 percent of the prevailing charge, as determined under § 405.504 of this chapter, established for rental of the item in January 1987, as adjusted by the change in the level of the CPI-U for the 6-month period ending December 1987.

(2) For 1991 and subsequent years, the monthly fee schedule amount for rental of other covered durable medical equipment equals 10 percent of the purchase price recognized as determined under paragraph (c) of this section for each of the first 3 months and 7.5 percent of the purchase price for each of the remaining months.

(3) For power-driven wheelchairs furnished on or after January 1, 2011, the monthly fee schedule amount for rental equipment equals 15 percent of the purchase price recognized as determined under paragraph (c) of this section for each of the first 3 months and 6 percent of the purchase price for each of the remaining months.

(c) *Determination of purchase price.* The purchase price of other covered durable medical equipment is determined as follows:

(1) For *1989 and 1990.* (i) The carrier determines a base local purchase price amount equal to the average of the purchase prices submitted on an assignment-related basis of new items supplied during the 6-month period ending December 1986.

(ii) The purchase price is equal to the base local purchase price adjusted by the change in the level of the CPI-U for the 6-month period ending December 1987.

(2) For *1991.* (i) The local payment amount is the purchase price for the preceding year adjusted by the covered item update for 1991 and decreased by

the percentage by which the average of the reasonable charges for claims paid for all other items described in §414.229, is lower than the average of the purchase prices submitted for such items during the final 9 months of 1988.

(ii) The purchase price for 1991 is the national limited payment amount as determined using the methodology contained in §414.220(f).

(3) *For years after 1991.* The purchase price is determined using the methodology contained in paragraphs (d) through (f) of §414.220.

(d) *Purchase option.* Suppliers must offer a purchase option to beneficiaries during the 10th continuous rental month and, for power-driven wheelchairs, the purchase option must also be made available at the time the equipment is initially furnished.

(1) Suppliers must offer beneficiaries the option of purchasing power-driven wheelchairs at the time the supplier first furnishes the item. On or after January 1, 2011, this option is available only for complex rehabilitative power-driven wheelchairs. Payment must be on a lump-sum fee schedule purchase basis if the beneficiary chooses the purchase option. The purchase fee is the amount established in paragraph (c) of this section.

(2) Suppliers must offer beneficiaries the option of converting capped rental items (including power-driven wheelchairs not purchased when initially furnished) to purchased equipment during their 10th continuous rental month. Beneficiaries have one month from the date the supplier makes the offer to accept the purchase option.

(i) If the beneficiary does not accept the purchase option, payment continues on a rental basis not to exceed a period of continuous use of longer than 15 months. After 15 months of rental payments have been paid, the supplier must continue to provide the item without charge, other than a charge for maintenance and servicing fees, until medical necessity ends or Medicare coverage ceases. A period of continuous use is determined under the provisions in §414.230.

(ii) If the beneficiary accepts the purchase option, payment continues on a rental basis not to exceed a period of continuous use of longer than 13 months. On the first day after 13 continuous rental months during which payment is made, the supplier must transfer title to the equipment to the beneficiary.

(e) *Payment for maintenance and servicing.* (1) The carrier establishes a reasonable fee for maintenance and servicing for each rented item of other durable medical equipment. The fee may not exceed 10 percent of the purchase price recognized as determined under paragraph (c) of this section.

(2) Payment of the fee for maintenance and servicing of other durable medical equipment that is rented is made only for equipment that continues to be used after 15 months of rental payments have been made and is limited to the following:

(i) For the first 6-month period, no payments are to be made.

(ii) For each succeeding 6-month period, payment may be made during the first month of that period.

(3) Payment for maintenance and servicing DME purchased in accordance with paragraphs (d)(1) and (d)(2)(ii) of this section, is made on the basis of reasonable and necessary charges.

(f) *Rules for capped rental items furnished beginning on or after January 1, 2006.* (1) For items furnished on or after January 1, 2006, payment is made based on a monthly rental fee schedule amount during the period of medical need, but for no longer than a period of continuous use of 13 months. A period of continuous use is determined under the provisions in §414.230.

(2) The supplier must transfer title to the item to the beneficiary on the first day that begins after the 13th continuous month in which payments are made under paragraph (f)(1) of this section.

(3) Payment for maintenance and servicing of beneficiary-owned equipment is made in accordance with §414.210(e).

(g) *Additional supplier requirements for capped rental items that are furnished beginning on or after January 1, 2007.* (1) The supplier that furnishes an item for the first month during which payment is made using the methodology described in paragraph (f)(1) of this section must continue to furnish the

equipment until medical necessity ends, or the 13-month period of continuous use ends, whichever is earlier, unless—

(i) The item becomes subject to a competitive acquisition program implemented in accordance with section 1847(a) of the Act;

(ii) The beneficiary relocates to an area that is outside the normal service area of the supplier that initially furnished the equipment;

(iii) The beneficiary elects to obtain the equipment from a different supplier prior to the expiration of the 13-month rental period; or

(iv) CMS or the carrier determines that an exception should apply in an individual case based on the circumstances.

(2) A capped rental item furnished under this section may not be replaced by the supplier prior to the expiration of the 13-month rental period unless:

(i) The supplier replaces an item with the same, or equivalent, make and model of equipment because the item initially furnished was lost, stolen, irreparably damaged, is being repaired, or no longer functions;

(ii) A physician orders different equipment for the beneficiary. If the need for different equipment is based on medical necessity, then the order must indicate why the equipment initially furnished is no longer medically necessary and the supplier must retain this order in the beneficiary's medical record;

(iii) The beneficiary chooses to obtain a newer technology item or upgraded item and signs an advanced beneficiary notice (ABN); or

(iv) CMS or the carrier determines that a change in equipment is warranted.

(3) Before furnishing a capped rental item, the supplier must disclose to the beneficiary its intentions regarding whether it will accept assignment of all monthly rental claims for the duration of the rental period. A supplier's intentions could be expressed in the form of a written agreement between the supplier and the beneficiary.

(4) No later than two months before the date on which the supplier must transfer title to a capped rental item to the beneficiary, the supplier must disclose to the beneficiary whether it can maintain and service the item after the beneficiary acquires title to it. CMS or its carriers may make exceptions to this requirement on a case-by-case basis.

(h) *Purchase of power-driven wheelchairs furnished on or after January 1, 2006.* (1) Suppliers must offer beneficiaries the option to purchase power-driven wheelchairs at the time the equipment is initially furnished.

(2) Payment is made on a lump-sum purchase basis if the beneficiary chooses this option.

(3) On or after January 1, 2011, this option is available only for complex rehabilitative power-driven wheelchairs.

[57 FR 57691, Dec. 7, 1992, as amended at 60 FR 35498, July 10, 1995; 71 FR 65934, Nov. 9, 2006; 75 FR 73622, Nov. 29, 2010]

§ 414.230 Determining a period of continuous use.

(a) *Scope.* This section sets forth the rules that apply in determining a period of continuous use for rental of durable medical equipment.

(b) *Continuous use.* (1) A period of continuous use begins with the first month of medical need and lasts until a beneficiary's medical need for a particular item of durable medical equipment ends.

(2) In the case of a beneficiary receiving oxygen equipment on December 31, 2005, the period of continuous use for the equipment begins on January 1, 2006.

(c) *Temporary interruption.* (1) A period of continuous use allows for temporary interruptions in the use of equipment.

(2) An interruption of not longer than 60 consecutive days plus the days remaining in the rental month in which use ceases is temporary, regardless of the reason for the interruption.

(3) Unless there is a break in medical necessity that lasts longer than 60 consecutive days plus the days remaining in the rental month in which use ceases, medical necessity is presumed to continue.

(d) *Criteria for a new rental period.* If an interruption in the use of equipment continues for more than 60 consecutive days plus the days remaining in the rental month in which use ceases, a

new rental period begins if the supplier submits all of the following information—

(1) A new prescription.

(2) New medical necessity documentation.

(3) A statement describing the reason for the interruption and demonstrating that medical necessity in the prior episode ended.

(e) *Beneficiary moves.* A permanent or temporary move made by a beneficiary does not constitute an interruption in the period of continuous use.

(f) *New equipment.* (1) If a beneficiary changes equipment or requires additional equipment based on a physician's prescription, and the new or additional equipment is found to be necessary, a new period of continuous use begins for the new or additional equipment. A new period of continuous use does not begin for base equipment that is modified by an addition.

(2) A new period of continuous use does not begin when a beneficiary changes from one stationary oxygen equipment modality to another or from one portable oxygen equipment modality to another.

(g) *New supplier.* If a beneficiary changes suppliers, a new period of continuous use does not begin.

(h) *Oxygen equipment furnished after the 36-month rental period.* A new period of continuous use does not begin under any circumstance in the case of oxygen equipment furnished after the 36-month rental period in accordance with § 414.226(h) until the end of the reasonable useful lifetime established for such equipment in accordance with § 414.210(h).

[56 FR 50823, Oct. 9, 1991, as amended at 57 FR 57111, Dec. 3, 1992; 71 FR 65935, Nov. 9, 2006; 73 FR 69937, Nov. 19, 2008; 83 FR 57072, Nov. 14, 2018]

§ 414.232 Special payment rules for transcutaneous electrical nerve stimulators (TENS).

(a) *General payment rule.* Except as provided in paragraph (b) of this section, payment for TENS is made on a purchase basis with the purchase price determined using the methodology for purchase of inexpensive or routinely purchased items as described in § 414.220. The payment amount for TENS computed under § 414.220(c)(2) is reduced according to the following formula:

(1) Effective April 1, 1990—the original payment amount is reduced by 15 percent.

(2) Effective January 1, 1991—the reduced payment amount in paragraph (a)(1) is reduced by 15 percent.

(3) Effective January 1, 1994—the reduced payment amount in paragraph (a)(1) is reduced by 45 percent.

(b) *Exception.* In order to permit an attending physician time to determine whether the purchase of the TENS is medically appropriate for a particular patient, two months of rental payments may be made in addition to the purchase price. The rental payments are equal to 10 percent of the purchase price.

[57 FR 57692, Dec. 7, 1992, as amended at 60 FR 35498, July 10, 1995]

§ 414.234 Prior authorization for items frequently subject to unnecessary utilization.

(a) *Definitions.* For the purpose of this section, the following definitions apply:

Prior authorization is a process through which a request for provisional affirmation of coverage is submitted to CMS or its contractors for review before the item is furnished to the beneficiary and before the claim is submitted for processing.

Provisional affirmation is a preliminary finding that a future claim meets Medicare's coverage, coding, and payment rules.

Required Prior Authorization List is a list of DMEPOS items selected from the Master List and subject to the requirements of prior authorization as a condition of payment.

Unnecessary utilization means the furnishing of items that do not comply with one or more of Medicare's coverage, coding, and payment rules.

(b) *Master List of Items Potentially Subject to Face-To-Face Encounter and Written Order Prior to Delivery and/or Prior Authorization Requirements.*(1) Master List Inclusion Criteria are as follows:

(i) Any DMEPOS items included in the DMEPOS Fee Schedule that have

an average purchase fee of $500 (adjusted annually for inflation using consumer price index for all urban consumers (CPI–U), and reduced by the 10-year moving average of changes in annual economy-wide private nonfarm business multifactor productivity (MFP) (as projected by the Secretary for the 10-year period ending with the applicable FY, year, cost reporting period, or other annual period)) or greater, or an average monthly rental fee schedule of $50 (adjusted annually for inflation using consumer price index for all urban consumers (CPI–U), and reduced by the 10-year moving average of changes in annual economy-wide private nonfarm business multifactor productivity (MFP) (as projected by the Secretary for the 10-year period ending with the applicable FY, year, cost reporting period, or other annual period)) or greater, or are identified as accounting for at least 1.5 percent of Medicare expenditures for all DMEPOS items over a 12-month period that are:

(A) Identified as having a high rate of potential fraud or unnecessary utilization in an Office of Inspector General (OIG) or Government Accountability Office (GAO) report that is national in scope and published in 2015 or later, or

(B) Listed in the 2018 or later Comprehensive Error Rate Testing (CERT) Medicare Fee-for-Service (FFS) Supplemental Improper Payment Data report as having a high improper payment rate, or

(ii) The annual Master List updates shall include any items with at least 1,000 claims and 1 million dollars in payments during a recent 12-month period that are determined to have aberrant billing patterns and lack explanatory contributing factors (for example, new technology or coverage policies). Items with aberrant billing patterns would be identified as those items with payments during a 12-month timeframe that exceed payments made during the preceding 12-months, by the greater of:

(A) Double the percent change of all DMEPOS claim payments for items that meet the above claim and payment criteria, from the preceding 12-month period, or

(B) Exceeding a 30 percent increase in payment, or

(iii) Any item statutorily requiring a face-to-face encounter, a written order prior to delivery, or prior authorization.

(2) The Master List is self-updating at a minimum annually, and is published in the FEDERAL REGISTER.

(3) DMEPOS items identified as having a high rate of fraud or unnecessary utilization in any of the following reports that are national in scope and meeting the payment threshold criteria set forth in paragraph (b)(1) of this section are added to the Master List:

(i) OIG reports published after 2020.

(ii) GAO reports published after 2020.

(iii) Listed in the CERT Medicare FFS Supplemental Improper Payment Data report(s) published after 2020 as having a high improper payment rate.

(4) Items are removed from the Master List after 10 years from the date the item was added to the Master List, unless the item was identified in an OIG report, GAO report, or having been identified in the CERT Medicare FFS Supplemental Improper Payment Data report as having a high improper payment rate, within the 5-year period preceding the anticipated date of expiration.

(5) Items that are discontinued or are no longer covered by Medicare are removed from the Master List.

(6) An item is removed from the list if the cost drops below the payment threshold criteria set forth in paragraph (b)(1)(i) of this section.

(7) An item is removed from the Master List and replaced by its equivalent when the Healthcare Common Procedure Coding System (HCPCS) code representing the item has been discontinued and cross-walked to an equivalent item.

(c) *Condition of payment*—(1) *Items requiring prior authorization.* CMS publishes in the FEDERAL REGISTER and posts on the CMS Prior Authorization Web site a list of items, the Required Prior Authorization List, that require prior authorization as a condition of payment.

(i) The Required Prior Authorization List specified in paragraph (c)(1) of this section is selected from the Master List. CMS may consider factors such as geographic location, item utilization

or cost, system capabilities, emerging trends, vulnerabilities identified in official agency reports, or other analysis and may implement prior authorization nationally or locally.

(ii) CMS may elect to limit the prior authorization requirement to a particular region of the country if claims data analysis shows that unnecessary utilization of the selected item(s) is concentrated in a particular region. CMS may elect to exempt suppliers from prior authorization upon demonstration of compliance with Medicare coverage, coding, and payment rules through such prior authorization process.

(iii) The Required Prior Authorization List is effective no less than 60 days after publication and posting.

(2) *Denial of claims.* (i) CMS or its contractors denies a claim for an item that requires prior authorization if the claim has not received a provisional affirmation.

(ii) Claims receiving a provisional affirmation may be denied based on either of the following:

(A) Technical requirements that can only be evaluated after the claim has been submitted for formal processing.

(B) Information not available at the time of a prior authorization request.

(d) *Submission of prior authorization requests.* A prior authorization request must do the following:

(1) Include all relevant documentation necessary to show that the item meets applicable Medicare coverage, coding, and payment rules, including those outlined in § 410.38 and all of the following:

(i) Written order/prescription.

(ii) Relevant information from the beneficiary's medical record.

(iii) Relevant supplier produced documentation.

(2) Be submitted before the item is furnished to the beneficiary and before the claim is submitted for processing.

(e) *Review of prior authorization requests.* (1) After receipt of a prior authorization request, CMS or its contractor reviews the prior authorization request for compliance with applicable Medicare coverage, coding, and payment rules.

(2) If applicable Medicare coverage, coding, and payment rules are met, CMS or its contractor issues a provisional affirmation to the requester.

(3) If applicable Medicare coverage, coding, and payment rules are not met, CMS or its contractor issues a non-affirmation decision to the requester.

(4) If the requester receives a non-affirmation decision, the requester may resubmit a prior authorization request before the item is furnished to the beneficiary and before the claim is submitted for processing.

(5) A prior authorization request for an expedited review must include documentation that shows that processing a prior authorization request using a standard timeline for review could seriously jeopardize the life or health of the beneficiary or the beneficiary's ability to regain maximum function. If CMS or its contractor agrees that processing a prior authorization request using a standard timeline for review could seriously jeopardize the life or health of the beneficiary or the beneficiary's ability to regain maximum function, then CMS or its contractor expedites the review of the prior authorization request and communicates the decision following the receipt of all applicable Medicare required documentation.

(f) *Suspension of prior authorization requests.* (1) CMS may suspend prior authorization requirements generally or for a particular item or items at any time and without undertaking rulemaking.

(2) CMS provides notification of the suspension of the prior authorization requirements via—

(i) FEDERAL REGISTER notice; and

(ii) Posting on the CMS prior authorization Web site.

[80 FR 81706, Dec. 30, 2015, as amended at 84 FR 60807, Nov. 8, 2019]

§ 414.236 Continuity of pricing when HCPCS codes are divided or combined.

(a) *General rule.* If a new HCPCS code is added, CMS or contractors make every effort to determine whether the item and service has a fee schedule pricing history. If there is a fee schedule pricing history, the previous fee schedule amounts for the old code(s) are mapped to the new code(s) to ensure continuity of pricing.

(b) *Mapping fee schedule amounts based on different kinds of coding changes.* When the code for an item is divided into several codes for the components of that item, the total of the separate fee schedule amounts established for the components must not be higher than the fee schedule amount for the original item. When there is a single code that describes two or more distinct complete items (for example, two different but related or similar items), and separate codes are subsequently established for each item, the fee schedule amounts that applied to the single code continue to apply to each of the items described by the new codes. When the codes for the components of a single item are combined in a single global code, the fee schedule amounts for the new code are established by totaling the fee schedule amounts used for the components (that is, use the total of the fee schedule amounts for the components as the fee schedule amount for the global code). When the codes for several different items are combined into a single code, the fee schedule amounts for the new code are established using the average (arithmetic mean), weighted by allowed services, of the fee schedule amounts for the formerly separate codes.

[84 FR 60808, Nov. 8, 2019]

§ 414.238 Establishing fee schedule amounts for new HCPCS codes for items and services without a fee schedule pricing history.

(a) *General rule.* If a HCPCS code is new and describes items and services that do not have a fee schedule pricing history (classified and paid for previously under a different code), the fee schedule amounts for the new code are established based on the process described in paragraphs (b) or (c) of this section.

(b) *Comparability.* Fee schedule amounts for new HCPCS codes for items and services without a fee schedule pricing history are established using existing fee schedule amounts for comparable items when items with existing fee schedule amounts are determined to be comparable to the new items and services based on a comparison of: Physical components; mechanical components; electrical components; function and intended use; and additional attributes and features. If there are no items with existing fee schedule amounts that are comparable to the items and services under the new code, the fee schedule amounts for the new code are established in accordance with paragraph (c) of this section.

(c) *Use of supplier or commercial price lists.* (1) Fee schedule amounts for items and services without a fee schedule pricing history described by new HCPCS codes that are not comparable to items and services with existing fee schedule amounts may be established using supplier price lists, including catalogs and other retail price lists (such as internet retail prices) that provide information on commercial pricing for the item. Potential appropriate sources for such commercial pricing information can also include payments made by Medicare Advantage plans, as well as verifiable information from supplier invoices and non-Medicare payer data. If the only available price information is from a period other than the fee schedule base period, deflation factors are applied against current pricing in order to approximate the base period price.

(i) The annual deflation factors are specified in program instructions and are based on the percentage change in the consumer price index for all urban consumers (CPI–U) from the mid-point of the year the prices are in effect to the mid-point of the fee schedule base period, as calculated using the following formula: ((base CPI–U minus current CPI–U) divided by current CPI–U) plus one.

(ii) The deflated amounts are then increased by the update factors specified in section 1834(a)(14) of the Act for DME, section 1834(h)(4) of the Act for prosthetic devices, prosthetics, orthotics, and therapeutic shoes and inserts, and section 1834(i)(1)(B) of the Act for surgical dressings.

(2) If within 5 years of establishing fee schedule amounts using supplier or commercial prices, the prices decrease by less than 15 percent, a one-time adjustment to the fee schedule amounts is made using the new prices. The new prices would be used to establish the new fee schedule amounts in the same

way that the older prices were used, including application of the deflation formula in paragraph (c)(1) of this section.

[84 FR 60808, Nov. 8, 2019]

§ 414.240 Procedures for making benefit category determinations and payment determinations for new durable medical equipment, prosthetic devices, orthotics and prosthetics, surgical dressings, and therapeutic shoes and inserts.

(a) *Definitions.* For the purpose of this subpart—

Benefit category determination means a national determination regarding whether an item or service meets the Medicare definition of durable medical equipment at section 1861(n) of the Act, a prosthetic device at section 1861(s)(8) of the Act and further defined under section 1834(h)(4) of the Act, an orthotic or leg, arm, back or neck brace, a prosthetic or artificial leg, arm or eye at section 1861(s)(9) of the Act, is a surgical dressing, or is a therapeutic shoe or insert subject to sections 1834(a), (h), or (i) of the Act and the rules of this subpart and is not otherwise excluded from coverage by statute.

(b) *General rule.* The procedures for determining whether new items and services addressed in a request for a HCPCS Level II code(s) or by other means meet the definition of items and services paid for in accordance with this subpart are as follows:

(1) At the start of a HCPCS coding cycle, CMS performs an analysis to determine if the item or service is statutorily excluded from coverage under Medicare under section 1862 of the Act, and, if not excluded by statute, whether the item or service is durable medical equipment, a prosthetic device as further defined under section 1834(h)(4) of the Act, an orthotic or prosthetic, a surgical dressing, or a therapeutic shoe or insert.

(2) If a preliminary determination is made that the item or service is durable medical equipment, a prosthetic device, an orthotic or prosthetic, a surgical dressing, or a therapeutic shoe or insert, CMS makes a preliminary payment determination for the item or service.

(3) CMS posts preliminary benefit category determinations and payment determinations on *CMS.gov* approximately 2 weeks prior to a public meeting.

(4) After consideration of public consultation provided at a public meeting on preliminary benefit category determinations and payment determinations for items and services, CMS establishes the benefit category determinations and payment determinations for items and services through program instructions.

[86 FR 73911, Dec. 28, 2021]

Subpart E—Determination of Reasonable Charges Under the ESRD Program

§ 414.300 Scope of subpart.

This subpart sets forth criteria and procedures for payment of the following services furnished to ESRD patients:

(a) Physician services related to renal dialysis.

(b) Physician services related to renal transplantation.

(c) Home dialysis equipment, supplies, and support services.

(d) Epoetin (EPO) furnished by a supplier of home dialysis equipment and supplies to a home dialysis patient for use in the home.

[55 FR 23441, June 8, 1990, as amended at 56 FR 43710, Sept. 4, 1991; 59 FR 1285, Jan. 10, 1994]

§ 414.310 Determination of reasonable charges for physician services furnished to renal dialysis patients.

(a) *Principle.* Physician services furnished to renal dialysis patients are subject to payment if the services are otherwise covered by the Medicare program and if they are considered reasonable and medically necessary in accordance with section 1862(a)(1)(A) of the Act.

(b) *Scope and applicability*—(1) *Scope.* This section pertains to physician services furnished to the following patients:

(i) Outpatient maintenance dialysis patients who dialyze—

(A) In an independent or hospital-based ESRD facility, or

(B) At home.

(ii) Hospital inpatients for which the physician elects to continue payment under the monthly capitation payment (MCP) method described in § 414.314.

(2) *Applicability.* These provisions apply to routine professional services of physicians. They do not apply to administrative services performed by physicians, which are paid for as part of a prospective payment for dialysis services made to the facility under § 413.170 of this chapter.

(c) *Definitions.* For purposes of this section, the following definitions apply:

Administrative services are physician services that are differentiated from routine professional services and other physician services because they are supervision, as described in the definition of ''supervision of staff'' of this section, or are not related directly to the care of an individual patient, but are supportive of the facility as a whole and of benefit to patients in general. Examples of administrative services include supervision of staff, staff training, participation in staff conferences and in the management of the facility, and advising staff on the procurement of supplies.

Dialysis session is the period of time that begins when the patient arrives at the facility and ends when the patient departs from the facility. In the case of home dialysis, the period begins when the patient prepares for dialysis and generally ends when the patient is disconnected from the machine. In this context, a dialysis facility includes only those parts of the building used as a facility. It does not include any areas used as a physician's office.

Medical direction, in contrast to supervision of staff, is a routine professional service that entails substantial direct involvement and the physical presence of the physician in the delivery of services directly to the patient.

Routine professional services include all physicians' services furnished during a dialysis session and all services listed in paragraph (d) of this section that meet the following requirements:

(1) They are personally furnished by a physician to an individual patient.

(2) They contribute directly to the diagnosis or treatment of an individual patient.

(3) They ordinarily must be performed by a physician.

Supervision of staff, in contrast to medical direction, is an administrative service that does not necessarily require the physician to be present at the dialysis session. It is a general activity primarily concerned with monitoring performance of and giving guidance to other health care personnel (such as nurses and dialysis technicians) who deliver services to patients.

(d) *Types of routine professional services.* Routine professional services include at least all of the following services when medically appropriate:

(1) Visits to the patient during dialysis, and review of laboratory test results, nurses' notes and any other medical documentation, as a basis for—

(i) Adjustment of the patient's medication or diet, or the dialysis procedure;

(ii) Prescription of medical supplies; and

(iii) Evaluation of the patient's psychosocial status and the appropriateness of the treatment modality.

(2) Medical direction of staff in delivering services to a patient during a dialysis session.

(3) Pre-dialysis and post-dialysis examinations, or examinations that could have been furnished on a pre-dialysis or post-dialysis basis.

(4) Insertion of catheters for patients who are on peritoneal dialysis and do not have indwelling catheters.

(e) *Payment for routine professional services.* Beginning August 7, 1990, routine professional services furnished by physicians may be paid under either the ''initial method'' of payment described in § 414.313, (if all of the physicians at the facility elect the initial method) or under the ''physician MCP method'' described in § 414.314. Physician services furnished after July 31, 1983 and before August 6, 1990, are payable only under the MCP method described in § 414.314.

§ 414.313 Initial method of payment.

(a) *Basic rule.* Under this method, the intermediary pays the facility for routine professional services furnished by

physicians. Payment is in the form of an add-on to the facility's composite rate payment, which is described in part 413, subpart H of this subchapter.

(b) *Services for which payment is not included in the add-on payment.* (1) Physician administrative services are considered to be facility services and are paid for as part of the facility's composite rate.

(2) The carrier pays the physician or the beneficiary (as appropriate) under the reasonable charge criteria set forth in subpart E of part 405 of this chapter for the following services:

(i) Physician services that must be furnished at a time other than during the dialysis session (excluding pre-dialysis and post-dialysis examinations and examinations that could have been furnished on a pre-dialysis or post-dialysis basis), such as monthly and semi-annual examinations to review health status and treatment.

(ii) Physician surgical services other than insertion of catheters for patients who are on peritoneal dialysis and do not have indwelling catheters.

(iii) Physician services furnished to hospital inpatients who were not admitted solely to receive maintenance dialysis.

(iv) Administration of hepatitis B vaccine.

(c) *Physician election of the initial method.* (1) Each physician in a facility must submit to the appropriate carrier and intermediary that serve the facility a statement of election of the initial method of payment for all the ESRD facility patients that he or she attends.

(2) The initial method of payment applies to dialysis services furnished beginning with the second calendar month after the month in which all physicians in the facility elect the initial method and continues until the effective date of a termination of the election described in paragraph (d) of this section.

(d) *Termination of the initial method.* (1) Physicians may terminate the initial method of payment by written notice to the carrier(s) that serves each physician and to the intermediary that serves the facility.

(2) If the notice terminating the initial method is received by the carrier(s) and intermediary—

(i) On or before November 1, the effective date of the termination is January 1 of the year following the calendar year in which the termination notice is received by the carrier(s) and intermediary; or

(ii) After November 1, the effective date of the termination is January 1 of the second year after the calendar year in which the notice is received by the carrier(s) and intermediary.

(e) *Determination of payment amount.* The factors used in determining the add-on amount are related to program experience. They are re-evaluated periodically and may be adjusted, as determined necessary by CMS, to maintain the payment at a level commensurate with the prevailing charges of other physicians for comparable services.

(f) *Publication of payment amount.* Revisions to the add-on amounts are published in the FEDERAL REGISTER in accordance with the Department's established rulemaking procedures.

[55 FR 23441, June 8, 1990, as amended at 62 FR 43674, Aug. 15, 1997]

§414.314 Monthly capitation payment method.

(a) *Basic rules.* (1) Under the monthly capitation payment (MCP) method, the carrier pays an MCP amount for each patient, to cover all professional services furnished by the physician, except those listed in paragraph (b) of this section.

(2) The carrier pays the MCP amount, subject to the deductible and coinsurance provisions, either to the physician if the physician accepts assignment or to the beneficiary if the physician does not accept assignment.

(3) The MCP method recognizes the need of maintenance dialysis patients for physician services furnished periodically over relatively long periods of time, and the capitation amounts are consistent with physicians' charging patterns in their localities.

(4) Payment of the capitation amount for any particular month is contingent upon the physician furnishing to the patient all physician services required by the patient during

the month, except those listed in paragraph (b) of this section.

(5) Payment for physician administrative services (§ 414.310) is made to the dialysis facility as part of the facility's composite rate (part 413, subpart H of this subchapter) and not to the physician under the MCP.

(b) *Services not included in the MCP.* (1) Services that are not included in the MCP and which may be paid in accordance with the reasonable charge rules set forth in subpart E of part 405 of this chapter are limited to the following:

(i) Administration of hepatitis B vaccine.

(ii) Covered physician services furnished by another physician when the patient is not available to receive, or the attending physician is not available to furnish, the outpatient services as usual (see paragraph (b)(3) of this section).

(iii) Covered physician services furnished to hospital inpatients, including services related to inpatient dialysis, by a physician who elects not to continue to receive the MCP during the period of inpatient stay.

(iv) Surgical services, including declotting of shunts, other than the insertion of catheters for patients on maintenance peritoneal dialysis who do not have indwelling catheters.

(v) Needed physician services that are—

(A) Furnished by the physician furnishing renal care or by another physician;

(B) Not related to the treatment of the patient's renal condition; and

(C) Not furnished during a dialysis session or an office visit required because of the patient's renal condition.

(2) For the services described in paragraph (b)(1)(v) of this section, the following rules apply:

(i) The physician must provide documentation to show that the services are not related to the treatment of the patient's renal condition and that additional visits are required.

(ii) The carrier's medical staff, acting on the basis of the documentation and appropriate medical consultation obtained by the carrier, determines whether additional payment for the additional services is warranted.

(3) The MCP is reduced in proportion to the number of days the patient is—

(i) Hospitalized and the physician elects to bill separately for services furnished during hospitalization; or

(ii) Not attended by the physician or his or her substitute for any reason, including when the physician is not available to furnish patient care or when the patient is not available to receive care.

(c) *Determination of payment amount.* The amount of payment for the MCP is determined under the Medicare physician fee schedule described in this part 414.

[55 FR 23441, June 8, 1990, as amended at 59 FR 63463, Dec. 8, 1994; 62 FR 43674, Aug. 15, 1997]

§ 414.316 Payment for physician services to patients in training for self-dialysis and home dialysis.

(a) For each patient, the carrier pays a flat amount that covers all physician services required to create the capacity for self-dialysis and home dialysis.

(b) CMS determines the amount on the basis of program experience and reviews it periodically.

(c) The payment is made at the end of the training course, is subject to the deductible and coinsurance provisions, and is in addition to any amounts payable under the initial or MCP methods set forth in §§ 414.313 and 414.314, respectively.

(d) If the training is not completed, the payment amount is proportionate to the time spent in training.

§ 414.320 Determination of reasonable charges for physician renal transplantation services.

(a) *Comprehensive payment for services furnished during a 60-day period.* (1) The comprehensive payment is subject to the deductible and coinsurance provisions and is for all surgeon services furnished during a period of 60 days in connection with a renal transplantation, including the usual preoperative and postoperative care, and for immunosuppressant therapy if supervised by the transplant surgeon.

(2) Additional sums, in amounts established on the basis of program experience, may be included in the comprehensive payment for other surgery

performed concurrently with the transplant operation.

(3) The amount of the comprehensive payment may not exceed the lower of the following:

(i) The actual charges made for the services.

(ii) Overall national payment levels established under the ESRD program and adjusted to give effect to variations in physician's charges throughout the nation. (These adjusted amounts are the maximum allowances in a carrier's service area for renal transplantation surgery and related services by surgeons.)

(4) Maximum allowances computed under these instructions are revised at the beginning of each calendar year to the extent permitted by the lesser of the following:

(i) Changes in the economic index as described in §405.504(a)(3)(i) of this chapter.

(ii) Percentage changes in the weighted average of the carrier's prevailing charges (before adjustment by the economic index) for—

(A) A unilateral nephrectomy; or

(B) Another medical or surgical service designated by CMS for this purpose.

(b) *Other payments.* Payments for covered medical services furnished to the transplant beneficiary by other specialists, as well as for services by the transplant surgeon after the 60-day period covered by the comprehensive payment, are made under the reasonable charge criteria set forth in §405.502 (a) through (d) of this chapter. The payments for physicians' services in connection with renal transplantations are changed on the basis of program experience and the expected advances in the medical art for this operation.

§414.330 Payment for home dialysis equipment, supplies, and support services.

(a) *Equipment and supplies*—(1) *Basic rule.* Except as provided in paragraph (a)(2) of this section, Medicare pays for home dialysis equipment and supplies only under the prospective payment rates established at §413.210.

(2) *Exception for equipment and supplies furnished prior to January 1, 2011.* If the conditions in subparagraphs (a)(2)(i) through (iv) of this section are met, Medicare pays for home analysis equipment and supplies on a reasonable charge basis in accordance with subpart E (Criteria for Determination of Reasonable Charges; Reimbursement for Services of Hospital Interns, Residents, and Supervising Physicians) of part 405, but the amount of payment may not exceed the limit for equipment and supplies in paragraph (c)(2) of this section.

(i) The patient elects to obtain home dialysis equipment and supplies from a supplier that is not a Medicare approved dialysis facility.

(ii) The patient certifies to CMS that he or she has only one supplier for all home dialysis equipment and supplies. This certification is made on CMS Form 382 (the ''ESRD Beneficiary Selection'' form).

(iii) In writing, the supplier—

(A) Agrees to receive Medicare payment for home dialysis supplies and equipment only on an assignment-related basis; and

(B) Certifies to CMS that it has a written agreement with one Medicare approved dialysis facility or, if the beneficiary is also entitled to military or veteran's benefits, one military or Veterans Administration hospital, for each patient. (See part 494 of this chapter for the requirements for a Medicare approved dialysis facility.) Under the agreement, the facility or military or VA hospital agrees to the following:

(*1*) To furnish all home dialysis support services for each patient in accordance with part 494 (Conditions for Coverage for End-Stage Renal Disease Facilities) of this chapter. (§410.52 sets forth the scope and conditions of Medicare Part B coverage of home dialysis services, supplies, and equipment.)

(*2*) To furnish institutional dialysis services and supplies. (§410.50 sets forth the scope and conditions for Medicare Part B coverage of institutional dialysis services and supplies.)

(*3*) To furnish dialysis-related emergency services.

(*4*) To arrange for a Medicare approved laboratory to perform dialysis-related laboratory tests that are covered under the composite rate established at §413.170 and to arrange for the laboratory to seek payment from the facility. The facility then includes

these laboratory services in its claim for payment for home dialysis support services.

(*5*) To arrange for a Medicare approved laboratory to perform dialysis-related laboratory tests that are not covered under the composite rate established at § 413.170 and for which the laboratory files a Medicare claim directly.

(*6*) To furnish all other necessary dialysis services and supplies (that is, those which are not home dialysis equipment and supplies).

(*7*) To satisfy all documentation, recordkeeping and reporting requirements in part 494 (Conditions for Coverage for End-Stage Renal Disease Facilities) of this chapter. This includes maintaining a complete medical record of ESRD related items and services furnished by other parties. The facility must report, on the forms required by CMS or the ESRD network, all data for each patient in accordance with subpart U.

(iv) The facility with which the agreement is made must be located within a reasonable distance from the patient's home (that is, located so that the facility can actually furnish the needed services in a practical and timely manner, taking into account variables like the terrain, whether the patient's home is located in an urban or rural area, the availability of transportation, and the usual distances traveled by patients in the area to obtain health care services).

(C) Agrees to report to the ESRD facility providing support services, at least every 45 days, all data (meaning information showing what supplies and services were provided to the patient and when each was provided) for each patient regarding services and items furnished to the patient in accordance with § 494.100(c)(2) of this chapter.

(b) *Support services*—(1) *Basic rule.* Except as provided in paragraph (b)(2) of this section, Medicare pays for support services only under the prospective payment rates established in § 413.210 of this chapter.

(2) *Exception for home support services furnished prior to January 1, 2011.* If the patient elects to obtain home dialysis equipment and supplies from a supplier that is not an approved ESRD facility, Medicare pays for support services, other than support services furnished by military or VA hospitals referred to in paragraph (a)(2)(iii)(B) of this section, under paragraphs (b)(2) (i) and (ii) of this section but in no case may the amount of payment exceed the limit for support services in paragraph (c)(1) of this section:

(i) For support services furnished by a hospital-based ESRD facility, Medicare pays on a reasonable cost basis in accordance with part 413 of this chapter.

(ii) For support services furnished by an independent ESRD facility, Medicare pays on the basis of reasonable charges that are related to costs and allowances that are reasonable when the services are furnished in an effective and economical manner.

(c) Payment limits for support services, equipment and supplies, and notification of changes to the payment limits apply prior to January 1, 2011 as follows:

(1) *Support services.* The amount of payment for home dialysis support services is limited to the national average Medicare-allowed charge per patient per month for home dialysis support services, as determined by CMS, plus the median cost per treatment for all dialysis facilities for laboratory tests included under the composite rate, as determined by CMS, multiplied by the national average number of treatments per month.

(2) *Equipment and supplies.* Payment for home dialysis equipment and supplies is limited to an amount equal to the result obtained by subtracting the support services payment limit in paragraph (c)(1) of this section from the amount (or, in the case of continuous cycling peritoneal dialysis, 130 percent) of the national median payment as determined by CMS that would have been made under the prospective payment rates established in § 413.170 of this chapter for hospital-based facilities.

(3) *Notification of changes to the payment limits.* Updated data are incorporated into the payment limits when the prospective payment rates established at § 413.170 of this chapter are updated, and changes are announced by notice in the FEDERAL REGISTER without a public comment period. Revisions of the methodology for determining the

limits are published in the FEDERAL REGISTER in accordance with the Department's established rulemaking procedures.

[57 FR 54187, Nov. 17, 1992, as amended at 73 FR 20474, Apr. 15, 2008; 75 FR 49202, Aug. 12, 2010]

§ 414.335 Payment for EPO furnished to a home dialysis patient for use in the home.

(a) Prior to January 1, 2011, payment for EPO used at home by a home dialysis patient is made only to either a Medicare approved ESRD facility or a supplier of home dialysis equipment and supplies. Effective January 1, 2011, payment for EPO used at home by a home dialysis patient is made only to a Medicare-approved ESRD facility in accordance with the per treatment payment as defined in § 413.230.

(b) After January 1, 2011, a home and self training amount is added to the per treatment base rate for adult and pediatric patients as defined in § 413.230

[75 FR 49202, Aug. 12, 2010]

Subpart F—Competitive Bidding for Certain Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS)

§ 414.400 Purpose and basis.

This subpart implements competitive bidding programs for certain DMEPOS items as required by sections 1847(a) and (b) of the Act.

[72 FR 18084, Apr. 10, 2007]

§ 414.402 Definitions.

For purposes of this subpart, the following definitions apply:

Affected party means a contract supplier that has been notified that their DMEPOS CBP contract will be terminated for a breach of contract.

Bid means an offer to furnish an item or items for a particular price and time period that includes, where appropriate, any services that are directly related to the furnishing of the item or items.

Bidding entity means the entity whose legal business name is identified in the ''Form A: Business Organization Information'' section of the bid.

Breach of contract means any deviation from contract requirements, including a failure to comply with a governmental agency or licensing organization requirements, constitutes a breach of contract.

Competitive bidding area (CBA) means an area established by the Secretary under this subpart.

Competitive bidding program means a program established under this subpart within a designated CBA.

Composite bid means the bid submitted by the supplier for the lead item in the product category.

Contract supplier means an entity that is awarded a contract by CMS to furnish items under a competitive bidding program.

Corrective action plan (CAP) means a contract supplier's written document with supporting information that describes the actions the contract supplier will take within a specified timeframe to remedy a breach of contract.

Covered document means a financial, tax, or other document required to be submitted by a bidder as part of an original bid submission under a competitive acquisition program in order to meet the required financial standards.

Covered document review date means the later of—

(1) The date that is 30 days before the final date for the closing of the bid window; or

(2) The date that is 30 days after the opening of the bid window.

DMEPOS stands for durable medical equipment, prosthetics, orthotics, and supplies.

Grandfathered item means all rented items within a product category for which payment was made prior to the implementation of a competitive bidding program to a grandfathered supplier that chooses to continue to furnish the items in accordance with § 414.408(j) of this subpart and that fall within the following payment categories for competitive bidding:

(1) An inexpensive or routinely purchased item described in § 414.220 of this part.

(2) An item requiring frequent and substantial servicing, as described in § 414.222 of this part.

(3) Oxygen and oxygen equipment described in § 414.226 of this part.

(4) Other DME described in § 414.229 of this part.

Grandfathered supplier means a noncontract supplier that chooses to continue to furnish grandfathered items to a beneficiary in a CBA.

Hearing officer means an individual, who was not involved with the CBIC recommendation to take action for a breach of a DMEPOS Competitive Bidding Program contract, who is designated by CMS to review and make an unbiased and independent recommendation when there is an appeal of CMS's initial determination to take action for a breach of a DMEPOS Competitive Bidding Program contract.

Hospital has the same meaning as in section 1861(e) of the Act.

Item means a product included in a competitive bidding program that is identified by a HCPCS code, which may be specified for competitive bidding (for example, a product when it is furnished through mail order), or a combination of codes with or without modifiers, and includes the services directly related to the furnishing of that product to the beneficiary. Items that may be included in a competitive bidding program are as follows:

(1) DME other than class III devices under the Federal Food, Drug and Cosmetic Act, as defined in § 414.402, group 3 complex rehabilitative power wheelchairs, complex rehabilitative manual wheelchairs, manual wheelchairs described by HCPCS codes E1235, E1236, E1237, E1238, and K0008, and related accessories when furnished in connection with such wheelchairs, and further classified into the following categories:

(i) Inexpensive or routinely purchased items, as specified in § 414.220(a).

(ii) Items requiring frequent and substantial servicing, as specified in § 414.222(a).

(iii) Oxygen and oxygen equipment, as specified in § 414.226(c)(1).

(iv) Other DME (capped rental items), as specified in § 414.229.

(2) Supplies necessary for the effective use of DME other than inhalation and infusion drugs.

(3) Enteral nutrients, equipment, and supplies.

(4) Off-the-shelf orthotics, which are orthotics described in section 1861(s)(9) of the Act that require minimal self-adjustment for appropriate use and do not require expertise in trimming, bending, molding, assembling or customizing to fit a beneficiary.

(5) Lymphedema compression treatment items.

Item weight is a number assigned to an item based on its beneficiary utilization rate using national data when compared to other items in the same product category.

Lead item is the item in a product category with multiple items with the highest total nationwide Medicare allowed charges of any item in the product category prior to each competition.

Mail order contract supplier is a contract supplier that furnishes items through the mail to beneficiaries who maintain a permanent residence in a competitive bidding area.

Mail order item means any item (for example, diabetic testing supplies) shipped or delivered to the beneficiary's home, regardless of the method of delivery.

Metropolitan Statistical Area (MSA) has the same meaning as that given by the Office of Management and Budget.

Minimal self-adjustment means an adjustment that the beneficiary, caretaker for the beneficiary, or supplier of the device can perform and does not require the services of a certified orthotist (that is, an individual certified by either the American Board for Certification in Orthotics and Prosthetics, Inc., or the Board for Orthotist/Prosthetist Certification) or an individual who has specialized training.

National mail order DMEPOS competitive bidding program means a program whereby contracts are awarded to suppliers for the furnishing of mail order items across the nation.

Nationwide competitive bidding area means a CBA that includes the United States, its Territories, and the District of Columbia.

Nationwide mail order contract supplier means a mail order contract supplier that furnishes items in a nationwide competitive bidding area.

Network means a group of small suppliers that form a legal entity to provide competitively bid items throughout the entire CBA.

Noncontract supplier means a supplier that is not awarded a contract by CMS to furnish items included in a competitive bidding program.

Non-mail order item means any item (for example, diabetic testing supplies) that a beneficiary or caregiver picks up in person at a local pharmacy or supplier storefront.

Parties to the hearing means the DMEPOS contract supplier and CMS.

Physician has the same meaning as in section 1861(r) of the Act.

Pivotal bid means the lowest composite bid based on bids submitted by suppliers for a product category that includes a sufficient number of suppliers to meet beneficiary demand for the items in that product category.

Price inversion means any situation where the following occurs: One item (HCPCS code) in a grouping of similar items (*e.g.*, walkers, enteral infusion pumps, or power wheelchairs) in a product category includes a feature that another, similar item in the same product category does not have (*e.g.*, wheels, alarm, or Group 2 performance); the average of the 2015 fee schedule amounts (or initial, unadjusted fee schedule amounts for subsequent years for new items) for the code with the feature is higher than the average of the 2015 fee schedule amounts for the code without the feature; and, following a competition, the SPA for the code with the feature is lower than the SPA for the code without that feature.

Product category means a grouping of related items that are used to treat a similar medical condition.

Regional competitive bidding area means a CBA that consists of a region of the United States, its Territories, and the District of Columbia.

Regional mail order contract supplier means a mail order contract supplier that furnishes items in a regional competitive bidding area.

Single payment amount means the allowed payment for an item furnished under a competitive bidding program.

Small supplier means, a supplier that generates gross revenue of $3.5 million or less in annual receipts including Medicare and non-Medicare revenue.

Supplier means an entity with a valid Medicare supplier number, including an entity that furnishes an item through the mail.

Total nationwide allowed services means the total number of services allowed for an item furnished in all states, territories, and the District of Columbia where Medicare beneficiaries reside and can receive covered DMEPOS items and services.

Treating practitioner means a physician assistant, nurse practitioner, or clinical nurse specialist, as those terms are defined in section 1861(aa)(5) of the Act.

Weighted bid means the item weight multiplied by the bid price submitted for that item.

[72 FR 18084, Apr. 10, 2007, as amended at 74 FR 2880, Jan. 16, 2009; 74 FR 62009, Nov. 25, 2009; 75 FR 73622, Nov. 29, 2010; 76 FR 70314, Nov. 10, 2011; 81 FR 77966, Nov. 4, 2016; 83 FR 21925, May 11, 2018; 83 FR 57072, Nov. 14, 2018; 86 FR 42422, Aug. 4, 2021; 88 FR 77875, Nov. 13, 2023]

§ 414.404 Scope and applicability.

(a) *Applicability.* Except as specified in paragraph (b) of this section, this subpart applies to all suppliers that furnish the items defined in § 414.402 to beneficiaries, including providers, physicians, treating practitioners, physical therapists, and occupational therapists that furnish such items under Medicare Part B.

(b) *Exceptions.* (1) Physicians, treating practitioners, and hospitals may furnish certain types of competitively bid durable medical equipment without submitting a bid and being awarded a contract under this subpart, provided that all of the following conditions are satisfied:

(i) The items furnished are limited to crutches, canes, walkers, folding manual wheelchairs, blood glucose monitors, and infusion pumps that are DME, and off-the-shelf (OTS) orthotics.

(ii) The items are furnished by the physician or treating practitioner to his or her own patients as part of his or her professional service or by a hospital to its own patients during an admission or on the date of discharge.

(iii) The items are billed under a billing number assigned to the hospital, physician, the treating practitioner (if possible), or a group practice to which the physician or treating practitioner has reassigned the right to receive Medicare payment.

(2) A physical therapist in private practice (as defined in § 410.60(c) of this chapter) or an occupational therapist in private practice (as defined in § 410.59(c) of this chapter) may furnish competitively bid off-the-shelf orthotics without submitting a bid and being awarded a contract under this subpart, provided that the items are furnished only to the therapist's own patients as part of the physical or occupational therapy service.

(3) Payment for items furnished in accordance with paragraphs (b)(1) and (b)(2) of this section will be paid in accordance with § 414.408(a).

[72 FR 18084, Apr. 10, 2007, as amended at 74 FR 2880, Jan. 16, 2009; 75 FR 73623, Nov. 29, 2010; 76 FR 70314, Nov. 10, 2011]

§ 414.406 Implementation of programs.

(a) *Implementation contractor.* CMS designates one or more implementation contractors for the purpose of implementing this subpart.

(b) *Competitive bidding areas.* CMS designates through program instructions or by other means, such as the request for bids, each CBA in which a competitive bidding program may be implemented under this subpart.

(c) *Revisions to competitive bidding areas.* CMS may revise the CBAs designated under paragraph (b) of this section.

(d) *Competitively bid items.* CMS designates the items that are included in a competitive bidding program through program instructions or by other means

(e) *Claims processing.* The Durable Medical Equipment Medicare Administrative Contractor designated to process DMEPOS claims for a particular geographic region also processes claims for items furnished under a competitive bidding program in the same geographic region.

[71 FR 48409, Aug. 18, 2006, as amended at 72 FR 18085, Apr. 10, 2007]

§ 414.408 Payment rules.

(a) *Payment basis.* (1) The payment basis for an item furnished under a competitive bidding program is 80 percent of the single payment amount calculated for the item under § 414.416 for the CBA in which the beneficiary maintains a permanent residence.

(2) If an item that is included in a competitive bidding program is furnished to a beneficiary who does not maintain a permanent residence in a CBA, the payment basis for the item is 80 percent of the lesser of the actual charge for the item, or the applicable fee schedule amount for the item, as determined under subpart C or subpart D.

(b) *No changes to the single payment amount.* The single payment amount calculated for each item under each competitive bidding program is paid for the duration of the competitive bidding program and will not be adjusted by any update factor.

(c) *Payment on an assignment-related basis.* Payment for an item furnished under this subpart is made on an assignment-related basis.

(d) *Applicability of advanced beneficiary notice.* Implementation of a program in accordance with this subpart does not preclude the use of an advanced beneficiary notice.

(e) *Requirement to obtain competitively bid items from a contract supplier.* (1) *General rule.* Except as provided in paragraph (e)(2) of this section, all items that are included in a competitive bidding program must be furnished by a contract supplier for that program.

(2) *Exceptions.* (i) A grandfathered supplier may furnish a grandfathered item to a beneficiary in accordance with paragraph (j) of this section.

(ii) Medicare may make a secondary payment for an item furnished by a noncontract supplier that the beneficiary is required to use under his or her primary insurance policy. The provisions of this paragraph do not supersede Medicare secondary payer statutory and regulatory provisions, including the Medicare secondary payment rules located in §§ 411.32 and 411.33 of this subchapter, and payment will be calculated in accordance with those rules.

(iii) If a beneficiary is outside of the CBA in which he or she maintains a permanent residence, he or she may obtain an item from a—

(A) Contract supplier, if the beneficiary obtains the item in another CBA and the item is included in the competitive bidding program for that CBA; or

(B) Supplier with a valid Medicare billing number, if the beneficiary obtains the item in an area that is not a CBA, or if the beneficiary obtains the item in another CBA but the item is not included in the competitive bidding program for that CBA.

(iv) A physician, treating practitioner, physical therapist in private practice, occupational therapist in private practice, or hospital may furnish an item in accordance with §414.404(b) of this subpart.

(3) Unless paragraph (e)(2) of this section applies:

(i) Medicare will not make payment for an item furnished in violation of paragraph (e)(1) of this section, and

(ii) A beneficiary has no financial liability to a noncontract supplier that furnishes an item included in the competitive bidding program for a CBA in violation of paragraph (e)(1) of this section, unless the beneficiary has signed an advanced beneficiary notice.

(4) CMS separately designates the Medicare billing number of all noncontract suppliers to monitor compliance with paragraphs (e)(1) and (e)(2) of this section.

(f) *Purchased equipment.* (1) The single payment amounts for new purchased durable medical equipment, including power wheelchairs that are purchased when the equipment is initially furnished and enteral nutrition equipment are calculated based on the bids submitted and accepted for these items. For contracts entered into beginning on or after January 1, 2011, payment on a lump sum purchase basis is only available for power wheelchairs classified as complex rehabilitative power wheelchairs.

(2) Payment for used purchased durable medical equipment and enteral nutrition equipment is made in an amount equal to 75 percent of the single payment amounts calculated for new purchased equipment under paragraph (f)(1) of this section.

(g) *Purchased supplies and orthotics.* The single payment amounts for the following purchased items are calculated based on the bids submitted and accepted for the following items:

(1) Supplies used in conjunction with durable medical equipment.

(2) Enteral nutrients.

(3) Enteral nutrition supplies.

(4) OTS orthotics.

(5) Lymphedema compression treatment items.

(h) *Rented equipment*—(1) *Capped rental DME.* Subject to the provisions of paragraph (h)(2) of this section, payment for capped rental durable medical equipment is made in an amount equal to 10 percent of the single payment amounts calculated for new durable medical equipment under paragraph (f)(1) of this section for each of the first 3 months, and 7.5 percent of the single payment amounts calculated for these items for each of the remaining months 4 through 13.

(2) For contracts entered into beginning on or after January 1, 2011, the monthly fee schedule amount for rental of power wheelchairs equals 15 percent of the single payment amounts calculated for new durable medical equipment under paragraph (f)(1) of this section for each of the first 3 months, and 6 percent of the single payment amounts calculated for these items for each of the remaining months 4 through 13.

(3) *Additional payment to certain contract suppliers for capped rental DME.* (i) Except as specified in paragraph (h)(3)(ii) of this section, Medicare makes 13 monthly payments to a contract supplier that furnishes capped rental durable medical equipment to a beneficiary who would otherwise be entitled to obtain the item from a grandfathered supplier under paragraph (j) of this section. Payment is made using the methodology described in paragraph (h)(1) of this section. The contract supplier must transfer title to the item to the beneficiary on the first day that begins after the 13th continuous month in which payments are made in accordance with this paragraph.

(ii) Medicare does not make payment to a contract supplier under paragraph (h)(3)(i) of this section if the contract supplier furnishes capped rental durable medical equipment to a beneficiary who previously rented the equipment from another contract supplier.

(4) *Maintenance and servicing of rented DME.* Separate maintenance and servicing payments are not made for any rented durable medical equipment.

(5) *Payment for rented enteral nutrition equipment.* Payment for rented enteral nutrition equipment is made in an amount equal to 10 percent of the single payment amounts calculated for new enteral nutrition equipment under paragraph (f)(1) of this section for each of the first 3 months, and 7.5 percent of the single payment amount calculated for these items under paragraph (f)(1) of this section for each of the remaining months 4 through 15. The contract supplier to which payment is made in month 15 for furnishing enteral nutrition equipment on a rental basis must continue to furnish, maintain and service the equipment until a determination is made by the beneficiary's physician or treating practitioner that the equipment is no longer medically necessary.

(6) *Maintenance and servicing of rented enteral nutrition equipment.* Payment for the maintenance and servicing of rented enteral nutrition equipment beginning 6 months after 15 months of rental payments is made in an amount equal to 5 percent of the single payment amounts calculated for these items under paragraph (f)(1) of this section.

(7) *Payment for inexpensive or routinely purchased durable medical equipment.* Payment for inexpensive or routinely purchased durable medical equipment furnished on a rental basis is made in an amount equal to 10 percent of the single payment amount calculated for new purchased equipment.

(8) *Payment amounts for rented DME requiring frequent and substantial servicing*—(i) *General rule.* Except as provided in paragraph (h)(7)(ii) of this section, the single payment amounts for rented durable medical equipment requiring frequent and substantial servicing are calculated based on the rental bids submitted and accepted for the furnishing of these items on a monthly basis.

(ii) *Exception.* The single payment amounts for continuous passive motion exercise devices are calculated based on the bids submitted and accepted for the furnishing of these items on a daily basis.

(i) *Monthly payment amounts for oxygen and oxygen equipment*—(1) *Basic payment amount.* Subject to the provisions of paragraph (i)(2) of this section, the single payment amounts for oxygen and oxygen equipment are calculated based on the bids submitted and accepted for the furnishing on a monthly basis of each of the five classes of oxygen and oxygen equipment described in § 414.226(c)(1).

(2) *Additional payment to certain contract suppliers.* (i) Except as specified in paragraph (i)(2)(iii) of this section, Medicare makes monthly payments to a contract supplier that furnishes oxygen equipment to a beneficiary who would otherwise be entitled to obtain the item from a grandfathered supplier under paragraph (j) of this section as follows:

(A) If Medicare made 26 or less monthly payments to the former supplier, Medicare makes a monthly payment to the contract supplier for up to the number of months equal to the difference between 36 and the number of months for which payment was made to the former supplier.

(B) If Medicare made 27 or more monthly payments to the former supplier, Medicare makes 10 monthly payments to the contract supplier.

(ii) Payment is made using the methodology described in paragraph (i)(1) of this section. On the first day after the month in which the final rental payment is made under paragraph (i)(2)(i) of this section, the contract supplier must transfer title of the oxygen equipment to the beneficiary.

(iii) Medicare does not make payment to a contract supplier under paragraph (i)(2) of this section if the contract supplier furnishes oxygen equipment to a beneficiary who previously rented the equipment from another contract supplier.

(j) *Special rules for certain rented durable medical equipment and oxygen and oxygen equipment*—(1) *Supplier election.* (i)

A supplier that is furnishing durable medical equipment or is furnishing oxygen or oxygen equipment on a rental basis to a beneficiary prior to the implementation of a competitive bidding program in the CBA where the beneficiary maintains a permanent residence may elect to continue furnishing the item as a grandfathered supplier.

(ii) A supplier that elects to be a grandfathered supplier must continue to furnish the grandfathered items to all beneficiaries who elect to continue receiving the grandfathered items from that supplier for the remainder of the rental period for that item.

(2) *Payment for grandfathered items furnished during the first competitive bidding program implemented in a CBA.* Payment for grandfathered items furnished during the first competitive bidding program implemented in a CBA is made as follows:

(i) For inexpensive and routinely purchased items described in §414.220(a), payment is made in the amount determined under §414.220(b).

(ii) For other durable medical equipment or capped rental items described in §414.229, payment is made in the amount determined under §414.229(b).

(iii) For items requiring frequent and substantial servicing described in §414.222, payment is made in accordance with paragraph (a)(1) of this section.

(iv) For oxygen and oxygen equipment described in §414.226(c)(1), payment is made in accordance with paragraph (a)(1) of this section.

(3) *Payment for grandfathered items furnished during all subsequent competitive bidding programs in a CBA.* Beginning with the second competitive bidding program implemented in a CBA, payment is made for grandfathered items in accordance with paragraph (a)(1) of this section.

(4) *Choice of suppliers.* (i) Beneficiaries who are renting an item that meets the definition of a grandfathered item in §414.402 of this subpart may elect to obtain the item from a grandfathered supplier.

(ii) A beneficiary who is otherwise entitled to obtain a grandfathered item from a grandfathered supplier under paragraph (j) of this section may elect to obtain the same item from a contract supplier at any time after a competitive bidding program is implemented.

(iii) If a beneficiary elects to obtain the same item from a contract supplier, payment is made for the item accordance with paragraph (a)(1) of this section.

(5) *Notification of beneficiaries and CMS by suppliers that choose to become grandfathered suppliers.* (i) *Notification of beneficiaries by suppliers.* (A) *Requirements of notification.* A noncontract supplier that elects to become a grandfathered supplier must provide a 30-day written notification to each Medicare beneficiary that resides in a competitive bidding area and is currently renting a competitively bid item from that supplier. The 30-day notification to the beneficiary must meet the following requirements:

(*1*) Be sent by the supplier to the beneficiary at least 30 business days before the start date of the implementation of the competitive bidding program for the CBA in which the beneficiary resides.

(*2*) Identify the grandfathered items that the supplier is willing to continue to rent to the beneficiary.

(*3*) Be in writing (for example, by letter or postcard) and the supplier must maintain proof of delivery.

(*4*) State that the supplier is willing to continue to furnish certain rented Durable Medical Equipment (DME), oxygen and oxygen equipment, and supplies that the supplier is currently furnishing to the beneficiary (that is, before the start of the competitive bidding program) and is willing to continue to provide these items to the beneficiary for the remaining rental months.

(*5*) State that the beneficiary has the choice to continue to receive a grandfathered item(s) from the grandfathered supplier or may elect to receive the item(s) from a contract supplier after the end of the last month for which a rental payment is made to the noncontract supplier.

(*6*) Provide the supplier's telephone number and instruct the beneficiary to call the supplier with any questions and to notify the supplier of his or her decision to use or not use the supplier as a grandfathered supplier.

(*7*) State that the beneficiary can obtain information about the competitive bidding program by calling 1–800–MEDICARE or on the Internet at *http://www.Medicare.gov*.

(B) *Record of beneficiary's choice.* The supplier should obtain an election from the beneficiary regarding whether to use or not use the supplier as a grandfathered supplier. The supplier must maintain a record of its attempts to communicate with the beneficiary to obtain the beneficiary's election regarding grandfathering. When the supplier obtains such an election, the supplier must maintain a record of the beneficiary decision including the date the choice was made, and how the beneficiary communicated his or her choice to the supplier.

(C) *Notification.* If the beneficiary chooses not to continue to receive a grandfathered item(s) from their current supplier, the supplier must provide the beneficiary with 2 more notices in addition to the 30-day notice prior to the supplier picking up its equipment.

(*1*) *10-day notification:* Ten business days prior to picking up the item, the supplier should have direct contact (for example, a phone call) with the beneficiary or the beneficiary's caregiver and receive acknowledgement that the beneficiary understands their equipment will be picked up. This should occur on the first anniversary date after the start of the CBP or on another date agreed to by the beneficiary or the beneficiary's caregiver. The beneficiary's anniversary date occurs every month and is the date of the month on which the item was first delivered to the beneficiary by the current supplier. When a date other than the anniversary date is chosen by the beneficiary or the beneficiary's caregiver, the noncontract supplier will still receive payment up to the anniversary date after the start of the CBP, and the new contract supplier may not bill for any period of time before the anniversary date.

(*2*) *2-day notification:* Two business days prior to picking up the item the supplier should contact the beneficiary or the beneficiary's caregiver by phone to notify the beneficiary of the date the supplier will pick up the item. This date should not be before the beneficiary's first anniversary date that occurs after the start of the competitive bidding program unless an alternative arrangement has been made with the beneficiary and the new contract supplier.

(D) *Pickup procedures.* (*1*) The pickup of the noncontract supplier's equipment and the delivery of the new contract supplier's equipment should occur on the same date, that is, the first rental anniversary date of the equipment that occurs after the start of the competitive bidding program unless an alternative arrangement has been made with the beneficiary and the new contract supplier.

(*2*) Under no circumstance should a supplier pick up a rented item prior to the supplier's receiving acknowledgement from the beneficiary that the beneficiary is aware of the date on which the supplier is picking up the item and the beneficiary has made arrangements to have the item replaced on that date by a contract supplier.

(*3*) When a beneficiary chooses to switch to a new contract supplier, the current noncontract supplier and the new contract supplier must make arrangements that are suitable to the beneficiary.

(*4*) The contract supplier may not submit a claim with a date of delivery for the new equipment that is prior to the first anniversary date that occurs after the beginning of the CBP, and the contract supplier may not begin billing until the first anniversary date that occurs after the beginning of the CBP.

(*5*) The noncontract supplier must submit a claim to be paid up to the first anniversary date that occurs after the beginning of the CBP. Therefore, they should not pick up the equipment before that date unless an alternative arrangement has been made with the beneficiary and the new contract supplier.

(ii) *Notification to CMS by suppliers.* A noncontract supplier that elects to become a grandfathered supplier must provide a written notification to CMS of this decision. This notification must meet the following requirements:

(A) State that the supplier agrees to continue to furnish certain rented DME, oxygen and oxygen equipment

that it is currently furnishing to beneficiaries (that is, before the start of the competitive bidding program) in a CBA and will continue to provide these items to these beneficiaries for the remaining months of the rental period.

(B) Include the following information:

(*1*) Name and address of the supplier.

(*2*) The 6-digit NSC number of the supplier.

(*3*) Product category(s) by CBA for which the supplier is willing to be a grandfathered supplier.

(C) State that the supplier agrees to meet all the terms and conditions pertaining to grandfathered suppliers.

(D) Be provided by the supplier to CMS in writing at least 30 business days before the start date of the implementation of the Medicare DMEPOS Competitive Bidding Program.

(6) *Suppliers that choose not to become grandfathered suppliers.* (i) *Requirement for non-grandfathered supplier.* A noncontract supplier that elects not to become a grandfathered supplier is required to pick up the item it is currently renting to the beneficiary from the beneficiary's home after proper notification.

(ii) *Notification.* Proper notification includes a 30-day, a 10-day, and a 2-day notice of the supplier's decision not to become a grandfathered supplier to its Medicare beneficiaries who are currently renting certain DME competitively bid item(s) and who reside in a CBA.

(iii) *Requirements of notification.* These notifications must meet all of the requirements listed in paragraph (j)(5)(i) of this section for the 30-day, 10-day and 2-day notices that must be sent by suppliers who decide to be grandfathered suppliers, with the following exceptions for the 30-day notice.

(A) State that, for those items for which the supplier has decided not to be a grandfathered supplier, the supplier will only continue to rent these competitively bid item(s) to its beneficiaries up to the first anniversary date that occurs after the start of the Medicare DMEPOS Competitive Bidding Program.

(B) State that the beneficiary must select a contract supplier for Medicare to continue to pay for these items.

(C) Refer the beneficiary to the contract supplier locator tool on and to 1–800–MEDICARE to obtain information about the availability of contract suppliers for the beneficiary's area.

(iv) *Pickup procedures.* (A) The pickup of the noncontract supplier's equipment and the delivery of the new contract supplier's equipment should occur on the same date, that is, the first rental anniversary date of the equipment that occurs after the start of the competitive bidding program unless an alternative arrangement has been made with the beneficiary and the new contract supplier.

(B) Under no circumstance should a supplier pick up a rented item prior to the supplier's receiving acknowledgement from the beneficiary that the beneficiary is aware of the date on which the supplier is picking up the item and the beneficiary has made arrangements to have the item replaced on that date by a contract supplier.

(C) When a beneficiary chooses to switch to a new contract supplier, the current noncontract supplier and the new contract supplier must make arrangements that are agreeable to the beneficiary.

(D) The contract supplier cannot submit a claim with a date of delivery for the new equipment that is prior to the first anniversary date that occurs after the beginning of the CBP.

(7) *Payment for accessories and supplies for grandfathered items.* Accessories and supplies that are used in conjunction with and are necessary for the effective use of a grandfathered item may be furnished by the same grandfathered supplier that furnishes the grandfathered item. Payment is made in accordance with paragraph (a)(1) of this section.

(k) *Payment for maintenance, servicing and replacement of beneficiary-owned items.* (1) Payment is made for the maintenance and servicing of beneficiary-owned items, provided the maintenance and servicing is performed by a contract supplier or a noncontract supplier having a valid Medicare billing number, as follows:

(i) Payment for labor is made in accordance with §414.210(e)(1) of subpart D.

(ii) Payment for parts that are not items (as defined in §414.402) is made in

accordance with § 414.210(e)(1) of subpart D.

(iii) Payment for parts that are items (as defined in § 414.402) is made in accordance with paragraph (a)(1) of this section.

(2) Additional payments are made in accordance with § 414.210(e)(2), (e)(3) and (e)(5) of this part for the maintenance and servicing of oxygen equipment if performed by a contract supplier or a noncontract supplier having a valid Medicare billing number.

(3) Beneficiaries must obtain a replacement of a beneficiary-owned item, other than parts needed for the repair of beneficiary-owned equipment from a contract supplier. Payment is made for the replacement item in accordance with paragraph (a)(1) of this section.

(l) *Exceptions for certain items and services paid in accordance with special payment rules.* The payment rules in paragraphs (f) thru (h), (j)(2), (j)(3), and (j)(7), and (k) of this section do not apply to items and services paid in accordance with the special payment rules at § 414.409.

[72 FR 18085, Apr. 10, 2007, as amended at 74 FR 2880, Jan. 16, 2009; 74 FR 62009, Nov. 25, 2009; 75 FR 73623, Nov. 29, 2010; 76 FR 70315, Nov. 10, 2011; 79 FR 66264, Nov. 6, 2014; 88 FR 77875, Nov. 13, 2023]

§ 414.409 Special payment rules.

(a) *Payment on a bundled, continuous rental basis.* In no more than 12 CBAs, in conjunction with competitions that begin after January 1, 2015, payment is made on a bundled, continuous monthly rental basis for standard power wheelchairs and continuous positive airway pressure (CPAP) devices. The CBAs and competitions where these payment rules apply are announced in advance of each competition, with the payment rules in this section used in lieu of the payment rules at § 414.408(f) thru (h), (j)(2), (j)(3), and (j)(7), and (k). The single payment amounts are established based on bids submitted and accepted for furnishing rented standard power wheelchairs and CPAP devices on a monthly basis for each month of medical need during the contract period. The single payment amount for the monthly rental of the DME includes payment for the rented equipment, maintenance and servicing of the rented equipment, and replacement of supplies and accessories necessary for the effective use of the rented equipment. Separate payment for replacement of equipment, repair or maintenance and servicing of equipment, or for replacement of accessories and supplies necessary for the effective use of equipment is not allowed under any circumstance.

(b) *Payment for grandfathered DME items paid on a bundled, continuous rental basis.* Payment to a supplier that elects to be a grandfathered supplier of DME furnished in CBPs where these special payment rules apply is made in accordance with § 414.408(a)(1).

(c) *Supplier transitions for DME paid on a bundled, continuous rental basis.* Changes from a non-contract supplier to a contract supplier at the beginning of a CBP where payment is made on a bundled, continuous monthly rental basis results in the contract supplier taking on responsibility for meeting all of the monthly needs for furnishing the covered DME. In the event that a beneficiary relocates from a CBA where these special payment rules apply to an area where rental cap rules apply, a new period of continuous use begins for the capped rental item as long as the item is determined to be medically necessary.

(d) *Responsibility for repair and maintenance and servicing of power wheelchairs.* In no more than 12 CBAs where payment for power wheelchairs is made on a capped rental basis, for power wheelchairs furnished in conjunction with competitions that begin after January 1, 2015, contract suppliers that furnish power wheelchairs under contracts awarded based on these competitions shall continue to repair power wheelchairs they furnish following transfer of title to the equipment to the beneficiary. The responsibility of the contract supplier to repair, maintain and service beneficiary-owned power wheelchairs does not apply to power wheelchairs that the contract supplier did not furnish to the beneficiary. For power wheelchairs that the contract supplier furnishes during the contract period, the responsibility of the contract supplier to repair, maintain and service the power wheelchair once it is owned by the beneficiary continues

until the reasonable useful lifetime of the equipment expires, coverage for the power wheelchair ends, or the beneficiary relocates outside the CBA where the item was furnished. The contract supplier may not charge the beneficiary or the program for any necessary repairs or maintenance and servicing of a beneficiary-owned power wheelchair it furnished during the contract period.

[79 FR 66264, Nov. 6, 2014]

§414.410 Phased-in implementation of competitive bidding programs.

(a) *Phase-in of competitive bidding programs.* CMS phases in competitive bidding programs so that competition under the programs occurs—

(1) In CY 2009, in Cincinnati—Middletown (Ohio, Kentucky and Indiana), Cleveland—Elyria—Mentor (Ohio), Charlotte—Gastonia—Concord (North Carolina and South Carolina), Dallas—Fort Worth—Arlington (Texas), Kansas City (Missouri and Kansas), Miami—Fort Lauderdale—Miami Beach (Florida), Orlando (Florida), Pittsburgh (Pennsylvania), and Riverside—San Bernardino—Ontario (California).

(2) In CY 2011, in an additional 91 MSAs (the additional 70 MSAs selected by CMS as of June 1, 2008, and the next 21 largest MSAs by total population based on 2009 population estimates, and not already phased in as of June 1, 2008). CMS may subdivide any of the 91 MSAs with a population of greater than 8,000,000 into separate CBAs, thereby resulting in more than 91 CBAs.

(3) After CY 2011, additional CBAs (or, in the case of national mail order for items and services, after CY 2010).

(4) For competitions (other than for national mail order items and services) after CY 2011 and prior to CY 2015, the following areas are excluded:

(i) Rural areas.

(ii) MSAs not selected under paragraphs (a)(1) or (a)(2) of this section with a population of less than 250,000.

(iii) An area with low population density within an MSA not selected under paragraphs (a)(1) or (a)(2) of this section.

(b) *Selection of MSAs for CY 2007 and CY 2009.* CMS selects the MSAs for purposes of designating CBAs in CY 2007 and CY 2009 by considering the following variables:

(1) The total population of an MSA.

(2) The Medicare allowed charges for DMEPOS items per fee-for-service beneficiary in an MSA.

(3) The total number of DMEPOS suppliers per fee-for-service beneficiary who received DMEPOS items in an MSA.

(4) An MSA's geographic location.

(c) *Exclusions from a CBA.* CMS may exclude from a CBA a rural area (as defined in §412.64(b)(1)(ii)(C) of this subchapter), or an area with low population density based on one or more of the following factors—

(1) Low utilization of DMEPOS items by Medicare beneficiaries receiving fee-for-service benefits relative to similar geographic areas;

(2) Low number of DMEPOS suppliers relative to similar geographic areas; or

(3) Low number of Medicare fee-for-service beneficiaries relative to similar geographic areas.

(d) *Selection of additional CBAs after CY 2009.* (1) Beginning after CY 2009, CMS designates through program instructions or by other means additional CBAs based on CMS' determination that the implementation of a competitive bidding program in a particular area would be likely to result in significant savings to the Medicare program.

(2) Beginning after CY 2009, CMS may designate through program instructions or by other means a nationwide CBA or one or more regional CBAs for purposes of implementing competitive bidding programs for items that are furnished through the mail by nationwide or regional mail order contract suppliers.

[72 FR 18085, Apr. 10, 2007, as amended at 74 FR 2880, Jan. 16, 2009; 75 FR 73623, Nov. 29, 2010; 76 FR 70315, Nov. 10, 2011]

§414.411 Special rule in case of competitions for diabetic testing strips conducted on or after January 1, 2011.

(a) *National mail order competitions.* A supplier must demonstrate that their bid submitted as part of a national mail order competition for diabetic testing strips covers the furnishing of a sufficient number of different types of

diabetic testing strip products that, in the aggregate, and taking into account volume for the different products, includes at least 50 percent of all the different types of products on the market. A type of diabetic testing strip means a specific brand and model of testing strips.

(b) *Other competitions.* CMS may apply this special rule to non-mail order or local competitions for diabetic testing strips.

[75 FR 73623, Nov. 29, 2010]

§ 414.412 Submission of bids under a competitive bidding program.

(a) *Requirement to submit a bid.* Except as provided under § 414.404(b), in order for a supplier to receive payment for items furnished to beneficiaries under a competitive bidding program, the supplier must submit a bid to furnish those items and be awarded a contract under this subpart.

(b) *Grouping of items into product categories.* (1) Composite bids, as defined in § 414.402, are submitted for lead items, as defined in § 414.402.

(2) The bid submitted for each lead item and product category cannot exceed the payment amount that would otherwise apply to the lead item under—

(i) Subpart C of this part, without the application of § 414.210(g);

(ii) Subpart D of this part, without the application of § 414.105; or

(iii) Subpart Q of this part, without the application of § 414.1690.

(3) The bids submitted for standard power wheelchairs paid in accordance with the special payment rules at § 414.409(a) cannot exceed the average monthly payment for the bundle of items and services that would otherwise apply to the item under subpart D of this part.

(4) The bids submitted for continuous positive airway pressure (CPAP) devices paid in accordance with the special payment rules at § 414.409(a) cannot exceed the 1993 fee schedule amounts for these items, increased by the covered item update factors provided for these items in section 1834(a)(14) of the Act.

(5) Suppliers shall take into consideration the special payment rules at § 414.409(d) when submitting bids for furnishing power wheelchairs under competitions where these rules apply.

(c) *Furnishing of items.* A bid must include all costs related to furnishing all items in the product category, including all services directly related to the furnishing of the items.

(d) *Commonly-owned or controlled suppliers.* (1) For purposes of this paragraph—

(i) An ownership interest is the possession of equity in the capital, stock or profits of another supplier;

(ii) A controlling interest exists if one or more of owners of a supplier is an officer, director or partner in another supplier; and

(iii) Two or more suppliers are commonly-owned if one or more of them has an ownership interest totaling at least 5 percent in the other(s).

(2) A supplier must disclose in its bid each supplier in which it has an ownership or controlling interest and each supplier which has an ownership or controlling interest in it.

(3) Commonly-owned or controlled suppliers must submit a single bid to furnish a product category in a CBA. Each commonly-owned or controlled supplier that is located in the CBA for which the bid is being submitted must be included in the bid. The bid must also include any commonly-owned or controlled supplier that is located outside of the CBA but would furnish the product category to the beneficiaries who maintain a permanent residence in the CBA.

(e) *Mail order suppliers.* (1) Suppliers that furnish items through the mail must submit a bid to furnish these items in a CBA in which a mail order competitive bidding program that includes the items is implemented.

(2) Suppliers that submit one or more bids under (e)(1) of this section may submit the same bid amount for each item under each competitive bidding program for which it submits a bid.

(f) *Applicability of the mail order competitive bidding program.* Suppliers that do not furnish items through the mail are not required to participate in a nationwide or regional mail order competitive bidding program that includes the same items. Suppliers may continue to furnish these items in—

(1) A CBA, if the supplier is awarded a contract under this subpart; or

(2) An area not designated as a CBA.

(g) *Requiring bid surety bonds for bidding entities*—(1) *Bidding requirements.* For competitions beginning on or after January 1, 2017, and no later than January 1, 2019, a bidding entity may not submit a bid(s) for a CBA unless it obtains a bid surety bond for the CBA from an authorized surety on the Department of the Treasury's Listing of Certified Companies and provides proof of having obtained the bond by submitting a copy to CMS by the deadline for bid submission.

(2) *Bid surety bond requirements.* (i) The bid surety bond issued must include at a minimum:

(A) The name of the bidding entity as the principal/obligor;

(B) The name and National Association of Insurance Commissioners number of the authorized surety;

(C) CMS as the named obligee;

(D) The conditions of the bond as specified in paragraph (g)(3) of this section;

(E) The CBA covered by the bond;

(F) The bond number;

(G) The date of issuance; and

(H) The bid bond value of $50,000.00.

(ii) The bid surety bond must be maintained until it is either collected upon due to forfeiture or the liability is returned for not meeting bid forfeiture conditions.

(3) *Forfeiture of bid surety bond.* (i) When a bidding entity is offered a contract for a CBA/product category (''competition'') and its composite bid for the competition is at or below the median composite bid rate for all bidding entities included in the calculation of the single payment amounts within the competition and the bidding entity does not accept the contract offer, its bid surety bond submitted for that CBA will be forfeited and CMS will collect on the bond via Electronic Funds Transfer (EFT) from the respective bonding company. As one bid surety bond is required for each CBA in which the bidding entity is submitting a bid, the failure to accept a contract offer for any product category within the CBA when the entity's bid is at or below the median composite bid rate will result in forfeiture of the bid surety bond for that CBA.

(ii) Where the bid(s) does not meet the specified forfeiture conditions in paragraph (h)(3)(i) of this section, the bid surety bond liability will be returned within 90 days of the public announcement of contract suppliers for the CBA. CMS will notify the bidding entity that it did not meet the specified forfeiture requirements and the bid surety bond will not be collected by CMS.

(4) *Penalties.* (i) A bidding entity that has been determined to have falsified its bid surety bond may be prohibited from participation in the DMEPOS Competitive Bidding Program for the current round of the Competitive Bidding Program in which it submitted a bid and also from participating in the next round of the Competitive Bidding Program. Offending suppliers will also be referred to the Office of Inspector General and Department of Justice for further investigation.

(ii) A bidding entity, whose composite bid is at or below the median composite bid rate, that—

(A) Accepts a contract award; and

(B) Is found to be in breach of contract for nonperformance of the contract to avoid forfeiture of the bid surety bond will have its contract terminated and will be precluded from participation in the in the next round of the DMEPOS Competitive Bidding Program.

[72 FR 18085, Apr. 10, 2007, as amended at 79 FR 66264, Nov. 6, 2014; 81 FR 77966, Nov. 4, 2016; 83 FR 21925, May 11, 2018; 83 FR 57072, Nov. 14, 2018; 88 FR 77876, Nov. 13, 2023]

§414.414 Conditions for awarding contracts.

(a) *General rule.* The rules set forth in this section govern the evaluation and selection of suppliers for contract award purposes under a competitive bidding program.

(b) *Basic supplier eligibility.* (1) Each supplier must meet the enrollment standards specified in §424.57(c) of this chapter.

(2) Each supplier must disclose information about any prior or current legal actions, sanctions, revocations from the Medicare program, program-

related convictions as defined in section 1128(a)(1) through (a)(4) of the Act, exclusions or debarments imposed against it, or against any members of the board of directors, chief corporate officers, high-level employees, affiliated companies, or subcontractors, by any Federal, State, or local agency. The supplier must certify in its bid that this information is completed and accurate.

(3) Each supplier must have all State and local licenses required to perform the services identified in the request for bids. CMS may not award a contract to any entity in a CBA unless the entity meets applicable State licensure requirements.

(4) Each supplier must submit a bona fide bid that complies with all the terms and conditions contained in the request for bids.

(5) Each network must meet the requirements specified in § 414.418.

(c) *Quality standards and accreditation.* Each supplier furnishing items and services directly or as a subcontractor must meet applicable quality standards developed by CMS in accordance with section 1834(a)(20) of the Act and be accredited by a CMS-approved organization that meets the requirements of § 424.58 of this subchapter, unless a grace period is specified by CMS.

(d) *Financial standards*—(1) *General rule.* Each supplier must submit along with its bid the applicable covered documents (as defined in § 414.402) specified in the request for bids.

(2) *Process for reviewing covered documents*—(i) *Submission of covered documents for CMS review.* To receive notification of whether there are missing covered documents, the supplier must submit its applicable covered documents by the later of the following covered document review dates:

(A) The date that is 30 days before the final date for the closing of the bid window; or

(B) The date that is 30 days after the opening of the bid window.

(ii) *CMS feedback to a supplier with missing covered documents.* (A) *For Round 1 bids.* CMS has up to 45 days after the covered document review date to review the covered documents and to notify suppliers of any missing documents.

(B) *For subsequent Round bids.* CMS has 90 days after the covered document review date to notify suppliers of any missing covered documents.

(iii) *Submission of missing covered documents.* Suppliers notified by CMS of missing covered documents have 10 business days after the date of such notice to submit the missing documents. CMS does not reject the supplier's bid on the basis that the covered documents are late or missing if all the applicable missing covered documents identified in the notice are submitted to CMS not later than 10 business days after the date of such notice.

(e) Evaluation of bids. CMS evaluates composite bids submitted for a lead item within a product category by—

(1) Calculating the expected beneficiary demand in the CBA for the lead item in the product category;

(2) Calculating the total supplier capacity that would be sufficient to meet the expected beneficiary demand in the CBA for the lead item in the product category;

(3) Arraying the composite bids from the lowest composite bid price to the highest composite bid price;

(4) Calculating the pivotal bid for the product category; and

(5) Selecting all suppliers and networks whose composite bids are less than or equal to the pivotal bid for that product category, and that meet the requirements in paragraphs (b) through (d) of this section.

(f) *Expected savings.* A contract is not awarded under this subpart unless CMS determines that the amounts to be paid to contract suppliers for an item under a competitive bidding program are expected to be less than the amounts that would otherwise be paid for the same item under subpart C or subpart D.

(g) *Special rules for small suppliers*—(1) *Target for small supplier participation.* CMS ensures that small suppliers have the opportunity to participate in a competitive bidding program by taking the following steps:

(i) Setting a target number for small supplier participation by multiplying 30 percent by the number of suppliers that meet the requirements in paragraphs (b) through (d) of this section and whose composite bids are equal to

or lower than the pivotal bid calculated for the product category;

(ii) Identifying the number of qualified small suppliers whose composite bids are at or below the pivotal bid for the product category;

(iii) Selecting additional small suppliers whose composite bids are above the pivotal bid for the product category in ascending order based on the proximity of each small supplier's composite bid to the pivotal bid, until the number calculated in paragraph (g)(1)(i) of this section is reached or there are no more composite bids submitted by small suppliers for the product category.

(2) The bids by small suppliers that are selected under paragraph (g)(1)(iii) of this section are not used to calculate the single payment amounts for any items under §414.416 of this subpart.

(h) *Sufficient number of suppliers.* (1) Except as provided in paragraph (h)(3) of this section. CMS will award at least five contracts, if there are five suppliers satisfying the requirements in paragraphs (b) through (f) of this section; or

(2) CMS will award at least two contracts, if there are less than five suppliers meeting these requirements and the suppliers satisfying these requirements have sufficient capacity to satisfy beneficiary demand for the product category calculated under paragraph (e)(1) of this section.

(3) The provisions of paragraph (h)(1) of this section do not apply to regional or nationwide mail order CBAs under §414.410(d)(2) of this subpart.

(i) *Selection of new suppliers after bidding.* (1) Subsequent to the awarding of contracts under this subpart, CMS may award additional contracts if it determines that additional contract suppliers are needed to meet beneficiary demand for items under a competitive bidding program. CMS selects additional contract suppliers by—

(i) Referring to the arrayed list of suppliers that submitted bids for the product category included in the competitive bidding program for which beneficiary demand is not being met; and

(ii) Beginning with the supplier whose composite bid is the first composite bid above the pivotal bid for that product category, determining if that supplier is willing to become a contract supplier under the same terms and conditions that apply to other contract suppliers in the CBA.

(2) Before CMS awards additional contracts under paragraph (i)(1) of this section, a supplier must submit updated information demonstrating that the supplier meets the requirements under paragraphs (b) through (d) of this section.

[72 FR 18085, Apr. 10, 2007, as amended at 74 FR 2880, Jan. 16, 2009; 76 FR 70315, Nov. 10, 2011; 79 FR 66264, Nov. 6, 2014; 81 FR 77967, Nov. 4, 2016; 83 FR 21925, May 11, 2018; 83 FR 57072, Nov. 14, 2018]

§414.416 Determination of competitive bidding payment amounts.

(a) *General rule.* CMS establishes a single payment amount for each item furnished under a competitive bidding program.

(b) *Methodology for setting payment amount.* (1) The single payment amount for a lead item furnished under a competitive bidding program is equal to the maximum bid submitted for that item by suppliers whose composite bids for the product category that includes the item are equal to or below the pivotal bid for that product category.

(2) The single payment amount for a lead item must be less than or equal to the amount that would otherwise be paid for the same item under subpart C or subpart D of this part.

(3) The single payment amount for an item in a product category furnished under a competitive bidding program that is not a lead item for that product category is equal to the single payment amount for the lead item in the same product category multiplied by the ratio of the average of the 2015 fee schedule amounts for all areas (that is, all states, the District of Columbia, Puerto Rico, the United States Virgin Islands), for the item to the average of the 2015 fee schedule amounts for all areas for the lead item.

[72 FR 18085, Apr. 10, 2007, as amended at 81 FR 77967, Nov. 4, 2016; 83 FR 57072, Nov. 14, 2018]

§ 414.418 Opportunity for networks.

(a) A network may be comprised of at least 2 but not more than 20 small suppliers.

(b) The following rules apply to networks that seek contracts under this subpart:

(1) Each network must form a single legal entity that acts as the bidder and submits the bid. Any agreement entered into for purposes of forming a network must be submitted to CMS. The network must identify itself as a network and identify all of its members.

(2) Each member of the network must satisfy the requirements in § 414.414(b) through (d).

(3) A small supplier may join one or more networks but cannot submit an individual bid to furnish the same product category in the same CBA as any network in which it is a member. A small supplier may not be a member of more than one network if those networks submit bids to furnish the same product category in the same CBA.

(4) The network cannot be anticompetitive, and this section does not supersede any Federal law or regulation that regulates anticompetitive behavior.

(5) A bid submitted by a network must include a statement from each network member certifying that the network member joined the network because it is unable independently to furnish all of the items in the product category for which the network is submitting a bid to beneficiaries throughout the entire geographic area of the CBA.

(6) At the time that a network submits a bid, the network's total market share for each product category that is the subject of the network's bid cannot exceed 20 percent of the Medicare demand for that product category in the CBA.

(c) If the network is awarded a contract, each supplier must submit its own claims and will receive payment directly from Medicare for the items that it furnishes under the competitive bidding program.

[72 FR 18085, Apr. 10, 2007]

§ 414.420 Physician or treating practitioner authorization and consideration of clinical efficiency and value of items.

(a) *Prescription for a particular brand item or mode of delivery.* (1) A physician or treating practitioner may prescribe, in writing, a particular brand of an item for which payment is made under a competitive bidding program, or a particular mode of delivery for an item, if he or she determines that the particular brand or mode of delivery would avoid an adverse medical outcome for the beneficiary.

(2) When a physician or treating practitioner prescribes a particular brand or mode of delivery of an item under paragraph (a)(1) of this section, the physician or treating practitioner must document the reason in the beneficiary's medical record why the particular brand or mode of delivery is medically necessary to avoid an adverse medical outcome.

(b) *Furnishing of a prescribed particular brand item or mode of delivery.* If a physician or treating practitioner prescribes a particular brand of an item or mode of delivery, the contract supplier must—

(1) Furnish the particular brand or mode of delivery as prescribed by the physician or treating practitioner;

(2) Consult with the physician or treating practitioner to find an appropriate alternative brand of item or mode of delivery for the beneficiary and obtain a revised written prescription from the physician or treating practitioner; or

(3) Assist the beneficiary in locating a contract supplier that can furnish the particular brand of item or mode of delivery prescribed by the physician or treating practitioner.

(c) *Payment for a particular brand of item or mode of delivery.* Medicare does not make an additional payment to a contract supplier that furnishes a particular brand or mode of delivery for an item, as directed by a prescription written by the beneficiary's physician or treating practitioner.

(d) *Prohibition on billing for an item different from the particular brand of item*

or mode of delivery prescribed. A contract supplier is prohibited from submitting a claim to Medicare if it furnishes an item different from that specified in the written prescription received from the beneficiary's physician or treating practitioner. Payment will not be made to a contract supplier that submits a claim prohibited by this paragraph.

[72 FR 18085, Apr. 10, 2007]

§414.422 Terms of contracts.

(a) *Basic rule.* CMS specifies the terms and conditions of the contracts entered into with contract suppliers under this subpart. A contract supplier must comply with all terms of its contract, including any option exercised by CMS, for the full duration of the contract period.

(b) *Recompeting competitive bidding contracts.* CMS recompetes competitive bidding contracts at least once every 3 years.

(c) *Nondiscrimination.* The items furnished by a contract supplier under this subpart must be the same items that the contract supplier makes available to other customers.

(d) *Change of ownership (CHOW).* (1) CMS may transfer a contract to a successor entity that merges with, or acquires, a contract supplier if the successor entity—

(i) Meets all requirements applicable to contract suppliers for the applicable competitive bidding program;

(ii) Submits to CMS the documentation described under §414.414(b) through (d) if documentation has not previously been submitted by the successor entity or if the documentation is no longer sufficient for CMS to make a financial determination. A successor entity is not required to duplicate previously submitted information if the previously submitted information is not needed to make a financial determination. This documentation must be submitted prior to the effective date of the CHOW; and

(iii) Submits to CMS a signed novation agreement acceptable to CMS stating that it assumes all obligations under the contract. This documentation must be submitted no later than 10 days after the effective date of the CHOW.

(2) Except as specified in paragraph (d)(3) of this section, CMS may transfer the entire contract, including all product categories and competitive bidding areas, to a successor entity.

(3) For contracts issued in the Round 2 Recompete and subsequent rounds in the case of a CHOW where a contract supplier sells a distinct company (for example, a subsidiary) that furnishes a specific product category or services a specific CBA, CMS may transfer the portion of the contract performed by that company to a successor entity, if the following conditions are met:

(i) Every CBA, product category, and location of the company being sold must be transferred to the successor entity that meets all competitive bidding requirements; that is, financial, accreditation, and licensure;

(ii) All CBAs and product categories in the original contract that are not explicitly transferred by CMS remain unchanged in that original contract for the duration of the contract period unless transferred by CMS pursuant to a subsequent CHOW;

(iii) All requirements of paragraph (d)(1) of this section are met;

(iv) The sale of the distinct company includes all of the contract supplier's assets associated with the CBA and/or product category(s); and

(v) CMS determines that transfer of part of the original contract will not result in disruption of service or harm to beneficiaries.

(e) *Furnishing of items.* Except as otherwise prohibited under section 1877 of the Act, or any other applicable law or regulation:

(1) A contract supplier must agree to furnish items under its contract to any beneficiary who maintains a permanent residence in, or who visits, the CBA and who requests those items from that contract supplier.

(2) A skilled nursing facility defined under section 1819(a) of the Act or a nursing facility defined under section 1919(a) of the Act that has elected to furnish items only to its own residents and that is also a contract supplier may furnish items under a competitive bidding program to its own patients to whom it would otherwise furnish Part B services.

(3) Contract suppliers for diabetic testing supplies must furnish the brand of diabetic testing supplies that work with the home blood glucose monitor selected by the beneficiary. The contract supplier is prohibited from influencing or incentivizing the beneficiary by persuading, pressuring, or advising them to switch from their current brand or for new beneficiaries from their preferred brand of glucose monitor and testing supplies. The contract supplier may not furnish information about alternative brands to the beneficiary unless the beneficiary requests such information.

(f) *Disclosure of subcontracting arrangements.* (1) *Initial disclosure.* Not later than 10 days after the date a supplier enters into a contract under this section the supplier must disclose information on both of the following:

(i) Each subcontracting arrangement that the supplier has in furnishing items and services under the contract.

(ii) Whether each subcontractor meets the requirement of section 1834(a)(20)(F)(i) of the Act if applicable to such subcontractor.

(2) *Subsequent disclosure.* Not later than 10 days after the date a supplier enters into a subcontracting arrangement subsequent to contract award with CMS, the supplier must disclose information on both of the following:

(i) The subcontracting arrangement that the supplier has in furnishing items and services under the contract.

(ii) Whether the subcontractor meets the requirement of section 1834(a)(20)(F)(i) of the Act, if applicable to such subcontractor.

(g) *Breach of contract.* (1) Any deviation from contract requirements, including a failure to comply with governmental agency or licensing organization requirements, constitutes a breach of contract.

(2) In the event a contract supplier breaches its contract, CMS may take one or more of the following actions, which will be specified in the notice of breach of contract:

(i) Suspend the contract supplier's contract;

(ii) Terminate the contract;

(iii) Preclude the contract supplier from participating in the competitive bidding program; or

(iv) Avail itself of other remedies allowed by law.

[72 FR 18085, Apr. 10, 2007, as amended at 74 FR 2881, Jan. 16, 2009; 75 FR 73623, Nov. 29, 2010; 76 FR 70315, Nov. 10, 2011; 79 FR 66264, Nov. 6, 2014; 81 FR 77967, Nov. 4, 2016; 83 FR 57073, Nov. 14, 2018; 84 FR 60808, Nov. 8, 2019]

§ 414.423 Appeals process for breach of a DMEPOS competitive bidding program contract actions.

This section implements an appeals process for suppliers that CMS has determined are in breach of their Medicare DMEPOS Competitive Bidding Program contract and where CMS has issued a notice of breach of contract indicating its intent to take action(s) pursuant to § 414.422(g)(2).

(a) *Breach of contract.* CMS may take one or more of the actions specified in § 414.422(g)(2) as a result of a supplier's breach of their DMEPOS Competitive Bidding Program contract.

(b) *Notice of breach of contract*—(1) *CMS notification.* If CMS determines a supplier to be in breach of its contract, it will notify the supplier of the breach of contract in a notice of breach of contract.

(2) *Content of the notice of breach of contract.* The CMS notice of breach of contract will include the following:

(i) The details of the breach of contract.

(ii) The action(s) that CMS is taking as a result of the breach of the contract pursuant to § 414.422(g)(2), and the duration of or timeframe(s) associated with the action(s), if applicable.

(iii) The right to request a hearing by a CBIC hearing officer and, depending on the nature of the breach, the supplier may also be allowed to submit a corrective action plan (CAP) in lieu of requesting a hearing by a CBIC hearing officer, as specified in paragraph (c)(1)(i) of this section.

(iv) The address to which the written request for a hearing must be submitted.

(v) The address to which the CAP must be submitted, if applicable.

(vi) The effective date of the action(s) that CMS is taking is the date specified by CMS in the notice of breach of contract, or 45 days from the date of the notice of breach of contract unless:

(A) A timely hearing request has been filed; or

(B) A CAP has been submitted within 30 days of the date of the notice of breach of contract where CMS allows a supplier to submit a CAP.

(c) *Corrective action plan (CAP)*—(1) *Option for a CAP.* (i) CMS has the option to allow a supplier to submit a written CAP to remedy the deficiencies identified in the notice at its sole discretion, including where CMS determines that the delay in the effective date of the breach of contract action(s) caused by allowing a CAP will not cause harm to beneficiaries. CMS will not allow a CAP if the supplier has been excluded from any Federal program, debarred by a Federal agency, or convicted of a healthcare-related crime, or for any other reason determined by CMS.

(ii) If a supplier chooses not to submit a CAP, if CMS determines that a supplier's CAP is insufficient, or if CMS does not allow the supplier the option to submit a CAP, the supplier may request a hearing on the breach of contract action(s).

(2) *Submission of a CAP.* (i) If allowed by CMS, a CAP must be submitted within 30 days from the date on the notice of breach of contract. If the supplier decides not to submit a CAP the supplier may, within 30 days of the date on the notice, request a hearing by a CBIC hearing officer.

(ii) Suppliers will have the opportunity to submit a CAP when they are first notified that they have been determined to be in breach of contract. If the CAP is not acceptable to CMS or is not properly implemented, suppliers will receive a subsequent notice of breach of contract. The subsequent notice of breach of contract may, at CMS' discretion, allow the supplier to submit another written CAP pursuant to paragraph (c)(1)(i) of this section.

(d) *The purpose of the CAP.* The purpose of the CAP is:

(1) For the supplier to remedy all of the deficiencies that were identified in the notice of breach of contract.

(2) To identify the timeframes by which the supplier will implement each of the components of the CAP.

(e) *Review of the CAP.* (1) The CBIC will review the CAP. Suppliers may only revise their CAP one time during the review process based on the deficiencies identified by the CBIC. The CBIC will submit a recommendation to CMS for each applicable breach of contract action concerning whether the CAP includes the steps necessary to remedy the contract deficiencies as identified in the notice of breach of contract.

(2) If CMS accepts the CAP, including the supplier's designated timeframe for its completion, the supplier must provide a follow-up report within 5 days after the supplier has fully implemented the CAP that verifies that all of the deficiencies identified in the CAP have been corrected in accordance with the timeframes accepted by CMS.

(3) If the supplier does not implement a CAP that was accepted by CMS, or if CMS does not accept the CAP submitted by the supplier, then the supplier will receive a subsequent notice of breach of contract, as specified in paragraph (b) of this section.

(f) *Right to request a hearing by the CBIC Hearing Officer.* (1) A supplier who receives a notice of breach of contract (whether an initial notice of breach of contract or a subsequent notice of breach of contract under §414.422(e)(3)) has the right to request a hearing before a CBIC hearing officer who was not involved with the original breach of contract determination.

(2) A supplier that wishes to appeal the breach of contract action(s) specified in the notice of breach of contract must submit a written request to the CBIC. The request for a hearing must be submitted to the CBIC within 30 days from the date of the notice of breach of contract.

(3) A request for hearing must be in writing and submitted by an authorized official of the supplier.

(4) The appeals process for the Medicare DMEPOS Competitive Bidding Program is not to be used in place of other existing appeals processes that apply to other parts of Medicare.

(5) If the supplier is given the opportunity to submit a CAP and a CAP is not submitted and the supplier fails to timely request a hearing, the breach of contract action(s) will take effect 45 days from the date of the notice of breach of contract.

(g) *The CBIC Hearing Officer schedules and conducts the hearing.* (1) Within 30 days from the receipt of the supplier's timely request for a hearing the hearing officer will contact the parties to schedule the hearing.

(2) The hearing may be held in person or by telephone at the parties' request.

(3) The scheduling notice to the parties must indicate the time and place for the hearing and must be sent to the parties at least 30 days before the date of the hearing.

(4) The hearing officer may, on his or her own motion, or at the request of a party, change the time and place for the hearing, but must give the parties to the hearing 30 days' notice of the change.

(5) The hearing officer's scheduling notice must provide the parties to the hearing the following information:

(i) A description of the hearing procedure.

(ii) The specific issues to be resolved.

(iii) The supplier has the burden to prove it is not in violation of the contract or that the breach of contract action(s) is not appropriate.

(iv) The opportunity for parties to the hearing to submit additional evidence to support their positions, if requested by the hearing officer.

(v) A notification that all evidence submitted, both from the supplier and CMS, will be provided in preparation for the hearing to all affected parties at least 15 days prior to the scheduled date of the hearing.

(h) *Burden of proof and evidence submission.* (1) The burden of proof is on the Competitive Bidding Program contract supplier to demonstrate to the hearing officer with convincing evidence that it has not breached its contract or that the breach of contract action(s) is not appropriate.

(2) The supplier's evidence must be submitted with its request for a hearing.

(3) If the supplier fails to submit the evidence at the time of its submission, the Medicare DMEPOS supplier is precluded from introducing new evidence later during the hearing process, unless permitted by the hearing officer.

(4) CMS also has the opportunity to submit evidence to the hearing officer within 10 days of receiving the scheduling notice.

(5) The hearing officer will share all evidence submitted by the supplier and/or CMS, with all parties to the hearing at least 15 days prior to the scheduled date of the hearing.

(i) *Role of the hearing officer.* The hearing officer will conduct a thorough and independent review of the evidence including the information and documentation submitted for the hearing and other information that the hearing officer considers pertinent for the hearing. The role of the hearing officer includes, at a minimum, the following:

(1) Conduct the hearing and decide the order in which the evidence and the arguments of the parties are presented;

(2) Determine the rules on admissibility of the evidence;

(3) Examine the witnesses, in addition to the examinations conducted by CMS and the contract supplier;

(4) The CBIC may assist CMS in the appeals process including being present at the hearing, testifying as a witness, or performing other, related ministerial duties;

(5) Determine the rules for requesting documents and other evidence from other parties;

(6) Ensure a complete record of the hearing is made available to all parties to the hearing;

(7) Prepare a file of the record of the hearing which includes all evidence submitted as well as any relevant documents identified by the hearing officer and considered as part of the hearing; and

(8) Comply with all applicable provisions of Title 18 and related provisions of the Act, the applicable regulations issued by the Secretary, and manual instructions issued by CMS.

(j) *Hearing officer recommendation.* (1) The hearing officer will issue a written recommendation(s) to CMS within 30 days of the close of the hearing unless an extension has been granted by CMS because the hearing officer has demonstrated that an extension is needed due to the complexity of the matter or heavy workload. In situations where there is more than one breach of contract action presented at the hearing, the hearing officer will issue separate

recommendations for each breach of contract action.

(2) The recommendation(s) will explain the basis and the rationale for the hearing officer's recommendation(s).

(3) The hearing officer must include the record of the hearing, along with all evidence and documents produced during the hearing along with its recommendation(s).

(k) *CMS' final determination.* (1) CMS' review of the hearing officer's recommendation(s) will not allow the supplier to submit new information.

(2) After reviewing the hearing officer's recommendation(s), CMS' decision(s) will be made within 30 days from the date of receipt of the hearing officer's recommendation(s). In situations where there is more than one breach of contract action presented at the hearing, and the hearing officer issues multiple recommendations, CMS will render separate decisions for each breach of contract action.

(3) A notice of CMS' decision will be sent to the supplier and the hearing officer. The notice will indicate:

(i) If any breach of contract action(s) included in the notice of breach of contract, specified in paragraph (b)(1) of this section, still apply and will be effectuated, and

(ii) The effective date for any breach of contract action specified in paragraph (k)(3)(i) of this section.

(4) This decision(s) is final and binding.

(l) *Effect of breach of contract action(s)*—(1) *Effect of contract suspension.* (i) All locations included in the contract cannot furnish competitive bid items to beneficiaries within a CBA and the supplier cannot be reimbursed by Medicare for these items for the duration of the contract suspension.

(ii) The supplier must notify all beneficiaries who are receiving rented competitive bid items or competitive bid items on a recurring basis of the suspension of their contract.

(A) The notice to the beneficiary from the supplier must be provided within 15 days of receipt of the final notice.

(B) The notice to the beneficiary must inform the beneficiary that they must select a new contract supplier to furnish these items in order for Medicare to pay for these items.

(2) *Effect of contract termination.* (i) All locations included in the contract can no longer furnish competitive bid items to beneficiaries within a CBA and the supplier cannot be reimbursed by Medicare for these items after the effective date of the termination.

(ii) The supplier must notify all beneficiaries, who are receiving rented competitive bid items or competitive bid items received on a recurring basis, of the termination of their contract.

(A) The notice to the beneficiary from the supplier must be provided within 15 days of receipt of the final notice of termination.

(B) The notice to the beneficiary must inform the beneficiary that they are going to have to select a new contract supplier to furnish these items in order for Medicare to pay for these items.

(3) *Effect of preclusion.* A supplier who is precluded will not be allowed to participate in a specific round of the Competitive Bidding Program, which will be identified in the original notice of breach of contract, as specified in paragraph (b)(1) of this section.

(4) *Effect of other remedies allowed by law.* If CMS decides to impose other remedies under §414.422(g)(2)(iv), the details of the remedies will be included in the notice of breach of contract, as specified in paragraph (b)(2) of this section.

[81 FR 77967, Nov. 4, 2016, as amended at 83 FR 57073, Nov. 14, 2018; 84 FR 60809, Nov. 8, 2019]

§414.424 Administrative or judicial review.

(a) There is no administrative or judicial review under this subpart of the following:

(1) Establishment of payment amounts.

(2) Awarding of contracts.

(3) Designation of CBAs.

(4) Phase-in of the competitive bidding programs.

(5) Selection of items for competitive bidding.

(6) Bidding structure and number of contract suppliers selected for a competitive bidding program.

(b) A denied claim is not appealable if the denial is based on a determination by CMS that a competitively bid item was furnished in a CBA in a manner not authorized by this subpart.

[72 FR 18085, Apr. 10, 2007]

§ 414.425 Claims for damages.

(a) *Eligibility for filing a claim for damages as a result of the termination of supplier contracts by the Medicare Improvements for Patients and Providers Act of 2008 (MIPPA).* (1) Any aggrieved supplier, including a member of a network that was awarded a contract for the Round 1 Durable Medical Prosthetics, Orthotics, and Supplies Competitive Bidding Program (DMEPOS CBP) that believes it has been damaged by the termination of its competitive bid contract, may file a claim under this section.

(2) A subcontractor of a contract supplier is not eligible to submit a claim under this section.

(b) *Timeframe for filing a claim.* (1) A completed claim, including all documentation, must be filed within 90 days of January 1, 2010 (the effective date of these damages provisions), unless that day is a Federal holiday or Sunday in which case it will fall to the next business day.

(2) The date of filing is the actual date of receipt by the CBIC of a completed claim that includes all the information required by this rule.

(c) *Information that must be included in a claim.* (1) Supplier's name, name of authorized official, U.S. Post Office mailing address, phone number, email address and bidding number, and National Supplier Clearinghouse Number;

(2) A copy of the signed contract entered into with CMS for the Round 1 DMEPOS Competitive Bidding Program;

(3) A detailed explanation of the damages incurred by this supplier as a direct result of the termination of the Round 1 competitive bid contract by MIPPA. The explanation must include all of the following:

(i) Documentation of the supplier's damages through receipts.

(ii) Records that substantiate the supplier's damages and demonstrate that the damages are directly related to performance of the Round 1 contract and are consistent with information the supplier provided as part of their bid.

(4) The supplier must explain how it would be damaged if not reimbursed.

(5) The claim must document steps the supplier took to mitigate any damages they may have incurred due to the contract termination, including a detailed explanation of the steps of all attempts to use for other purposes, return or dispose of equipment or other assets purchased or rented for the use in the Round 1 DMEPOS CBP contract performance.

(d) *Items that will not be considered in a claim.* The following items will not be considered in a claim:

(1) The cost of submitting a bid.

(2) Any fees or costs incurred for consulting or marketing.

(3) Costs associated with accreditation or licensure.

(4) Costs incurred before March 20, 2008.

(5) Costs incurred for contract performance after July 14, 2008 except for costs incurred to mitigate damages.

(6) Any profits a supplier may have expected from the contract.

(7) Costs that would have occurred without a contract having been awarded.

(8) Costs for items such as inventory, delivery vehicles, office space and equipment, personnel, which the supplier did not purchase specifically to perform the contract.

(9) Costs that the supplier has recouped by any means, and may include use of personnel, material, suppliers, or equipment in the supplier's business operations.

(e) *Filing a claim.* (1) A claim, with all supporting documentation, must be filed with the CMS Competitive Bidding Implementation Contractor (CBIC).

(2) Claims must include a statement from a supplier's authorized official certifying the accuracy of the information provided on the claim and all supporting documentation.

(3) The CBIC does not accept electronic submissions of claims for damages.

(f) *Review of claim.* (1) *Role of the CBIC.* (i) The CBIC will review the claim to ensure it is submitted timely,

complete, and by an eligible claimant. When the CBIC identifies that a claim is incomplete or not filed timely, it will make a recommendation to the Determining Authority not to process the claim further. Incomplete or untimely claims may be dismissed by the Determining Authority without further processing.

(ii) For complete, timely claims, the CBIC will review the claim on its merits to determine if damages are warranted and may seek further information from the claimant when making its recommendation to the Determining Authority. The CBIC may set a deadline for receipt of additional information. A claimant's failure to respond timely may result in a denial of the claim.

(iii) The CBIC will make a recommendation to the Determining Authority for each claim filed and include an explanation that supports its recommendation.

(iv) The recommendation must be either to award damages for a particular amount (which may not be the same amount requested by the claimant) or that no damages should be awarded.

(A) If the CBIC recommends that damages are warranted, the CBIC will calculate a recommended reasonable amount of damages based on the claim submitted.

(B) The reasonable amount will consider both costs incurred and the contractor's attempts and action to limit the damages;

(v) The recommendation will be sent to the Determining Authority for a final determination.

(2) *CMS' role as the Determining Authority*. (i) The Determining Authority shall review the recommendation of the CBIC.

(ii) The Determining Authority may seek further information from the claimant or the CBIC in making a concurrence or non-concurrence determination.

(iii) The Determining Authority may set a deadline for receipt of additional information. A claimant's failure to respond timely may result in a denial of the claim.

(iv) If the Determining Authority concurs with the CBIC recommendation, the Determining Authority shall submit a final signed decision to the CBIC and direct the CBIC to notify the claimant of the decision and the reasons for the final decision.

(v) If the Determining Authority non-concurs with the CBIC recommendation, the Determining Authority may return the claim for further processing or the Determining Authority may:

(A) Write a determination granting (in whole or in part) a claim for damages or denying a claim in its entirety;

(B) Direct the CBIC to write said determination for the Determining Authority's signature; or

(C) Return the claim to the CBIC with further instructions.

(vi) The Determining Authority's determination is final and not subject to administrative or judicial review.

(g) *Timeframe for determinations*. (1) Every effort will be made to make a determination within 120 days of initial receipt of the claim for damages by the CBIC or the receipt of additional information that was requested by the CBIC, whichever is later.

(2) In the case of more complex cases, or in the event of a large workload, a decision will be issued as soon as practicable.

(h) *Notification to claimant of damage determination*. The CBIC must mail the Determining Authority's determination to the claimant by certified mail return receipt requested, at the address provided in the claim.

[74 FR 62011, Nov. 25, 2009]

§414.426 Adjustments to competitively bid payment amounts to reflect changes in the HCPCS.

If a HCPCS code for a competitively bid item is revised after the contract period for a competitive bidding program begins, CMS adjusts the single payment amount for that item as follows:

(a) If a single HCPCS code for an item is divided into two or more HCPCS codes for the components of that item, the sum of single payment amounts for the new HCPCS codes equals the single payment amount for the original item. Contract suppliers must furnish the components of the item and submit claims using the new HCPCS codes.

(b) If a single HCPCS code is divided into two or more separate HCPCS codes, the single payment amount for each of the new separate HCPCS codes is equal to the single payment amount applied to the single HCPCS code. Contract suppliers must furnish the items and submit claims using the new separate HCPCS codes.

(c) If the HCPCS codes for components of an item are merged into a single HCPCS code for the item, the single payment amount for the new HCPCS code is equal to the total of the separate single payment amounts for the components. Contract suppliers must furnish the item and submit claims using the new HCPCS code.

(d) If multiple HCPCS codes for similar items are merged into a single HCPCS code, the items to which the new HCPCS codes apply may be furnished by any supplier that has a valid Medicare billing number. Payment for these items will be made in accordance with Subpart C or Subpart D.

[72 FR 18085, Apr. 10, 2007]

Subpart G—Payment for Clinical Diagnostic Laboratory Tests

SOURCE: 71 FR 69786, Dec. 1, 2006, unless otherwise noted.

§ 414.500 Basis and scope.

This subpart implements provisions of 1833(h)(8) of the Act and 1834A of the Act—procedures for determining the basis for, and amount of, payment for a clinical diagnostic laboratory test (CDLT).

[81 FR 41098, June 23, 2016]

§ 414.502 Definitions.

For purposes of this subpart—

Actual list charge means the publicly available rate on the first day the new advanced diagnostic laboratory test (ADLT) is obtainable by a patient who is covered by private insurance, or marketed to the public as a test a patient can receive, even if the test has not yet been performed on that date.

Advanced diagnostic laboratory test (ADLT) means a clinical diagnostic laboratory test (CDLT) covered under Medicare Part B that is offered and furnished only by a single laboratory and not sold for use by a laboratory other than the single laboratory that designed the test or a successor owner of that laboratory, and meets one of the following criteria:

(1) The test—

(i) Is an analysis of multiple biomarkers of deoxyribonucleic acid (DNA), ribonucleic acid (RNA), or proteins;

(ii) When combined with an empirically derived algorithm, yields a result that predicts the probability a specific individual patient will develop a certain condition(s) or respond to a particular therapy(ies);

(iii) Provides new clinical diagnostic information that cannot be obtained from any other test or combination of tests; and

(iv) May include other assays.

(2) The test is cleared or approved by the Food and Drug Administration.

Applicable information, with respect to each CDLT for a data collection period:

(1) Means—

(i) Each private payor rate for which final payment has been made during the data collection period;

(ii) The associated volume of tests performed corresponding to each private payor rate; and

(iii) The specific Healthcare Common Procedure Coding System (HCPCS) code associated with the test.

(2) Does not include information about a test for which payment is made on a capitated basis.

Applicable laboratory means an entity that:

(1) Is a laboratory, as defined in § 493.2 of this chapter;

(2) Bills Medicare Part B under its own National Provider Identifier (NPI);

(i) For hospital outreach laboratories—bills Medicare Part B on the CMS 1450 under bill type 14x;

(ii) [Reserved]

(3) In a data collection period, receives more than 50 percent of its Medicare revenues, which includes fee-for-service payments under Medicare Parts A and B, prescription drug payments under Medicare Part D, and any associated Medicare beneficiary deductible or coinsurance for services furnished during the data collection period from one or a combination of the following sources:

(i) This subpart G.

(ii) Subpart B of this part.

(4) Receives at least $12,500 of its Medicare revenues from this subpart G. Except, for a single laboratory that offers and furnishes an ADLT, this $12,500 threshold—

(i) Does not apply with respect to the ADLTs it offers and furnishes; and

(ii) Applies with respect to all the other CDLTs it furnishes.

Blood bank or center means an entity whose primary function is the performance or responsibility for the performance of, the collection, processing, testing, storage and/or distribution of blood or blood components intended for transfusion and transplantation.

Data collection period is the 6 months from January 1 through June 30, during which applicable information is collected and that precedes the data reporting period, except that for the data reporting period of January 1, 2026, through March 31, 2026, the data collection period is January 1, 2019, through June 30, 2019.

Data reporting period is the 3-month period, January 1 through March 31, during which a reporting entity reports applicable information to CMS and that follows the preceding data collection period, except that for the data collection period of January 1, 2019, through June 30, 2019, the data reporting period is January 1, 2026, through March 31, 2026.

National Provider Identifier (NPI) means the standard unique health identifier used by health care providers for billing payors, assigned by the National Plan and Provider Enumeration System (NPPES) in 45 CFR part 162.

New advanced diagnostic laboratory test (ADLT) means an ADLT for which payment has not been made under the clinical laboratory fee schedule prior to January 1, 2018.

New ADLT initial period means a period of 3 calendar quarters that begins on the first day of the first full calendar quarter following the later of the date a Medicare Part B coverage determination is made or ADLT status is granted by CMS.

New clinical diagnostic laboratory test (CDLT) means a CDLT that is assigned a new or substantially revised Healthcare Common Procedure Coding System (HCPCS) code, and that does not meet the definition of an ADLT.

New test means any clinical diagnostic laboratory test for which a new or substantially revised Healthcare Common Procedure Coding System Code is assigned on or after January 1, 2005.

Private payor means:

(1) A health insurance issuer, as defined in section 2791(b)(2) of the Public Health Service Act.

(2) A group health plan, as defined in section 2791(a)(1) of the Public Health Service Act.

(3) A Medicare Advantage plan under Medicare Part C, as defined in section 1859(b)(1) of the Act.

(4) A Medicaid managed care organization, as defined in section 1903(m)(1)(A) of the Act.

Private payor rate, with respect to applicable information:

(1) Is the final amount that is paid by a private payor for a CDLT after all private payor price concessions are applied and does not include price concessions applied by a laboratory.

(2) Includes any patient cost sharing amounts, if applicable.

(3) Does not include information about denied payments.

Publicly available rate means the lowest amount charged for an ADLT that is readily accessible in such forums as a company Web site, test registry, or price listing, to anyone seeking to know how much a patient who does not have the benefit of a negotiated rate would pay for the test.

Reporting entity is the entity that reports tax-related information to the Internal Revenue Service (IRS) using its Taxpayer Identification Number (TIN) for its components that are applicable laboratories.

Single laboratory, for purposes of an ADLT, means:

(1) The laboratory, as defined in 42 CFR 493.2, which furnishes the test, and that may also design, offer, or sell the test; and

(2) The following entities, which may design, offer, or sell the test:

(i) The entity that owns the laboratory.

(ii) The entity that is owned by the laboratory.

Specific HCPCS code means a HCPCS code that does not include an unlisted CPT code, as established by the American Medical Association, or a Not Otherwise Classified (NOC) code, as established by the CMS HCPCS Workgroup.

Substantially Revised Healthcare Common Procedure Coding System Code means a code for which there has been a substantive change to the definition of the test or procedure to which the code applies (such as a new analyte or a new methodology for measuring an existing analyte specific test).

Successor owner, for purposes of an ADLT, means a single laboratory, that has assumed ownership of the single laboratory that designed the test or of the single laboratory that is a successor owner to the single laboratory that designed the test, through any of the following circumstances:

(1) *Partnership.* The removal, addition, or substitution of a partner, unless the partners expressly agree otherwise, as permitted by applicable State law.

(2) *Unincorporated sole proprietorship.* Transfer of title and property to another party.

(3) *Corporation.* The merger of the single laboratory corporation into another corporation, or the consolidation of two or more corporations, including the single laboratory, resulting in the creation of a new corporation. Transfer of corporate stock or the merger of another corporation into the single laboratory corporation does not constitute change of ownership.

Taxpayer Identification Number (TIN) means a Federal taxpayer identification number or employer identification number as defined by the IRS in 26 CFR 301.6109–1.

[71 FR 69786, Dec. 1, 2006, as amended at 72 FR 66401, Nov. 27, 2007; 81 FR 41098, June 23, 2016; 83 FR 60074, Nov. 23, 2018; 84 FR 61490, Nov. 12, 2019; 85 FR 85028, Dec. 28, 2020; 87 FR 70225, Nov. 18, 2022; 88 FR 79531, Nov. 16, 2023; 89 FR 98559, Dec. 9, 2024]

§ 414.504 Data reporting requirements.

(a) In a data reporting period, a reporting entity must report applicable information for each CDLT furnished by its component applicable laboratories during the corresponding data collection period, as follows—

(1) For CDLTs that are not ADLTs, initially January 1, 2017 and every 3 years beginning January 1, 2026.

(2) For ADLTs that are not new ADLTs, every year beginning January 1, 2017.

(3) For new ADLTs—

(i) Initially, no later than the last day of the second quarter of the new ADLT initial period; and

(ii) Thereafter, every year.

(b) Applicable information must be reported in the form and manner specified by CMS.

(c) A laboratory seeking new ADLT status for its test must, in its new ADLT application, attest to the actual list charge.

(d) To certify data integrity, the President, CEO, or CFO of a reporting entity, or an individual who has been delegated authority to sign for, and who reports directly to, such an officer, must sign the certification statement and be responsible for assuring that the data provided are accurate, complete, and truthful, and meets all the reporting parameters described in this section.

(e) If the Secretary determines that a reporting entity has failed to report applicable information for its applicable laboratories, or made a misrepresentation or omission in reporting applicable information for its applicable laboratories, the Secretary may apply a civil monetary penalty to a reporting entity in an amount of up to $10,000 per day, as amended by the Federal Civil Penalties Inflation Adjustment Act Improvements Act of 2015 (Sec. 701 of the Bipartisan Budget Act of 2015, Pub. L. 114–74, November 2, 2015), for each failure to report or each such misrepresentation or omission. The provisions for civil monetary penalties that apply in general to the Medicare program under 42 U.S.C. 1320a–7b apply in the same manner to the laboratory data reporting process under this section.

(f) CMS or its contractors will not disclose applicable information reported to CMS under this section in a manner that would identify a specific payor or laboratory, or prices charged or payments made to a laboratory, except to permit the Comptroller General, the Director of the Congressional

Budget Office, and the Medicare Payment Advisory Commission, to review the information, or as CMS determines is necessary to implement this subpart, such as disclosures to the HHS Office of Inspector General or the Department of Justice for oversight and enforcement activities.

(g) Applicable information may not be reported for an entity that does not meet the definition of an applicable laboratory. For a single laboratory that offers and furnishes an ADLT that is not an applicable laboratory except with respect to its ADLTs, the applicable information of its CDLTs that are not ADLTs may not be reported.

[81 FR 41099, June 23, 2016, as amended at 85 FR 85028, Dec. 28, 2020; 87 FR 70225, Nov. 18, 2022; 88 FR 79531, Nov. 16, 2023; 89 FR 98559, Dec. 9, 2024]

§414.506 Procedures for public consultation for payment for a new clinical diagnostic laboratory test.

For a new CDLT, CMS determines the basis for and amount of payment after performance of the following:

(a) CMS makes available to the public (through CMS's Internet Web site) a list that includes codes for which establishment of a payment amount is being considered for the next calendar year.

(b) CMS publishes a FEDERAL REGISTER notice of a meeting to receive public comments and recommendations (and data on which recommendations are based) on the appropriate basis, as specified in §414.508, for establishing payment amounts for the list of codes made available to the public.

(c) Not fewer than 30 days after publication of the notice in the FEDERAL REGISTER, CMS convenes a meeting that includes representatives of CMS officials involved in determining payment amounts, to receive public comments and recommendations (and data on which the recommendations are based).

(d) Considering the comments and recommendations (and accompanying data) received at the public meeting, CMS develops and makes available to the public (through an Internet Web site and other appropriate mechanisms) a list of—

(1) Proposed determinations with respect to the appropriate basis for establishing a payment amount for each code, with an explanation of the reasons for each determination, the data on which the determinations are based, including recommendations from the Advisory Panel on CDLTs described in paragraph (e) of this section, and a request for written public comments within a specified time period on the proposed determination; and

(2) Final determinations of the payment amounts for tests, with the rationale for each determination, the data on which the determinations are based, and responses to comments and suggestions from the public.

(3) On or after January 1, 2018, in applying paragraphs (d)(1) and (2) of this section, CMS will provide an explanation of how it took into account the recommendations of the Advisory Panel on CDLTs described in paragraph (e) of this section.

(4) On or after January 1, 2018, in applying paragraphs (d)(1) and (2) of this section and §414.509(b)(2)(i) and (iii) when CMS uses the gapfilling method described in §414.508(b)(2), CMS will make available to the public an explanation of the payment rate for the test.

(e) CMS will consult with an expert outside advisory panel, called the Advisory Panel on CDLTs, composed of an appropriate selection of individuals with expertise, which may include molecular pathologists researchers, and individuals with expertise in laboratory science or health economics, in issues related to CDLTs. This advisory panel will provide input on the establishment of payment rates under §414.508 and provide recommendations to CMS under this subpart.

[71 FR 69786, Dec. 1, 2006, as amended at 72 FR 66401, Nov. 27, 2007; 81 FR 41099, June 23, 2016]

§414.507 Payment for clinical diagnostic laboratory tests.

(a) *General rule.* Except as provided in paragraph (d) of this section, and §§414.508 and 414.522, the payment rate for a CDLT furnished on or after January 1, 2018, is equal to the weighted median for the test, as calculated under paragraph (b) of this section. Each payment rate will be in effect for a period

of one calendar year for ADLTs and three calendar years for all other CDLTs, until the year following the next data collection period.

(b) *Methodology*. For each test under paragraph (a) of this section for which applicable information is reported, the weighted median is calculated by arraying the distribution of all private payor rates, weighted by the volume for each payor and each laboratory.

(c) The payment amounts established under this section are not subject to any adjustment, such as geographic, budget neutrality, annual update, or other adjustment.

(d) *Phase-in of payment reductions*. For years 2018 through 2028, the payment rates established under this section for each CDLT that is not a new ADLT or new CDLT, may not be reduced by more than the following amounts for—

(1) 2018—10 percent of the national limitation amount for the test in 2017.

(2) 2019—10 percent of the payment rate established in 2018.

(3) 2020—10 percent of the payment rate established in 2019.

(4) 2021—0.0 percent of the payment rate established in 2020.

(5) 2022—0.0 percent of the payment rate established in 2021.

(6) 2023–0.0 percent of the payment rate established in 2022.

(7) 2024—0.0 percent of the payment rate established in 2023.

(8) 2025—0.0 percent of the payment rate established in 2024.

(9) 2026—15 percent of the payment rate established in 2025.

(10) 2027—15 percent of the payment rate established in 2026.

(11) 2028—15 percent of the payment rate established in 2027.

(e) There is no administrative or judicial review under sections 1869 and 1878 of the Social Security Act, or otherwise, of the payment rates established under this subpart.

(f) For a CDLT for which CMS receives no applicable information, payment is made based on the crosswalking or gapfilling methods described in § 414.508(b)(1) and (2).

(g) For ADLTs that are furnished between April 1, 2014 and December 31, 2017, payment is based on the crosswalking or gapfilling methods described in § 414.508(a).

[81 FR 41099, June 23, 2016, as amended at 85 FR 85028, Dec. 28, 2020; 87 FR 70225, Nov. 18, 2022; 88 FR 79531, Nov. 16, 2023; 89 FR 98559, Dec. 9, 2024]

§ 414.508 Payment for a new clinical diagnostic laboratory test.

(a) For a new CDLT that is assigned a new or substantially revised code between January 1, 2005 and December 31, 2017, CMS determines the payment amount based on either of the following:

(1) *Crosswalking*. Crosswalking is used if it is determined that a new CDLT is comparable to an existing test, multiple existing test codes, or a portion of an existing test code.

(i) CMS assigns to the new CDLT code, the local fee schedule amounts and national limitation amount of the existing test.

(ii) Payment for the new CDLT code is made at the lesser of the local fee schedule amount or the national limitation amount.

(2) *Gapfilling*. Gapfilling is used when no comparable existing CDLT is available.

(i) In the first year, Medicare Administrative Contractor-specific amounts are established for the new CDLT code using the following sources of information to determine gapfill amounts, if available:

(A) Charges for the CDLT and routine discounts to charges;

(B) Resources required to perform the CDLT;

(C) Payment amounts determined by other payors; and

(D) Charges, payment amounts, and resources required for other tests that may be comparable or otherwise relevant.

(ii) In the second year, the test code is paid at the national limitation amount, which is the median of the contractor-specific amounts.

(iii) For a new CDLT for which a new or substantially revised HCPCS code was assigned on or before December 31, 2007, after the first year of gapfilling, CMS determines whether the contractor-specific amounts will pay for the test appropriately. If CMS determines that the contractor-specific

amounts will not pay for the test appropriately, CMS may crosswalk the test.

(b) For a new CDLT that is assigned a new or substantially revised HCPCS code on or after January 1, 2018, CMS determines the payment amount based on either of the following until applicable information is available to establish a payment amount under the methodology described in §414.507(b):

(1) *Crosswalking.* Crosswalking is used if it is determined that a new CDLT is comparable to an existing test, multiple existing test codes, or a portion of an existing test code.

(i) CMS assigns to the new CDLT code, the payment amount established under §414.507 of the comparable existing CDLT.

(ii) Payment for the new CDLT code is made at the payment amount established under §414.507.

(2) *Gapfilling.* Gapfilling is used when no comparable existing CDLT is available.

(i) In the first year, Medicare Administrative Contractor-specific amounts are established for the new CDLT code using the following sources of information to determine gapfill amounts, if available:

(A) Charges for the test and routine discounts to charges;

(B) Resources required to perform the test;

(C) Payment amounts determined by other payors;

(D) Charges, payment amounts, and resources required for other tests that may be comparable or otherwise relevant; and

(E) Other criteria CMS determines appropriate.

(ii) In the second year, the CDLT code is paid at the median of the Medicare Administrative Contractor-specific amounts.

[81 FR 41100, June 23, 2016]

§414.509 Reconsideration of basis for and amount of payment for a new clinical diagnostic laboratory test.

For a new CDLT, the following reconsideration procedures apply:

(a) *Reconsideration of basis for payment.* (1) CMS will receive reconsideration requests in written format for 60 days after making a determination of the basis for payment under §414.506(d)(2) regarding whether CMS should reconsider the basis for payment and why a different basis for payment would be more appropriate. If a requestor recommends that the basis for payment should be changed from gapfilling to crosswalking, the requestor may also recommend the code or codes to which to crosswalk the new test.

(2)(i) A requestor that submitted a request under paragraph (a)(1) of this section may also present its reconsideration request at the public meeting convened under §414.506(c), provided that the requestor requests an opportunity to present at the public meeting as part of its written submission under paragraph (a)(1) of this section.

(ii) If the requestor presents its reconsideration request at the public meeting convened under §414.506(c), members of the public may comment on the reconsideration request verbally at the public meeting and may submit written comments after the public meeting (within the timeframe for public comments established by CMS).

(3) Considering reconsideration requests and other comments received, CMS may reconsider its determination of the basis for payment. As the result of such a reconsideration, CMS may change the basis for payment from crosswalking to gapfilling or from gapfilling to crosswalking.

(4) If the basis for payment is revised as the result of a reconsideration, the new basis for payment is final and is not subject to further reconsideration.

(b) *Reconsideration of amount of payment*—(1) *Crosswalking.* (i) For 60 days after making a determination under §414.506(d)(2) of the code or codes to which a new test will be crosswalked, CMS receives reconsideration requests in written format regarding whether CMS should reconsider its determination and the recommended code or codes to which to crosswalk the new test.

(ii)(A) A requestor that submitted a request under paragraph (b)(1)(i) of this section may also present its reconsideration request at the public meeting convened under §414.506(c), provided that the requestor requests an opportunity to present at the public meeting

as part of its written submission under paragraph (b)(1)(i) of this section.

(B) If a requestor presents its reconsideration request at the public meeting convened under §414.506(c), members of the public may comment on the reconsideration request verbally at the public meeting and may submit written comments after the public meeting (within the timeframe for public comments established by CMS).

(iii) Considering comments received, CMS may reconsider its determination of the amount of payment. As the result of such a reconsideration, CMS may change the code or codes to which the new test is crosswalked.

(iv) If CMS changes the basis for payment from gapfilling to crosswalking as a result of a reconsideration, the crosswalked amount of payment is not subject to reconsideration.

(2) *Gapfilling.* (i) By April 30 of the year after CMS makes a determination under §414.506(d)(2) or paragraph (a)(3) of this section that the basis for payment for a CDLT will be gapfilling, CMS posts interim Medicare Administrative Contractor-specific amounts on the CMS Web site.

(ii) For 60 days after CMS posts interim Medicare Administrative Contractor-specific amounts on the CMS Web site, CMS will receive public comments in written format regarding the interim Medicare Administrative Contractor-specific amounts.

(iii) After considering the public comments, CMS will post final Medicare Administrative Contractor-specific amounts on the CMS Web site.

(iv) For 30 days after CMS posts final Medicare Administrative Contractor-specific payment amounts on the CMS Web site, CMS will receive reconsideration requests in written format regarding whether CMS should reconsider the final Medicare Administrative Contractor-specific payment amount and median of the Medicare Administrative Contractor-specific payment amount for the CDLT.

(v) Considering reconsideration requests received, CMS may reconsider its determination of the amount of payment. As the result of a reconsideration, CMS may revise the median of the Medicare Administrative Contractor-specific payment amount for the CDLT.

(3) For both gapfilled and crosswalked new tests, if CMS revises the amount of payment as the result of a reconsideration, the new amount of payment is final and is not subject to further reconsideration.

(c) *Effective date.* If CMS changes a determination as the result of a reconsideration, the new determination regarding the basis for or amount of payment is effective January 1 of the year following reconsideration. Claims for services with dates of service prior to the effective date will not be reopened or otherwise reprocessed.

(d) *Jurisdiction for reconsideration decisions.* Jurisdiction for reconsidering a determination rests exclusively with the Secretary. A decision whether to reconsider a determination is committed to the discretion of the Secretary. A decision not to reconsider an initial determination is not subject to administrative or judicial review.

[72 FR 66401, Nov. 27, 2007, as amended at 73 FR 2432, Jan. 15, 2008; 81 FR 41100, June 23, 2016]

§414.510 Laboratory date of service for clinical laboratory and pathology specimens.

The date of service for either a clinical laboratory test or the technical component of physician pathology service is as follows:

(a) Except as provided under paragraph (b) of this section, the date of service of the test must be the date the specimen was collected.

(b)(1) If a specimen was collected over a period that spans 2 calendar days, then the date of service must be the date the collection ended.

(2) In the case of a test performed on a stored specimen, if a specimen was stored for—

(i) Less than or equal to 30 calendar days from the date it was collected, the date of service of the test must be the date the test was performed only if—

(A) The test is ordered by the patient's physician at least 14 days following the date of the patient's discharge from the hospital;

(B) The specimen was collected while the patient was undergoing a hospital surgical procedure;

(C) It would be medically inappropriate to have collected the sample other than during the hospital procedure for which the patient was admitted;

(D) The results of the test do not guide treatment provided during the hospital stay; and

(E) The test was reasonable and medically necessary for the treatment of an illness.

(ii) More than 30 calendar days before testing, the specimen is considered to have been archived and the date of service of the test must be the date the specimen was obtained from storage.

(3) In the case of a chemotherapy sensitivity test performed on live tissue, the date of service of the test must be the date the test was performed only if—

(i) The decision regarding the specific chemotherapeutic agents to test is made at least 14 days after discharge;

(ii) The specimen was collected while the patient was undergoing a hospital surgical procedure;

(iii) It would be medically inappropriate to have collected the sample other than during the hospital procedure for which the patient was admitted;

(iv) The results of the test do not guide treatment provided during the hospital stay; and,

(v) The test was reasonable and medically necessary for the treatment of an illness.

(4) For purposes of this section, ''chemotherapy sensitivity test'' means a test identified by the Secretary as a test that requires a fresh tissue sample to test the sensitivity of tumor cells to various chemotherapeutic agents. The Secretary identifies such tests through program instructions.

(5) In the case of a molecular pathology test performed by a laboratory other than a blood bank or center, a test designated by CMS as an ADLT under paragraph (1) of the definition of an advanced diagnostic laboratory test in § 414.502, a test that is a cancer-related protein-based Multianalyte Assays with Algorithmic Analyses, or the test described by CPT code 81490, the date of service of the test must be the date the test was performed only if—

(i) The test was performed following a hospital outpatient's discharge from the hospital outpatient department;

(ii) The specimen was collected from a hospital outpatient during an encounter (as both are defined in § 410.2 of this chapter);

(iii) It was medically appropriate to have collected the sample from the hospital outpatient during the hospital outpatient encounter;

(iv) The results of the test do not guide treatment provided during the hospital outpatient encounter; and

(v) The test was reasonable and medically necessary for the treatment of an illness.

[71 FR 69786, Dec. 1, 2006, as amended at 72 FR 66402, Nov. 27, 2007; 82 FR 52636, Nov. 13, 2017; 82 FR 59496, Dec. 14, 2017; 84 FR 61490, Nov. 12, 2019; 85 FR 86301, Dec. 29, 2020]

§ 414.522 Payment for new advanced diagnostic laboratory tests.

(a) The payment rate for a new ADLT—

(1) During the new ADLT initial period, is equal to its actual list charge.

(2) Prior to the new ADLT initial period, is determined by the Medicare Administrative Contractor based on information provided by the laboratory seeking new ADLT status for its laboratory test.

(b) After the new ADLT initial period, the payment rate for a new ADLT is equal to the weighted median established under the payment methodology described in § 414.507(b).

(c) If, after the new ADLT initial period, the actual list charge of a new ADLT is greater than 130 percent of the weighted median established under the payment methodology described in § 414.507, CMS will recoup the difference between the ADLT actual list charge and 130 percent of the weighted median.

(d) If CMS does not receive any applicable information for a new ADLT by the last day of the second quarter of the new ADLT initial period, the payment rate for the test is determined either by the gapfilling or crosswalking method as described in § 414.508(b)(1) and (2).

[81 FR 41100, June 23, 2016]

§ 414.523 Payment for laboratory specimen collection fee and travel allowance.

(a) *Specimen collection fee and travel allowance.* In addition to the payment amounts provided under this subpart for CDLTs, new CDLTs, and new ADLTs, CMS pays a specimen collection fee, as set forth in paragraph (a)(1) of this section, and a travel allowance, as set forth in paragraph (a)(2) of this section.

(1) *Payment for specimen collection.* Except as provided in paragraph (a)(1)(v) of this section and subject to the annual update in paragraph (a)(1)(iv) of this section, beginning January 1, 2023, CMS pays $8.57 for all specimens collected in one patient encounter, where the specimen(s) is:

(i) Used to perform a CDLT paid under this subpart G;

(ii) Collected by a trained technician from a Medicare beneficiary who is——

(A) Homebound as described in 42 CFR 424.22(a)(1)(ii).

(B) A non-hospital inpatient, but only when no qualified personnel are available at the facility to collect the specimen;

(iii) Of the following type—

(A) Blood specimen collected through venipuncture.

(B) A urine sample collected by catheterization.

(iv) Beginning January 1, 2024, CMS updates the specimen collection fee amount under paragraph (a)(1) of this section for each calendar year by the percent change in the Consumer Price Index for All Urban Consumers (CPI–U) (U.S. city average) for the 12-month period ending June 30th of the year preceding the update year.

(v) For a specimen collected from a Medicare beneficiary.

(2) *Payment for travel allowance*—(i) *General requirement.* CMS pays a travel allowance, as calculated under paragraph (a)(2)(iii) of this section, where the specimen is one for which a specimen collection fee is paid under paragraph (a)(1) of this section.

(ii) *Travel allowance basis.* CMS pays a travel allowance on the following bases:

(A) *Flat-rate travel allowance.* The flat-rate travel allowance applies when the trained technician travels 20 eligible miles or less (calculated in accordance with paragraph (a)(2)(iii)(A) of this section) to and from one location for specimen collection from one or more Medicare beneficiaries; or

(B) *Per-mile travel allowance.* The per-mile travel allowance applies when:

(*1*) The trained technician travels more than 20 eligible miles (calculated in accordance with paragraph (a)(2)(iii)(A) of this section) to and from one location for specimen collection from one or more Medicare beneficiaries; or

(*2*) The trained technician travels to more than one location for specimen collection from more than one Medicare beneficiary.

(iii) *Travel allowance amount*—(A) *Eligible miles.* Eligible miles begin at the laboratory or the starting point of the technician's travel for specimen collection as specified in paragraph (a)(1) of this section, and end at the laboratory or the ending point of the technician's travel for specimen collection as specified in paragraph (a)(1) of this section. Eligible miles do not include miles traveled for any purpose unrelated to specimen collection as specified in paragraph (a)(1) of this section, such as collecting specimens from non-Medicare beneficiaries or for personal reasons.

(B) *Travel allowance mileage rate.* The travel allowance mileage rate is equal to the IRS standard mileage rate plus an amount to cover expenses for a trained technician equal to the most recent median hourly wage for phlebotomists, as published by the United States Bureau of Labor Statistics, divided by 40 to represent an average miles-per-hour driving speed.

(C) *Travel allowance amount calculation.* (*1*) For the flat-rate travel allowance basis specified in paragraph (a)(2)(ii)(A) of this section, the travel allowance amount is the travel allowance mileage rate specified in paragraph (a)(2)(iii)(B) of this section multiplied by ten, divided by the number of beneficiaries for whom a specimen collection fee is paid under paragraph (a)(1) of this section.

(*2*) For the per-mile travel allowance basis specified in paragraph (a)(2)(ii)(B) of this section, the travel allowance amount is the number of eligible miles

multiplied by the travel allowance mileage rate specified in paragraph (a)(2)(iii)(B) of this section, divided by the number of beneficiaries for whom a specimen collection fee is paid under paragraph (a)(1) of this section.

(b) [Reserved]

[87 FR 70225, Nov. 18, 2022]

Subpart H—Fee Schedule for Ambulance Services

SOURCE: 67 FR 9132, Feb. 27, 2002, unless otherwise noted.

§ 414.601 Purpose.

This subpart implements section 1834(l) of the Act by establishing a fee schedule for the payment of ambulance services. Section 1834(l) of the Act requires that, except for services furnished by certain critical access hospitals (see § 413.70(b)(5) of this chapter), payment for all ambulance services, otherwise previously payable on a reasonable charge basis or retrospective reasonable cost basis, be made under a fee schedule. Section 1834(l)(17) of the Act requires the development of a data collection system to collect cost, revenue, utilization, and other information determined appropriate from providers of services and suppliers of ground ambulance services.

[67 FR 9132, Feb. 27, 2002, as amended at 84 FR 63193, Nov. 15, 2019]

§ 414.605 Definitions.

As used in this subpart, the following definitions apply to both land and water (hereafter collectively referred to as ''ground'') ambulance services and to air ambulance services unless otherwise specified:

Advanced life support (ALS) assessment is an assessment performed by an ALS crew as part of an emergency response that was necessary because the patient's reported condition at the time of dispatch was such that only an ALS crew was qualified to perform the assessment. An ALS assessment does not necessarily result in a determination that the patient requires an ALS level of service.

Advanced life support (ALS) intervention means a procedure that is, in accordance with State and local laws, required to be furnished by ALS personnel.

Advanced life support, level 1 (ALS1) means transportation by ground ambulance vehicle, medically necessary supplies and services and either an ALS assessment by ALS personnel or the provision of at least one ALS intervention.

Advanced life support, level 2 (ALS2) means either transportation by ground ambulance vehicle, medically necessary supplies and services, and the administration of at least three medications by intravenous push/bolus or by continuous infusion, excluding crystalloid, hypotonic, isotonic, and hypertonic solutions (Dextrose, Normal Saline, Ringer's Lactate); or transportation, medically necessary supplies and services, and the provision of at least one of the following ALS procedures:

(1) Manual defibrillation/cardioversion.

(2) Endotracheal intubation.

(3) Central venous line.

(4) Cardiac pacing.

(5) Chest decompression.

(6) Surgical airway.

(7) Intraosseous line.

(8) Prehospital blood transfusion which includes:

(i) Administration of low titer O+ and O− whole blood (WBT);

(ii) Administration of packed red blood cells (PRBCs);

(iii) Administration of plasma; or

(iv) Administration of a combination of PRBCs and plasma.

Advanced life support (ALS) personnel means an individual trained to the level of the emergency medical technician-intermediate (EMT-Intermediate) or paramedic. The EMT-Intermediate is defined as an individual who is qualified, in accordance with State and local laws, as an EMT-Basic and who is also qualified in accordance with State and local laws to perform essential advanced techniques and to administer a limited number of medications. The EMT-Paramedic is defined as possessing the qualifications of the EMT-Intermediate and also, in accordance with State and local laws, as having enhanced skills that include being able to administer additional interventions and medications.

Basic life support (BLS) means transportation by ground ambulance vehicle and medically necessary supplies and services, plus the provision of BLS ambulance services. The ambulance must be staffed by at least two people who meet the requirements of state and local laws where the services are being furnished. Also, at least one of the staff members must be certified, at a minimum, as an emergency medical technician-basic (EMT-Basic) by the State or local authority where the services are furnished and be legally authorized to operate all lifesaving and life-sustaining equipment on board the vehicle. These laws may vary from State to State.

Conversion factor (CF) is the dollar amount established by CMS that is multiplied by relative value units to produce ground ambulance service base rates.

Emergency response means responding immediately at the BLS or ALS1 level of service to a 911 call or the equivalent in areas without a 911 call system. An immediate response is one in which the ambulance entity begins as quickly as possible to take the steps necessary to respond to the call.

Fixed wing air ambulance (FW) means transportation by a fixed wing aircraft that is certified as a fixed wing air ambulance and such services and supplies as may be medically necessary.

Geographic adjustment factor (GAF) means the practice expense (PE) portion of the geographic practice cost index (GPCI) from the physician fee schedule as applied to a percentage of the base rate. For ground ambulance services, the PE portion of the GPCI is applied to 70 percent of the base rate for each level of service. For air ambulance services, the PE portion of the GPCI is applied to 50 percent of the applicable base rate.

Ground ambulance organization means a Medicare provider or supplier of ground ambulance services.

Loaded mileage means the number of miles the Medicare beneficiary is transported in the ambulance vehicle.

Paramedic ALS intercept (PI) means EMT-Paramedic services furnished by an entity that does not furnish the ground ambulance transport, provided the services meet the requirements specified in § 410.40(d) of this chapter.

Point of pick-up means the location of the beneficiary at the time he or she is placed on board the ambulance.

Relative value units (RVUs) means a value assigned to a ground ambulance service.

Rotary wing air ambulance (RW) means transportation by a helicopter that is certified as an ambulance and such services and supplies as may be medically necessary.

Rural adjustment factor (RAF) means an adjustment applied to the base payment rate when the point of pick-up is located in a rural area.

Rural area means an area located outside an urban area, or a rural census tract within a Metropolitan Statistical Area as determined under the most recent version of the Goldsmith modification as determined by the Office of Rural Health Policy of the Health Resources and Services Administration.

Specialty care transport (SCT) means interfacility transportation of a critically injured or ill beneficiary by a ground ambulance vehicle, including medically necessary supplies and services, at a level of service beyond the scope of the EMT-Paramedic. SCT is necessary when a beneficiary's condition requires ongoing care that must be furnished by one or more health professionals in an appropriate specialty area, for example, nursing, emergency medicine, respiratory care, cardiovascular care, or a paramedic with additional training.

Urban area means a Metropolitan Statistical Area, as defined by the Executive Office of Management and Budget.

[67 FR 9132, Feb. 27, 2002, as amended at 68 FR 67693, Dec. 5, 2003; 71 FR 69787, Dec. 1, 2006; 80 FR 71382, Nov. 16, 2015; 84 FR 63193, Nov. 15, 2019; 89 FR 98559, Dec. 9, 2024]

§ 414.610 Basis of payment.

(a) *Method of payment.* Medicare payment for ambulance services is based on the lesser of the actual charge or the applicable fee schedule amount. The fee schedule payment for ambulance services equals a base rate for the level of service plus payment for mileage and applicable adjustment factors.

Except for services furnished by certain critical access hospitals or entities owned and operated by them, as described in §413.70(b) of this chapter, all ambulance services are paid under the fee schedule specified in this subpart (regardless of the vehicle furnishing the service).

(b) *Mandatory assignment.* Effective with implementation of the ambulance fee schedule described in §414.601 (that is, for services furnished on or after April 1, 2002), all payments made for ambulance services are made only on an assignment-related basis. Ambulance suppliers must accept the Medicare allowed charge as payment in full and may not bill or collect from the beneficiary any amount other than the unmet Part B deductible and Part B coinsurance amounts. Violations of this requirement may subject the provider or supplier to sanctions, as provided by law (part 402 of this chapter).

(c) *Formula for computation of payment amounts.* The fee schedule payment amount for ambulance services is computed according to the following provisions:

(1) *Ground ambulance service levels.* The CF is multiplied by the applicable RVUs for each level of service to produce a service-level base rate.

(i) For services furnished during the period July 1, 2004 through December 31, 2006, ambulance services originating in—

(A) Urban areas (both base rate and mileage) are paid based on a rate that is 1 percent higher than otherwise is applicable under this section; and

(B) Rural areas (both base rate and mileage) are paid based on a rate that is 2 percent higher than otherwise is applicable under this section.

(ii) For services furnished during the period July 1, 2008 through December 31, 2024, ambulance services originating in:

(A) Urban areas (both base rate and mileage) are paid based on a rate that is 2 percent higher than otherwise is applicable under this section.

(B) Rural areas (both base rate and mileage) are paid based on a rate that is 3 percent higher than otherwise is applicable under this section.

(iii) The service-level base rate is then adjusted by the GAF. Compare this amount to the actual charge. The lesser of the actual charge or the GAF adjusted base rate amount is added to the lesser of the actual mileage charges or the payment rate per mile, multiplied by the number of miles that the beneficiary was transported. When applicable, the appropriate RAF is applied to the ground mileage rate to determine the appropriate payment rates. The RVU scale for the ambulance fee schedule is as follows:

Service level	Relative value units (RVUs)
BLS	1.00
BLS-Emergency	1.60
ALS1	1.20
ALS1-Emergency	1.90
ALS2	2.75
SCT	3.25
PI	1.75

(2) *Air ambulance service levels.* The base payment rate for the applicable type of air ambulance service is adjusted by the GAF and, when applicable, by the appropriate RAF to determine the amount of payment. Air ambulance services have no CF or RVUs. This amount is compared to the actual charge. The lesser of the charge or the adjusted GAF rate amount is added to the payment rate per mile, multiplied by the number of miles that the beneficiary was transported. When applicable, the appropriate RAF is also applied to the air mileage rate.

(3) *Loaded mileage.* Payment is based on loaded miles. Payment for air mileage is based on loaded miles flown as expressed in statute miles. There are three mileage payment rates: a rate for FW services, a rate for RW services, and a rate for all levels of ground transportation.

(4) *Geographic adjustment factor (GAF).* For ground ambulance services, the PE portion of the GPCI from the physician fee schedule is applied to 70 percent of the base rate for ground ambulance services. For air ambulance services, the PE portion of the physician fee schedule GPCI is applied to 50 percent of the base rate for air ambulance services.

(5) *Rural adjustment factor (RAF).* (i) For ground ambulance services where the point of pickup is in a rural area,

the mileage rate is increased by 50 percent for each of the first 17 miles and, for services furnished before January 1, 2004, by 25 percent for miles 18 through 50. The standard mileage rate applies to every mile over 50 miles and, for services furnished after December 31, 2003, to every mile over 17 miles. For air ambulance services where the point of pickup is in a rural area, the total payment is increased by 50 percent; that is, the rural adjustment factor applies to the sum of the base rate and the mileage rate.

(ii) For services furnished during the period July 1, 2004 through December 31, 2024, the payment amount for the ground ambulance base rate is increased by 22.6 percent where the point of pickup is in a rural area determined to be in the lowest 25 percent of rural population arrayed by population density. The amount of this increase is based on CMS's estimate of the ratio of the average cost per trip for the rural areas in the lowest quartile of population compared to the average cost per trip for the rural areas in the highest quartile of population. In making this estimate, CMS may use data provided by the GAO.

(6) *Multiple patients.* The allowable amount per beneficiary for a single ambulance transport when more than one patient is transported simultaneously is based on the total number of patients (both Medicare and non-Medicare) on board. If two patients are transported simultaneously, then the payment allowance for the beneficiary (or for each of them if both patients are beneficiaries) is equal to 75 percent of the service payment allowance applicable for the level of care furnished to the beneficiary, plus 50 percent of the applicable mileage payment allowance. If three or more patients are transported simultaneously, the payment allowance for the beneficiary (or each of them) is equal to 60 percent of the service payment allowance applicable for the level of care furnished to the beneficiary, plus the applicable mileage payment allowance divided by the number of patients on board.

(7) *Payment rate for mileage greater than 50 miles.* For services furnished during the period July 1, 2004 through December 31, 2008, each loaded ambulance mile greater than 50 (that is, miles 51 and greater) for ambulance transports originating in either urban areas or in rural areas are paid based on a rate that is 25 percent higher than otherwise is applicable under this section.

(8) *Transport of an individual with end-stage renal disease for renal dialysis services.* For ambulance services furnished during the period October 1, 2013 through September 30, 2018, consisting of non-emergency basic life support (BLS) services involving transport of an individual with end-stage renal disease for renal dialysis services (as described in section 1881(b)(14)(B) of the Act) furnished other than on an emergency basis by a provider of services or a renal dialysis facility, the fee schedule amount otherwise applicable (both base rate and mileage) is reduced by 10 percent. For such services furnished on or after October 1, 2018, the fee schedule amount otherwise applicable (both base rate and mileage) is reduced by 23 percent.

(9) *Payment reduction for failure to report data.* In the case of a ground ambulance organization (as defined at § 414.605) that is selected by CMS under § 414.626(c) for a year that does not sufficiently submit data under § 414.626(b) and is not granted a hardship exemption under § 414.626(d), the payments made under this section are reduced by 10 percent for the applicable period. For purposes of this paragraph, the applicable period is the calendar year that begins following the date that CMS provided written notification to the ground ambulance organization under § 414.626(e)(1) that the ground ambulance did not sufficiently submit the required data.

(d) *Payment.* Payment, in accordance with this subpart, represents payment in full (subject to applicable Medicare Part B deductible and coinsurance requirements as described in subpart G of part 409 of this chapter or in subpart I of part 410 of this chapter) for all services, supplies, and other costs for an ambulance service furnished to a Medicare beneficiary. No direct payment will be made under this subpart if billing for the ambulance service is required to be consolidated with billing

for another benefit for which payment may be made under this chapter.

(e) *Point of pick-up.* The zip code of the point of pick-up must be reported on each claim for ambulance services so that the correct GAF and RAF may be applied, as appropriate.

(f) *Updates.* The CF, the air ambulance base rates, and the mileage rates are updated annually by an inflation factor established by law. The inflation factor is based on the consumer price index for all urban consumers (CPI–U) (U.S. city average) for the 12-month period ending with June of the previous year and, for 2011 and each subsequent year, is reduced by the productivity adjustment described in section 1886(b)(3)(B)(xi)(II) of the Act.

(g) *Adjustments.* The Secretary monitors payment and billing data on an ongoing basis and adjusts the CF and air ambulance rates as appropriate to reflect actual practices under the fee schedule. These rates are not adjusted solely because of changes in the total number of ambulance transports.

(h) *Treatment of certain areas for payment for air ambulance services.* Any area that was designated as a rural area for purposes of making payments under the ambulance fee schedule for air ambulance services furnished on December 31, 2006, must be treated as a rural area for purposes of making payments under the ambulance fee schedule for air ambulance services furnished during the period July 1, 2008 through June 30, 2013.

[67 FR 9132, Feb. 27, 2002, as amended at 68 FR 67693, Dec. 5, 2003; 69 FR 40292, July 1, 2004; 71 FR 69787, Dec. 1, 2006; 73 FR 69937, Nov. 19, 2008; 74 FR 62012, Nov. 25, 2009; 75 FR 73625, Nov. 29, 2010; 76 FR 70315, Nov. 10, 2011; 77 FR 69368, Nov. 16, 2012; 78 FR 74820, Dec. 10, 2013; 79 FR 68005, Nov. 13, 2014; 80 FR 71382, Nov. 16, 2015; 83 FR 60074, Nov. 23, 2018; 84 FR 63193, Nov. 15, 2019; 88 FR 79531, Nov. 16, 2023]

§414.615 Transition to the ambulance fee schedule.

The fee schedule for ambulance services will be phased in over 5 years beginning April 1, 2002. Subject to the first sentence in §414.610(a), payment for services furnished during the transition period is made based on a combination of the fee schedule payment for ambulance services and the amount the program would have paid absent the fee schedule for ambulance services, as follows:

(a) *2002 Payment.* For services furnished in 2002, the payment for the service component, the mileage component and, if applicable, the supply component is based on 80 percent of the reasonable charge for independent suppliers or on 80 percent of reasonable cost for providers, plus 20 percent of the ambulance fee schedule amount for the service and mileage components. The reasonable charge or reasonable cost portion of payment in CY 2002 is equal to the supplier's reasonable charge allowance or provider's reasonable cost allowance for CY 2001, multiplied by the statutory inflation factor for ambulance services.

(b) *2003 Payment.* For services furnished in CY 2003, payment is based on 60 percent of the reasonable charge or reasonable cost, as applicable, plus 40 percent of the ambulance fee schedule amount. The reasonable charge and reasonable cost portion in CY 2003 is equal to the supplier's reasonable charge or provider's reasonable cost for CY 2002, multiplied by the statutory inflation factor for ambulance services.

(c) *2004 Payment.* For services furnished in CY 2004, payment is based on 40 percent of the reasonable charge or reasonable cost, as applicable, plus 60 percent of the ambulance fee schedule amount. The reasonable charge and reasonable cost portion in CY 2004 is equal to the supplier's reasonable charge or provider's reasonable cost for CY 2003, multiplied by the statutory inflation factor for ambulance services.

(d) *2005 Payment.* For services furnished in CY 2005, payment is based on 20 percent of the reasonable charge or reasonable cost, as applicable, plus 80 percent of the ambulance fee schedule amount. The reasonable charge and reasonable cost portion in CY 2005 is equal to the supplier's reasonable charge or provider's reasonable cost for CY 2004, multiplied by the statutory inflation factor for ambulance services.

(e) *2006 and Beyond Payment.* For services furnished in CY 2006 and thereafter, the payment is based solely on the ambulance fee schedule amount.

(f) *Updates.* The portion of the transition payment that is based on the existing payment methodology (that is,

the non-fee-schedule portion) is updated annually for inflation by a factor equal to the percentage increase in the CPI-U (U.S. city average) for the 12-month period ending with June of the previous year. The CY 2002 inflation update factor used to update the 2001 payment amounts is applied to the annualized (average) payment amounts for CY 2001. For the period January 1, 2001 through June 30, 2001, the inflation update factor is 2.7 percent. For the period July 1, 2001 through December 31, 2001, the inflation update factor is 4.7 percent. The average for the year is 3.7 percent. Thus, the annualized (average) CY 2001 payment amounts used to derive the CY 2002 payment amounts are equivalent to the CY 2001 payment amounts that would have been determined had the inflation update factor for the entire CY 2001 been 3.7 percent. Both portions of the transition payment (that is, the portion that is based on reasonable charge or reasonable cost and the portion that is based on the ambulance fee schedule) are updated annually for inflation by the inflation factor described in §414.610(f).

(g) *Exception.* There will be no blended payment allowance as described in paragraphs (a), (b), (c), and (d) of this section for ground mileage in those States where the Medicare carrier paid separately for all out-of-county ground ambulance mileage, but did not, before the implementation of the Medicare ambulance fee schedule, make a separate payment for any ground ambulance mileage within the county in which the beneficiary was transported. Payment for ground ambulance mileage in that State will be made based on the full ambulance fee schedule amount for ground mileage. This exception applies only to carrier-processed claims and only in those States in which the carrier paid separately for out-of-county ambulance mileage, but did not make separate payment for any in-county mileage throughout the entire State.

§414.617 Transition from regional to national ambulance fee schedule.

For services furnished during the period July 1, 2004 through December 31, 2009, the amount for the ground ambulance base rate is subject to a floor amount determined by establishing nine fee schedules based on each of the nine census divisions using the same methodology as used to establish the national fee schedule. If the regional fee schedule methodology for a given census division results in an amount that is less than or equal to the national ground base rate, then it is not used, and the national FS amount applies. If the regional fee schedule methodology for a given census division results in an amount that is greater than the national ground base rate, then the FS portion of the base rate for that census division is equal to a blend of the national rate and the regional rate in accordance with the following schedule:

Time period	Regional percent	National percent
7/1/04–12/31/04	80	20
CY 2005	60	40
CY 2006	40	60
CY 2007–CY 2009	20	80
CY 2010 and thereafter	0	100

[69 FR 40292, July 1, 2004]

§414.620 Publication of the ambulance fee schedule.

(a) Changes in payment rates resulting from incorporation of the annual inflation factor and the productivity adjustment as described in §414.610(f) will be announced by CMS by instruction and on the CMS Web site.

(b) CMS will follow applicable rulemaking procedures in publishing revisions to the fee schedule for ambulance services that result from any factors other than those described in §414.610(f).

[75 FR 73626, Nov. 29, 2010]

§414.625 Limitation on review.

There will be no administrative or judicial review under section 1869 of the Act or otherwise of the amounts established under the fee schedule for ambulance services, including the following:

(a) Establishing mechanisms to control increases in expenditures for ambulance services.

(b) Establishing definitions for ambulance services that link payments to the type of services provided.

(c) Considering appropriate regional and operational differences.

(d) Considering adjustments to payment rates to account for inflation and other relevant factors.

(e) Phasing in the application of the payment rates under the fee schedule in an efficient and fair manner.

§ 414.626 Data reporting by ground ambulance organizations.

(a) *Definitions.* For purposes of this section, the following definitions apply:

Data collection period means, with respect to a year, the 12-month period that reflects the ground ambulance organization's annual accounting period.

Data reporting period means, with respect to a year, the 5-month period that begins the day after the last day of the ground ambulance organization's data collection period.

For a year means one of the calendar years from 2020 through 2024.

Medicare Ground Ambulance Data Collection Instrument means the single survey-based data collection instrument that can be accessed by sampled ambulance organizations under this section via a secure web-based system for reporting data under this section.

(b) *Data collection and submission requirement.* Except as provided in paragraph (d) of this section, a ground ambulance organization selected by CMS under paragraph (c) of this section must do the following:

(1) Within 30 days of the date that CMS notifies a ground ambulance organization under paragraph (c)(3) of this section that it has selected the ground ambulance organization to report data under this section, the ground ambulance organization must select a data collection period that corresponds with its annual accounting period and provide the start date of that data collection period to CMS or its contractor.

(2) Collect during its selected data collection period the data necessary to complete the Medicare Ground Ambulance Data Collection Instrument.

(3) Submit to CMS a completed Medicare Ground Ambulance Data Collection Instrument during the data reporting period that corresponds to the ground ambulance organization's selected data collection period.

(c) *Representative sample.* (1) *Random sample.* For purposes of the data collection described in paragraph (b) of this section, and for a year, CMS will select a random sample of 25 percent of eligible ground ambulance organizations that is stratified based on:

(i) Provider versus supplier status and ownership (for-profit, non-profit, and government);

(ii) Service area population density (transports originating in primarily urban, rural, and super rural zip codes); and

(iii) Medicare-billed transport volume categories.

(2) *Selection eligibility.* A ground ambulance organization is eligible to be selected for data reporting under this section for a year if it is enrolled in Medicare and has submitted to CMS at least one Medicare ambulance transport claim during the year prior to the selection under paragraph (b)(1) of this section.

(3) *Notification of selection for a year.* CMS will notify an eligible ground ambulance organization that it has been selected to report data under this section for a year at least 30 days prior to the beginning of the calendar year in which the ground ambulance organization must begin to collect data by posting a list of selected organizations on the CMS web page and providing written notification to each selected ground ambulance organization via email or U.S. mail.

(4) *Limitation.* CMS will not select the same ground ambulance organization under this paragraph (c) in 2 consecutive years, to the extent practicable.

(d) *Hardship exemption.* A ground ambulance organization selected under paragraph (c) of this section may request and CMS may grant an exception to the reporting requirements under paragraph (b) of this section in the event of a significant hardship, such as a natural disaster, bankruptcy, or similar situation that the Secretary determines interfered with the ability of the ground ambulance organization to submit such information in a timely manner for the data collection period selected by the ground ambulance organization.

(1) To request a hardship exemption, the ground ambulance organization must submit a request to CMS, in the form and manner specified by CMS,

within 90 calendar days of the date that CMS notified the ground ambulance organization that it would receive a 10 percent payment reduction as a result of not submitting sufficient information under the data collection system. The request form must include all of the following:

(i) Ground ambulance organization name.

(ii) NPI number.

(iii) Ground ambulance organization address.

(iv) Chief executive officer and any other designated personnel contact information, including name, email address, telephone number and mailing address (must include a physical address, a post office box address is not acceptable).

(v) Reason for requesting a hardship exemption.

(vi) Evidence of the impact of the hardship (such as photographs, newspaper or other media articles, financial data, bankruptcy filing, etc.).

(vii) Date when the ground ambulance organization would be able to begin collecting data under paragraph (b) of this section.

(viii) Date and signature of the chief executive officer or other designated personnel of the ground ambulance organization.

(2) CMS will provide a written response to the hardship exemption request within 30 days of its receipt of the hardship exemption form.

(e) *Notification of non-compliance and informal review.* (1) *Notification of non-compliance.* A ground ambulance organization selected under paragraph (c) of this section for a year that does not sufficiently report data under paragraph (b) of this section, will receive written notification from CMS that it will receive a payment reduction under § 414.610(c)(9).

(2) *Informal review.* A ground ambulance organization that receives a written notification under paragraph (e)(1) of a payment reduction under § 414.610(c)(9) may submit a request for an informal review within 90 days of the date it received the notificationby submitting a request to CMS, in the form and manner specified by CMS, that includes all of the following information:

(i) Ground ambulance organization name.

(ii) NPI number.

(iii) Chief executive officer and any other designated personnel contact information, including name, email address, telephone number and mailing address with the street location of the ground ambulance organization.

(iv) Ground ambulance organization's selected data collection period and data reporting period.

(v) A statement of the reasons why the ground ambulance organization does not agree with CMS' determination and any supporting documentation.

(f) *Public availability of data.* Beginning in 2024, and at least once every 2 years thereafter, CMS will post on its website data that it collected under this section, including but not limited to summary statistics and ground ambulance organization characteristics.

(g) *Limitations on review.* There is no administrative or judicial review under section 1869 or section 1878 of the Act, or otherwise of the data required for submission under paragraph (b) of this section or the selection of ground ambulance organizations under paragraph (c) of this section.

[84 FR 63193, Nov. 15, 2019, as amended at 86 FR 65669, Nov. 19, 2021; 87 FR 70226, Nov. 18, 2022]

Subpart I—Payment for Drugs and Biologicals

SOURCE: 69 FR 1116, Jan. 7, 2004, unless otherwise noted.

§ 414.701 Purpose.

This subpart implements section 1842(o) of the Act by specifying the methodology for determining the payment allowance limit for drugs and biologicals covered under Part B of Title XVIII of the Act (hereafter in this subpart referred to as the ''program'') that are not paid on a cost or prospective payment system basis. Examples of drugs that are subject to the rules contained in this subpart are: Drugs furnished incident to a physician's service; durable medical equipment (DME) drugs; separately billable drugs at independent dialysis facilities not

under the ESRD composite rate; statutorily covered drugs, for example, influenza, pneumococcal, hepatitis, and COVID–19 vaccines, antigens, hemophilia blood clotting factor, immunosuppressive drugs and certain oral anticancer drugs.

[85 FR 71197, Nov. 6, 2020]

§ 414.704 Definitions.

As used in this subpart, the following definition applies. *Drug* refers to both drugs and biologicals.

§ 414.707 Basis of payment.

(a) *Method of payment.* (1) Payment for a drug in calendar year 2004 is based on the lesser of—

(i) The actual charge on the claim for program benefits; or

(ii) 85 percent of the average wholesale price determined as of April 1, 2003, subject to the exceptions as specified in paragraphs (a)(2) through (a)(8) of this section.

(2) The payment limits for the following drugs are calculated using 95 percent of the average wholesale price:

(i) Blood clotting factors.

(ii) A drug or biological furnished during 2004 that was not available for Medicare payment as of April 1, 2003.

(iii) Pneumococcal, influenza, and COVID–19 vaccines as well as hepatitis B vaccine that is furnished to individuals at high or intermediate risk of contracting hepatitis B (as defined in § 410.63(a) of this subchapter).

(iv) A drug or biological furnished during 2004 in connection with the furnishing of renal dialysis services if separately billed by renal dialysis facilities.

(3) The payment limits for infusion drugs furnished through a covered item of durable medical equipment are calculated using 95 percent of the average wholesale price in effect on October 1, 2003.

(4) The payments limits for drugs contained in the following table are calculated based on the percentages of the average wholesale price determined as of April 1, 2003 that are specified in the table.

Drug	Percentage used to calculate 2004 payment limit
EPOETIN ALFA	87
LEUPROLIDE ACETATE	81
GOSERELIN ACETATE	80
RITUXIMAB	81
PACLITAXEL	81
DOCETAXEL	80
CARBOPLATIN	81
IRINOTECAN	80
GEMCITABINE HCL	80
PAMIDRONATE DISODIUM	85
DOLASETRON MESYLATE	80
FILGRASTIM	81
HYLAN G-F 20	82
MYCOPHENOLATE MOFETIL	86
GRANISETRON HCL	80
ONDANSETRON	87
VINORELBINE TARTATE	81
SARGRAMOSTIM	80
TOPOTECAN	84
IPRATROPIUM BROMIDE	80
ALBUTEROL SULFATE	80
IMMUNE GLOBULIN	80
LEUCOVORIN CALCIUM	80
DOXORUBICIN HCL	80
DEXAMETHOSONE SODIUM PHOSPHATE	86
HEPARIN SODIUM LOCK-FLUSH	80
CROMOLYN SODIUM	80
ACETYLCYSTEINE	80

(5) The payment limits for imiglucerase and alglucerase are calculated using 94 percent of the average wholesale price determined as of April 1, 2003.

(6) Exception. The payment limit for a drug otherwise subject to paragraph (a)(1)(ii) or paragraph (a)(4) of this section may be calculated using the percentage of the average wholesale price as the Secretary deems appropriate based on data and information submitted by the drug manufacturer.

(i) The manufacturer must submit data after October 15, 2003 and before January 1, 2004.

(ii) The percentage only applies for drugs furnished on or after April 1, 2004.

(7) In the case of blood and blood products (other than blood clotting factors), the payment limits shall be determined in the same manner as such payment limit was determined on October 1, 2003.

(b) *Mandatory assignment.* Effective with services furnished on or after February 1, 2001, payment for any drug covered under Part B of Medicare may be made on an assignment-related basis only. All billers must accept the program allowed charge as payment in full

and may not bill nor collect from the beneficiary any amount other than the unmet Part B deductible and Part B coinsurance amounts, if applicable. Violations of this requirement may subject the supplier to sanctions, as provided by the statute (See § 402 of this chapter).

(c) *Mandatory reporting of anemia quality indicators.* The following provisions are effective January 1, 2008:

(1) Each request for payment for anti-anemia drugs furnished to treat anemia resulting from the treatment of cancer must report the beneficiary's most recent hemoglobin or hematocrit level;

(2) Each request for payment for use of erythropoiesis stimulating agents must report the beneficiary's most recent hemoglobin or hematocrit level.

[69 FR 1116, Jan. 7, 2004, as amended at 72 FR 66402, Nov. 27, 2007; 85 FR 71197, Nov. 6, 2020; 87 FR 70226, Nov. 18, 2022]

Subpart J—Submission of Manufacturer's Average Sales Price Data

SOURCE: 69 FR 17938, Apr. 6, 2004, unless otherwise noted.

§ 414.800 Purpose.

This subpart implements section 1847A of the Act by specifying the requirements for submission of a manufacturer's average sales price data for certain drugs and biologicals covered under Part B of Title XVIII of the Act that are paid under sections 1842(o)(1)(D), 1847A, and 1881(b)(13)(A)(ii) of the Act.

§ 414.802 Definitions.

As used in this subpart, unless the context indicates otherwise—

Bona fide service fees means fees paid by a manufacturer to an entity, that represent fair market value for a bona fide, itemized service actually performed on behalf of the manufacturer that the manufacturer would otherwise perform (or contract for) in the absence of the service arrangement, and that are not passed on in whole or in part to a client or customer of an entity, whether or not the entity takes title to the drug.

Drug means a drug or a biological, and for purposes of applying section 1847A(f) of the Act, includes an item, service, supply, or product that is payable under Medicare Part B as a drug or biological.

Manufacturer means any entity that is engaged in the following (This term does not include a wholesale distributor of drugs or a retail pharmacy licensed under State law):

(1) Production, preparation, propagation, compounding, conversion or processing of prescription drug products, either directly or indirectly by extraction from substances of natural origin, or independently by means of chemical synthesis, or by a combination of extraction and chemical synthesis.

(2) The packaging, repackaging, labeling, relabeling, or distribution of prescription drug products.

Unit means the product represented by the 11-digit National Drug Code, unless otherwise specified by CMS to account for situations where labeling indicates that the amount of drug product represented by a National Drug Code varies. The method of counting units excludes units of CAP drugs (as defined in § 414.902 of this part) sold to an approved CAP vendor (as defined in § 414.902 of this part) for use under the CAP (as defined in § 414.902 of this part).

[69 FR 17938, Apr. 6, 2004, as amended at 71 FR 48143, Aug. 18, 2006; 71 FR 69787, Dec. 1, 2006; 74 FR 62012, Nov. 25, 2009; 76 FR 73473, Nov. 28, 2011; 86 FR 65669, Nov. 19, 2021]

§ 414.804 Basis of payment.

(a) *Calculation of manufacturer's average sales price.* (1) The manufacturer's average sales price for a quarter for a drug represented by a particular 11-digit National Drug Code must be calculated as the manufacturer's sales to all purchasers in the United States for that particular 11-digit National Drug Code (after excluding sales as specified in paragraph (a)(4) of this section and then deducting price concessions as specified in paragraphs (a)(2) and (a)(3) of this section) divided by the total number of units sold by the manufacturer in that quarter (after excluding units associated with sales as specified in paragraph (a)(4) of this section).

(2) *Price concessions.* (i) In calculating the manufacturer's average sales price, a manufacturer must deduct price concessions. Price concessions include the following types of transactions and items:

(A) Volume discounts.

(B) Prompt pay discounts.

(C) Cash discounts.

(D) Free goods that are contingent on any purchase requirement.

(E) Chargebacks and rebates (other than rebates under the Medicaid program).

(ii) For the purposes of paragraph (a)(2)(i), bona fide services fees are not considered price concessions.

(3) To the extent that data on price concessions, as described in paragraph (a)(2) of this section, are available on a lagged basis, the manufacturer must estimate this amount in accordance with the methodology described in this paragraph.

(i)(A) For each National Drug Code with at least 12 months of sales (including products for which the manufacturer has redesignated the National Drug Code for the specific product and package size and has 12 months of sales across the prior and current National Drug Codes), after adjusting for exempted sales, the manufacturer calculates a percentage equal to the sum of the price concessions for the most recent 12-month period available associated with sales subject to the average sales price reporting requirement divided by the total in dollars for the sales subject to the average sales price reporting requirement for the same 12-month period.

(B) For each National Drug Code with less than 12 months of sales, the calculation described in paragraph (i)(A) of this section is performed for the time period equaling the total number of months of sales.

(ii) The manufacturer multiplies the applicable percentage described in paragraph (a)(3)(i)(A) or (a)(3)(i)(B) of this section by the total in dollars for the sales subject to the average sales price reporting requirement (after adjusting for exempted sales) for the quarter being submitted. (The manufacturer must carry a sufficient number of decimal places in the calculation of the price concessions percentage in order to round accurately the net total sales amount for the quarter to the nearest whole dollar.) The result of this multiplication is then subtracted from the total in dollars for the sales subject to the average sales price reporting requirement (after adjusting for exempted sales) for the quarter being submitted.

(iii) The manufacturer uses the result of the calculation described in paragraph (a)(3)(ii) of this section as the numerator and the number of units sold in the quarter (after adjusting for exempted sales) as the denominator to calculate the manufacturer's average sales price for the National Drug Code for the quarter being submitted.

(iv) *Example.* After adjusting for exempted sales, the total lagged price concessions (discounts, rebates, etc.) over the most recent 12-month period available associated with sales for National Drug Code 12345–6789–01 subject to the ASP reporting requirement equal $200,000, and the total in dollars for the sales subject to the average sales price reporting requirement for the same period equals $600,000. The lagged price concessions percentage for this period equals 200,000/600,000 = 0.33333. The total in dollars for the sales subject to the average sales price reporting requirement for the quarter being reported, equals $50,000 for 10,000 units sold. The manufacturer's average sales price calculation for this National Drug Code for this quarter is: $50,000 − (0.33333 × $50,000) = $33,334 (net total sales amount); $33,334/10,000 = $3.33 (average sales price).

(4) *Exempted sales.* (i) In calculating the manufacturer's average sales price, a manufacturer must exclude sales that are exempt from inclusion in the determination of the best price under section 1927(c)(1)(C)(i) of the Act and sales that are merely nominal in amount as applied for purposes of section 1927(c)(1)(C)(ii)(III) of the Act, as limited by section 1927(c)(1)(D) of the Act.

(ii) In determining nominal sales exempted under section 1927(c)(1)(C)(ii)(III) of the Act, the manufacturer calculates the average manufacturer price as defined in section 1927(k) of the Act and then identifies sales that are eligible to be considered

a nominal sale under section 1927(c)(1)(D) of the Act and are at less than 10 percent of the average manufacturer price. To identify nominal sales, the manufacturer must use the average manufacturer price for the calendar quarter that is the same calendar quarter as the average sales price reporting period.

(5) The manufacturer's average sales price must be calculated by the manufacturer every calendar quarter and submitted to CMS within 30 days of the close of the quarter. The first quarter submission must be submitted by April 30, 2004. Subsequent reports are due not later than 30 days after the last day of each calendar quarter.

(6) The manufacturer's average sales price must be calculated based on the amount of product in a vial or other container as conspicuously reflected on the FDA approved label as defined by section 201(k) of the Food, Drug, and Cosmetic Act.

(7) Each report must be certified by one of the following:

(i) The manufacturer's Chief Executive Officer (CEO).

(ii) The manufacturer's Chief Financial Officer (CFO).

(iii) An individual who has delegated authority to sign for, and who reports directly to, the manufacturer's CEO or CFO.

(b) [Reserved]

[69 FR 17938, Apr. 6, 2004, as amended at 69 FR 55764, Sept. 16, 2004; 70 FR 70332, Nov. 21, 2005; 71 FR 69787, Dec. 1, 2006; 72 FR 18914, Apr. 16, 2007; 75 FR 73626, Nov. 29, 2010]

§ 414.806 Penalties associated with misrepresentation and the failure to submit timely and accurate ASP data.

(a) *Misrepresentation.* Section 1847A(d)(4)(A) of the Act specifies the penalties associated with misrepresentations in the reporting of the manufacturer's average sales price for a drug as defined at § 414.802.

(b) *Failure to provide timely information or the submission of false information.* (1) For a manufacturer that has entered into and has in effect a rebate agreement under section 1927 of the Act, section 1927(b)(3)(C) of the Act specifies the penalties associated with a manufacturer's failure to submit timely information or the submission of false information.

(2) For a manufacturer that has not entered into and does not have in effect a rebate agreement under section 1927 of the Act, sections 1847A(d)(4)(B) and (C) of the Act specify the penalties associated with a manufacturer's failure to submit timely information or the submission of false information.

[86 FR 65669, Nov. 19, 2021]

Subpart K—Payment for Drugs and Biologicals Under Part B

SOURCE: 69 FR 66424, Nov. 15, 2004, unless otherwise noted.

§ 414.900 Basis and scope.

(a) This subpart implements sections 1842(o), 1847A, and 1847B of the Act and outlines two payment methodologies applicable to drugs and biologicals covered under Medicare Part B that are not paid on a cost or prospective payment system basis.

(b) Examples of drugs that are subject to the requirements specified in this subpart are:

(1) Drugs furnished incident to a physician's service; durable medical equipment (DME) drugs.

(2) Separately billable drugs at independent dialysis facilities not under the ESRD composite rate.

(3) Statutorily covered drugs, for example—

(i) Influenza.

(ii) Pneumococcal, Hepatitis B, and COVID–19 vaccines.

(iii) Antigens.

(iv) Hemophilia blood clotting factor.

(v) Immunosuppressive drugs.

(vi) Certain oral anti-cancer drugs.

[69 FR 66424, Nov. 15, 2004, as amended at 70 FR 39093, July 6, 2005; 85 FR 71197, Nov. 6, 2020]

§ 414.902 Definitions.

As used in this subpart, unless the context indicates otherwise—

Applicable five-year period means:

(1) For a qualifying biosimilar biological product for which payment has been made under section 1847A(b)(8) of the Act as of September 30, 2022, the 5-year period beginning on October 1, 2022; and

(2) For a qualifying biosimilar biological product for which payment is first made under section 1847A(b)(8) of the Act during a calendar quarter during the period beginning October 1, 2022 and ending December 31, 2027, the 5-year period beginning on the first day of such calendar quarter during which such payment is first made.

Approved CAP vendor means an entity that has been awarded a contract by CMS to participate in the competitive acquisition program under 1847B of the Act.

Bid means an offer to furnish a CAP drug within a category of CAP drugs in a competitive acquisition area for a particular price and time period.

Biosimilar biological product means a biological product approved under an abbreviated application for a license of a biological product that relies in part on data or information in an application for another biological product licensed under section 351 of the Public Health Service Act (PHSA) as defined at section 1847A(c)(6)(H) of the Act.

CAP drug means a physician-administered drug or biological furnished on or after January 1, 2006 described in section 1842(o)(1)(C) of the Act and supplied by an approved CAP vendor under the CAP as provided in this subpart.

Competitive acquisition area means a geographic area established by the Secretary for purposes of implementing the CAP required by section 1847B of the Act.

Competitive acquisition program (CAP) means a program as defined under section 1847B of the Act.

Designated carrier means an entity assigned by CMS to process and pay claims for drugs and biologicals under the CAP.

Drug means both drugs and biologicals.

Emergency delivery means delivery of a CAP drug within one business day in appropriate shipping and packaging, in all areas of the United States and its territories, with the exception of the Pacific Territories. In the Pacific Territories, emergency delivery means delivery of a CAP drug within 5 business days in appropriate shipping and packaging. In each case, this timeframe shall be reduced if product stability requires it, meaning that the manufacturer's labeling instructions, drug compendia, or specialized drug stability references indicate that a shorter delivery timeframe is necessary to avoid adversely affecting the product's integrity, safety, or efficacy.

Emergency situation means, for the purposes of the CAP, an unforeseen occurrence or situation determined by the participating CAP physician, in his or her clinical judgment, to require prompt action or attention for purposes of permitting the participating CAP physician to use a drug from his or her own stock, if the other requirements of §414.906(e) are met.

Local carrier means an entity assigned by CMS to process and pay claims for administration of drugs and biologicals under the CAP.

Low volume dose means, with respect to determination of whether an increased applicable percentage is warranted, an FDA-labeled dose of a drug for which the volume removed from the vial or container containing the labeled dose does not exceed 0.4 mL.

Manufacturer's average sales price means the price calculated and reported by a manufacturer under part 414, subpart J of this chapter.

Multiple source drug means a drug described by section 1847A(c)(6)(C) of the Act.

New refund quarter means a calendar quarter that is included in a report described in §414.940(a) that is sent in the first year following the year in which the calendar quarter occurs.

Pacific Territories means, for purposes of the CAP, American Samoa, Guam, or the Northern Mariana Islands.

Participating CAP physician means a physician electing to participate in the CAP, as described in this subpart. The participating CAP physician must complete and sign the participating CAP physician election agreement. Physicians who do not participate in Medicare but who elect to participate in the CAP must agree to accept assignment for CAP drug administration claims.

Participating CAP physician election agreement means the agreement that the physician signs to notify CMS of the physician's election to participate in the CAP and to agree to the terms and conditions of CAP participation as set forth in this subpart.

Prescription order means a written order submitted by the participating CAP physician to the approved CAP vendor that meets the requirements of this subpart.

Qualifying biosimilar biological product means a biosimilar biological product (as described in section 1847A(b)(1)(C) of the Act) with an average sales price (as described in section 1847A(b)(8)(A)(i) of the Act) less than the average sales price of the reference biological for a calendar quarter during the applicable 5-year period.

Reference biological product means the biological product licensed under such section 351 of the PHSA that is referred to in the application of the biosimilar biological product as defined at section 1847A(c)(6)(I) of the Act.

Refundable single-dose container or single-use package drug means:

(1) A single source drug or biological or a biosimilar biological product for which payment is made under this part and that is—

(i) Furnished from a single-dose container or single-use package based on FDA-approved labeling or product information; or

(ii) Furnished from an ampule for which product labeling does not have discard statement or language indicating if the container is single-dose container, single-use package, multiple-dose container, or single-patient-use container; or

(iii) Furnished from a container with a total labeled volume of 2 mL or less for which product labeling does not have language indicating if the container is single-dose container, single-use package, multiple-dose container, or single-patient-use container.

(2) Excludes—

(i) A drug that is a therapeutic radiopharmaceutical, a diagnostic radiopharmaceutical, or an imaging agent as identified in the drug's FDA-approved labeling.

(ii) A drug for which the FDA-approved labeling for any National Drug Code assigned to a billing and payment code of such drug requires filtration during the drug preparation process, prior to dilution and administration and that any unused portion of such drug after the filtration process be discarded after the completion of such filtration process.

(iii) A drug approved or licensed by the FDA on or after November 15, 2021, until the last day of the sixth full quarter for which the drug has been marketed (as reported to CMS) for the first National Drug Code assigned to the billing and payment code of such drug.

(iv) A drug approved or licensed by FDA on or after November 15, 2021 and for which the date the drug was first marketed (as reported to CMS) does not adequately approximate the date of first payment under Part B due to an applicable national coverage determination, until the last day of the sixth full quarter for which the drug has been covered and paid under Medicare Part B for the first National Drug Code assigned to the billing and payment code of such drug.

Routine delivery means delivery of a drug within 2 business days in appropriate shipping and packaging in all areas of the United States and its territories, with the exception of the Pacific Territories. In the Pacific Territories, routine delivery of drug means delivery of a CAP drug within 7 business days in appropriate shipping and packaging. In each case, this timeframe will be reduced if product stability requires it, meaning that the manufacturer's labeling instructions, drug compendia, or specialized drug stability references indicate that a shorter delivery timeframe is necessary to avoid adversely affecting the product's integrity, safety, or efficacy.

Single source drug means a drug described by section 1847A(c)(6)(D) of the Act.

Timely delivery means delivery of a CAP drug within the defined routine and emergency delivery timeframes. Compliance with timely delivery standards is also a factor for evaluation of potential and approved CAP vendors.

Unit is defined as in part 414, subpart J of this chapter.

Updated refund quarter means a calendar quarter that is included in a report described in § 414.940(a) that is sent in the second year following the year in which the calendar quarter occurs.

Wholesale acquisition cost (WAC) means the price described by section 1847A(c)(6)(B) of the Act.

[69 FR 66424, Nov. 15, 2004, as amended at 70 FR 39093, July 6, 2005; 75 FR 73626, Nov. 29, 2010; 87 FR 70226, Nov. 18, 2022; 88 FR 79531, Nov. 16, 2023; 89 FR 98559, Dec. 9, 2024]

§414.904 Average sales price as the basis for payment.

(a) *Method of payment.* Payment for a drug furnished on or after January 1, 2005 is based on the lesser of—

(1) The actual charge on the claim for program benefits; or

(2) 106 percent of the average sales price, subject to the applicable limitations specified in paragraph (d) of this section or subject to the exceptions described in paragraph (e) of this section.

(3) For purposes of this paragraph—

(i) CMS calculates an average sales price payment limit based on the amount of product included in a vial or other container as reflected on the FDA-approved label.

(ii) Additional product contained in the vial or other container does not represent a cost to providers and is not incorporated into the ASP payment limit.

(iii) No payment is made for amounts of product in excess of that reflected on the FDA-approved label.

(b) *Multiple source drugs*—(1) *Average sales prices.* The average sales price for all drug products included within the same multiple source drug billing and payment code is the volume-weighted average of the manufacturers' average sales prices for those drug products.

(2) *Calculation of the average sales price.* (i) For dates of service before April 1, 2008, the average sales price is determined by—

(A) Computing the sum of the products (for each National Drug Code assigned to the drug products) of the manufacturer's average sales price and the total number of units sold; and

(B) Dividing that sum by the sum of the total number of units sold for all NDCs assigned to the drug products.

(ii) For dates of service on or after April 1, 2008, the average sales price is determined by—

(A) Computing the sum of the products (for each National Drug Code assigned to such drug products) of the manufacturer's average sales price, determined by the Secretary without dividing such price by the total number of billing units for the National Drug Code for the billing and payment code and the total number of units sold; and

(B) Dividing the sum determined under clause (A) by the sum of the products (for each National Drug Code assigned to such drug products) of the total number of units sold and the total number of billing units for the National Drug Code for the billing and payment code.

(iii) For purposes of this subsection and subsection (c), the term billing unit means the identifiable quantity associated with a billing and payment code, as established by CMS.

(c) *Single source drugs*—(1) *Average sales price.* The average sales price is the volume-weighted average of the manufacturers' average sales prices for all National Drug Codes assigned to the drug or biological product.

(2) *Calculation of the average sales price.* (i) For dates of service before April 1, 2008, the average sales price is determined by—

(A) Computing the sum of the products (for each National Drug Code assigned to the drug product) of the manufacturer's average sales price and the total number of units sold; and

(B) Dividing that sum by the sum of the total number of units sold for all NDCs assigned to the drug product.

(ii) For dates of service on or after April 1, 2008, the average sales price is determined by—

(A) Computing the sum of the products (for each National Drug Code assigned to such drug products) of the manufacturer's average sales price, determined by the Secretary without dividing such price by the total number of billing units for the National Drug Code for the billing and payment code and the total number of units sold; and

(B) Dividing the sum determined under clause (A) by the sum of the products (for each National Drug Code assigned to such drug products) of the total number of units sold and the total number of billing units for the National Drug Code for the billing and payment code.

(d) *Limitations on the average sales price*—(1) *Wholesale acquisition cost for a*

single source drug. The payment limit for a single source drug product is the lesser of 106 percent of the average sales price for the product or 106 percent of the wholesale acquisition cost for the product.

(2) *Payment limit for a drug furnished to an end-stage renal disease patient*. (i) Effective for drugs and biologicals furnished in 2005, the payment for such drugs and biologicals, including erythropoietin, furnished to an end-stage renal disease patient that is separately billed by an end-stage renal disease facility and not paid on a cost basis is acquisition cost as determined by the Inspector General report as required by section 623(c) of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 inflated by the percentage increase in the Producer Price Index.

(ii) Except as provided in paragraph (a) of this section, the payment for drugs and biologicals, furnished to an end-stage renal disease patient that is separately billed by an end-stage renal disease facility, is based on 106 percent of the average sales price.

(iii) Effective for drugs and biologicals furnished in CY 2006 and subsequent calendar years, the payment for such drugs and biologicals furnished in connection with renal dialysis services and separately billed by freestanding and hospital-based renal dialysis facilities not paid on a cost basis is the amount determined under section 1847A of the Act.

(3) *Widely available market price and average manufacturer price*. If the Inspector General finds that the average sales price exceeds the widely available market price or the average manufacturer price by the applicable threshold percentage specified in paragraph (d)(3)(iii) or (iv) of this section, the Inspector General is responsible for informing the Secretary (at such times as specified by the Secretary) and the payment amount for the drug or biological will be substituted subject to the following adjustments:

(i) The payment amount substitution will be applied at the next average sales price payment amount calculation period after the Inspector General informs the Secretary (at such times specified by the Secretary) about billing codes for which the average sales price has exceeded the average manufacturer price by the applicable threshold percentage, and will remain in effect for 1 quarter after publication.

(ii) Payment at 103 percent of the average manufacturer price for a billing code will be applied at such times when all of the following criteria are met:

(A) The threshold for making price substitutions, as defined in paragraph (d)(3)(iii) of this section is met.

(B) 103 percent of the average manufacturer price is less than the 106 percent of the average sales price for the quarter in which the substitution would be applied.

(C) Beginning in 2013, the drug and dosage form described by the HCPCS code is not identified by the FDA to be in short supply at the time that ASP calculations are finalized.

(iii) The applicable percentage threshold for average manufacturer price comparisons is 5 percent and is reached when—

(A) The average sales price for the billing code has exceeded the average manufacturer price for the billing code by 5 percent or more in 2 consecutive quarters, or 3 of the previous 4 quarters immediately preceding the quarter to which the price substitution would be applied; and

(B) The average manufacturer price for the billing code is calculated using the same set of National Drug Codes used for the average sales price for the billing code.

(iv) The applicable percentage threshold for widely available market price comparisons is 5 percent.

(4) *Payment adjustment for certain drugs for which there is a self-administered version*—(i) *In general*. Except as provided in paragraphs (d)(4)(ii) and (iii) of this section, if the Inspector General identifies a drug or biological product in a study described in section 1847A(g)(1) of the Act, the Secretary must apply the payment limit for the applicable billing and payment code as specified in paragraph (d)(4)(iv) of this section, beginning with the first day of the second quarter after such study is publicly available. The methodology

described in this paragraph will be recalculated each quarter thereafter, except when conditions described in paragraph (d)(4)(ii) are met.

(ii) *Exception.* The adjustment described in paragraph (d)(4)(i) of this section does not apply to the payment limit for a billing and payment code for a quarter if, at the time that ASP calculations are finalized for such quarter, the drug in the dosage form described by the billing and payment code is included by the FDA on the drug shortage list in effect under section 506E of the Federal Food, Drug, and Cosmetic Act.

(iii) *Special rule for certain billing and payment codes.* Effective July 1, 2021, for a billing and payment code described under section 1847A(g)(3) of the Act, the payment limit for the applicable billing and payment code must be determined as described in paragraph (d)(4)(iv) of this section, and the exception specified at paragraph (d)(4)(ii) of this section does not apply.

(iv) *Lesser-of methodology.* For purposes of this section, the payment limit is the lesser of:

(A) The payment limit determined under section 1847A of the Act for such billing and payment code if each National Drug Code for such product so identified under section 1847A(g)(1) of the Act were excluded from such determination; and

(B) The payment limit otherwise determined under section 1847A of the Act for such billing and payment code without application of section 1847A(g) of the Act.

(v) *NDC changes.* For an Inspector General-identified National Drug Code, as described under section 1847A(g)(1) or (3) of the Act, for which the manufacturer has redesignated the National Drug Code (without changes to the dosage form), the application of the lesser-of methodology described in this paragraph must use manufacturer-reported ASP data associated with the redesignated National Drug Code in the same manner as the one originally identified by the Inspector General.

(e) *Exceptions to the average sales price*—(1) *Vaccines.* The payment limits for hepatitis B vaccine furnished to individuals at high or intermediate risk of contracting hepatitis B (as defined in §410.63(a) of this subchapter), pneumococcal vaccine, influenza vaccine, and COVID–19 vaccine are calculated using 95 percent of the average wholesale price.

(2) *Infusion drugs furnished through a covered item of durable medical equipment.* The payment limit for an infusion drug furnished before January 1, 2017, through a covered item of durable medical equipment is calculated using 95 percent of the average wholesale price in effect on October 1, 2003.

(3) *Blood and blood products.* In the case of blood and blood products (other than blood clotting factors), the payment limits are determined in the same manner as the payment limits were determined on October 1, 2003.

(4) *Payment amount in a case where the average sales price during the first quarter of sales is unavailable.* During an initial period (not to exceed a full calendar quarter) in which data on the prices for sales of the drug are not sufficiently available from the manufacturer to compute an average sales price:

(i) *In general.* Except as provided in paragraph (e)(4)(ii) of this section,

(A) For dates of service before January 1, 2019, the payment amount for the drug is based on the wholesale acquisition cost or the Medicare Part B drug payment methodology in effect on November 1, 2003.

(B) For dates of service on or after January 1, 2019, the payment amount for the drug is an amount not to exceed 103 percent of the wholesale acquisition cost or based on the Medicare Part B drug payment methodologies in effect on November 1, 2003.

(ii) *Limitation on payment amount for biosimilar biological products during initial period.* For dates of service on or after July 1, 2024, the payment amount for a biosimilar biological product (as defined in §414.902) during the initial period is the lesser of the following:

(A) The payment amount for the biosimilar biological product as determined under clause (e)(4)(i)(B) of this section or

(B) 106 percent of the amount determined under section 1847A(b)(1)(B) of the Act for the reference biological product (as defined in §414.902).

(5) *Treatment of certain drugs.* Beginning with April 1, 2008, the payment amount for—

(i) Each single source drug or biological described in section 1842(o)(1)(G) that is treated as a multiple source drug because of the application of section 1847A(c)(6)(C)(ii) is the lower of—

(A) The payment amount that would be determined for such drug or biological applying section 1847A(c)(6)(C)(ii); or

(B) The payment amount that would have been determined for such drug or biological if section 1847A(c)(6)(C)(ii) were not applied.

(ii) A multiple source drug described in section 1842(o)(1)(G) (excluding a drug or biological that is treated as a multiple source drug because of the application of section 1847A(c)(6)(C)(ii)) is the lower of—

(A) The payment amount that would be determined for such drug or biological taking into account the application of section 1847A(c)(6)(C)(ii); or

(B) The payment amount that would have been determined for such drug or biological if section 1847A(c)(6)(C)(ii) were not applied.

(6) *Radiopharmaceuticals furnished in settings other than the hospital outpatient department.* Medicare administrative contractors must determine payment limits for radiopharmaceuticals based on any methodology used to determine payment limits for radiopharmaceuticals in place on or prior to November 2003. Such methodology may include, but is not limited to, the use of invoice-based pricing.

(f) Except as otherwise specified (see paragraph (e)(2) of this section) for infusion drugs, the payment limits are updated quarterly.

(g) The payment limit is computed without regard to any special packaging, labeling, or identifiers on the dosage form or product or package.

(h) The payment amount is subject to applicable deductible and coinsurance.

(i) *Manufacturer's average sales price (ASP) data not available prior to the publication deadline for quarterly payment limits.* For circumstances in which manufacturer's ASP data is not available prior to the publication deadline for quarterly payment limits as described in this section, payment limit must be determined as follows:

(1) For a multiple source drug (as defined in § 414.902)—

(i) In circumstances in which negative or zero manufacturer's ASP data is reported for one or more, but not all, NDCs associated with a billing and payment code for that drug for a given quarter, the payment limit for the given quarter is calculated using only NDCs for that drug with positive manufacturer's ASP data, except in circumstances described in paragraph (i)(1)(iii) of this section.

(ii) In circumstances in which negative or zero manufacturer's ASP data is reported for all NDCs associated with a billing and payment code for that drug for a given quarter, the payment limit for the given quarter is calculated by carrying over all positive manufacturer's ASP data from the most recently available previous quarter with positive manufacturer's ASP data for at least one NDC until at least one NDC for the drug has positive manufacturer's ASP data for a quarter.

(iii) In circumstances in which manufacturer's ASP data is not available and the unavailability of the manufacturer's ASP data results in a significant change in the ASP payment limit compared to the previous quarter, the payment limit is calculated by carrying over the most recently available ASP data for the individual NDC(s), adjusted by the weighted average of the change in the manufacturer's ASP data for the NDCs that were reported for both the most recently available previous quarter and the current quarter.

(2) For a single source drug, excluding biosimilar biological products (both as defined in § 414.902)—

(i) In circumstances in which negative or zero manufacturer's ASP data is reported for one or more, but not all, NDCs associated with a billing and payment code for that drug for a given quarter, the payment limit for the given quarter is calculated using only NDCs for that drug with positive manufacturer's ASP data.

(ii) In circumstances in which negative or zero manufacturer's ASP data is reported for all NDCs associated with a billing and payment code for

that drug for a given quarter, the payment limit for the given quarter is the lesser of the following until at least one NDC for the drug has positive manufacturer's ASP data for a quarter:

(A) 106 percent of the volume-weighted average of the most recently available positive manufacturer's ASP data from a previous quarter in which at least one NDC for the drug has positive manufacturer's ASP data for the quarter. If the payment limit from such quarter was based on 106 percent of the wholesale acquisition cost because of the application of paragraph (d)(1) of this section, that payment limit is carried over; or

(B) 106 percent of the wholesale acquisition cost. If there is more than one WAC per billing unit for the drug, the payment limit is set using the lowest WAC per billing unit.

(3) For a biosimilar biological product (as defined in §414.902)—

(i) In circumstances in which negative or zero manufacturer's ASP data is reported for one or more, but not all, NDCs for a given quarter, the payment limit for the given quarter is calculated using only NDCs with positive manufacturer's ASP data.

(ii) In circumstances in which negative or zero manufacturer's ASP data is reported for all NDCs for a given quarter, the payment limit for the given quarter is the sum of the following until at least one NDC for the drug has positive manufacturer's ASP data for a quarter:

(A) The volume-weighted average of the most recently available positive manufacturer's ASP data from a previous quarter; and

(B) Either:

(*1*) If the biosimilar is not a qualifying biosimilar (as both are defined at §414.902), 6 percent of the amount determined under section 1847A(b)(4) of the Act for the reference biological product (as defined in §414.902) for the given quarter; or

(*2*) If the biosimilar is a qualifying biosimilar (as both are defined at §414.902), 8 percent of the amount determined under section 1847A(b)(4) of the Act for the reference biological product (as defined in §414.902) for the given quarter.

(j) *Biosimilar biological products*—(1) *In general.* Except as provided in paragraph (j)(2), effective January 1, 2016, the payment amount for a biosimilar biological product (as defined in §414.902), for all NDCs assigned to such product, is the sum of the average sales price of all NDCs assigned to the biosimilar biological products included within the same billing and payment code as determined under section 1847A(b)(6) of the Act, and 6 percent of the amount determined under section 1847A(b)(4) of the Act for the reference biological product (as defined in §414.902).

(2) *Temporary increase in Medicare Part B payment for qualifying biosimilar biological products.* In the case of a qualifying biosimilar biological product (as defined in §414.902) that is furnished during the applicable 5-year period (as defined in §414.902) for such product, the payment amount for such product with respect to such period is the sum determined under as determined under section 1847A(b)(6) of the Act and 8 percent of the amount determined under section 1847A(b)(4) of the Act for the reference biological product (as defined in §414.902).

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§414.906 Competitive acquisition program as the basis for payment.

(a) *Program payment.* Beginning in 2006, as an alternative to payment under §414.904, payment for a CAP drug may be made through the CAP if the following occurs:

(1) The CAP drug is supplied under the CAP by an approved CAP vendor as specified in §414.908(b).

(2) The claim for the prescribed drug is submitted by the approved CAP vendor that supplied the drug, and payment is made only to that vendor.

(3) The approved CAP vendor collects applicable deductible and coinsurance with respect to the drug furnished

under the CAP only after the drug is administered to the beneficiary.

(4) The approved CAP vendor delivers CAP drugs directly to the participating CAP physician in unopened vials or other original containers as supplied by the manufacturer or from a distributor that has acquired the products directly from the manufacturer and includes language with the shipping material stating that the drug was acquired in a manner consistent with all statutory requirements. If the approved CAP vendor opts to split shipments, the participating CAP physician must be notified in writing which can be included with the initial shipment, and each incremental shipment must arrive at least 2 business days before the anticipated date of administration.

(5) The approved CAP vendor bills Medicare only for the amount of the drug administered to the patient, and the beneficiary's coinsurance will be calculated from the quantity of drug that is administered.

(b) *Exceptions to competitive acquisition.* Specific CAP drugs, including a category of these drugs, may be excluded from the CAP if the application of competitive bidding to these drugs—

(1) Is not likely to result in significant savings; or

(2) Is likely to have an adverse impact on access to those drugs.

(c) *Computation of payment amount.* Except as specified in paragraph (c)(2) of this section, payment for CAP drugs is based on bids submitted as a result of the bidding process as described in § 414.910 of this subpart.

(1) *Single payment amount.* (i) A single payment amount for each CAP drug in the competitive acquisition area is determined on the basis of the bids submitted and accepted and updated from the bidding period to the beginning of the payment year.

(ii) The single payment amount is then updated quarterly based on the approved CAP vendor's reasonable net acquisition costs for that category as determined by CMS, and limited by the weighted payment amount established under section 1847A of the Act across all drugs for which a composite bid is required in the category.

(iii) The payment amount for each other drug for which the approved CAP vendor submits a bid in accordance with § 414.910 of this subpart and each other drug that is approved by CMS for the approved CAP vendor to furnish under the CAP is also updated quarterly based on the approved CAP vendor's reasonable net acquisition costs for each HCPCS code and limited by the payment amount established under section 1847A of the Act.

(2) *Updates to payment amount.* (i) The first update is effective on the first day of claims processing for the first quarter of an approved CAP vendor's contract. The first quarterly contract update is based on the reasonable net acquisition cost (RNAC) data reported to CMS or its designee for any purchases of drug before the beginning of CAP claims processing for the contract period and reported to CMS no later than 30 days before the beginning of CAP claims processing.

(ii) For subsequent quarters, each approved CAP vendor must report to CMS or its designee RNAC data for a quarter of CAP drug purchases within 30 days of the close of that quarter.

(iii) For all quarters, only RNAC data from approved CAP vendors that are supplying CAP drugs under their CAP contract at the time updates are being calculated must be used to calculate updated CAP payment amounts.

(iv) CMS excludes such RNAC data submitted by an approved CAP vendor if, during the time calculations are being done, CMS knows that the approved CAP vendor will not be under contract for the applicable quarterly update.

(v) The payment amount weights must be calculated based on the more recent of the following:

(A) Contract bidding weights.

(B) CAP claims data.

(vi) The payment limit must be determined using the most recent payment limits available to CMS under section 1847A of the Act.

(vii) The following payment amount update calculation must be applied for the group of all drugs for which a composite bid is required.

(A) The most recent previous composite payment amount for the group is updated by—

(*1*) Calculating the percent change in reasonable net acquisition costs for each approved CAP vendor;

(*2*) Calculating the median of all participating approved CAP vendors' adjusted CAP payment amounts; and

(*3*) Limiting the payment as described in paragraph (c)(1) of this section.

(B) The median percent change, subject to the limit described in paragraph (c)(1) of this section, must be the update percentage for that quarter.

(C) The single update percentage must be applied to the payment amount for each drug in the group of drugs for which a composite bid is required in the category.

(viii) The following payment amount update calculation must be applied for each of the following items: Each HCPCS code not included in the composite bid list; Each HCPCS code added to the drug list during the contract period; and each drug that has not yet been assigned a HCPCS code, but for which a HCPCS code will be established.

(A) The most recent previous payment amount for each drug must be updated by calculating the percent change in reasonable net acquisition costs for each approved CAP vendor, then calculating the median of all participating approved CAP vendors' adjusted CAP payment amounts.

(B) The median percent change calculated for each drug, subject to the limit described in paragraph (c)(1) of this section, must be applied to the payment amount for each drug.

(3) *Alternative payment amount.* The alternative payment amount established under section 1847A of the Act may be used to establish payment for a CAP drug if—

(i) The drug is properly assigned to a category established under the CAP; and

(ii) It is a drug for which a HCPCS code must be established.

(d) *Adjustments.* There is an established process for adjustments to payments to account for drugs that were billed, but which were not administered.

(e) *Resupply of participating CAP physician drug inventory.* A participating CAP physician may acquire drugs under the CAP to resupply his or her private inventory if all of the following requirements are met:

(1) The drugs were required immediately.

(2) The participating CAP physician could not have anticipated the need for the drugs.

(3) The approved CAP vendor could not have delivered the drugs in a timely manner. For purposes of this section, timely manner means delivery within the emergency delivery timeframe, as defined in §414.902.

(4) The participating CAP physician administered the drugs in an emergency situation, as defined in §414.902.

(f) *Substitution or addition of drugs on an approved CAP vendor's CAP drug list*—(1) *Short-term substitution of a CAP drug.* On an occasional basis (for a period of time less than 2 weeks), an approved CAP vendor may agree to furnish a substitute NDC within a HCPCS code on the approved CAP vendor's CAP drug list if the approved CAP vendor—

(i) Is willing to accept the payment amount that was established for the HCPCS code under this section; and

(ii) Obtains the participating CAP physician's prior approval.

(2) *Long-term substitution or addition of a CAP drug.* An approved CAP vendor may submit a request, as specified in paragraph (f)(3) of this section, for approval to substitute an NDC supplied by the approved CAP vendor for another NDC within the same HCPCS code or to add an NDC to the approved CAP vendor's drug list, if at least one of the following criteria is met:

(i) Proposed substitution of an NDC for a period of 2 weeks or longer.

(ii) Proposed addition of one or more NDCs within a HCPCS code included in the CAP drug category specified by CMS or on the approved CAP vendor's approved CAP drug list.

(iii) Proposed addition of—

(A) One or more newly issued HCPCS codes; or

(B) One of the following single indication orphan drug J codes or their updates: J0205, J0256, J9300, J1785, J2355, J3240, J7513, J9010, J9015, J9017, J9160, J9216.

(iv) Beginning January 1, 2007, the proposed addition of a drug(s) that has

not yet been assigned a HCPCS code, but for which a HCPCS code must be established.

(v) On or after January 1, 2010, the proposed addition of drugs with similar therapeutic uses to drugs already supplied under the CAP by the approved CAP vendor(s).

(3) *Requesting the addition or substitution of CAP drug.* An approved CAP vendor that meets the one of the criteria specified in paragraph (f)(2) must submit a written request to CMS or its designee. The request must—

(i) Specify the NDC(s) and the respective HCPCS code that is to be added or substituted.

(ii) Address the rationale for the substitution or addition of the NDC(s) or the addition of the HCPCS code(s) as applicable; and

(iii) Address the impact of the substitution of the NDC(s) or the addition of the NDC(s) or HCPCS code(s), or both on—

(A) Patient and drug safety;

(B) Drug waste; and

(C) The potential for cost savings.

(iv) In the case of additions requested under paragraph (f)(2)(v) of this section, address and document the need for such an expansion based on demand for the product(s).

(4) *Approval of a request(s).* CMS or its designee notifies the approved CAP vendor of its decision.

(i) Except as specified in paragraph (f)(4)(ii) of this section, an approved request is effective at the beginning of the next calendar quarter.

(ii) Approved substitutions for request based on a drug shortage or other exigent circumstance may become effective immediately provided that—

(A) CMS approves the immediate substitution; and

(B) The approved CAP vendor's notifies its CAP participating physicians of the substitution immediately following CMS approval.

(5) *Payment for an approved drug change(s).* The payment for—

(i) Substituted or added CAP drugs that are within a HCPCS code for which payment is computed under paragraph (c)(1) of this section is the single payment for that HCPCS code, as determined and updated in accordance with paragraph (c)(1) of this section; or

(ii) Added CAP drugs that are not within a HCPCS code for which payment is computed under paragraph (c)(1) of this section is specified under paragraph (c)(2) of this section.

(g) *Deletion of drugs on an approved CAP vendor's CAP drug list.* Deletion of drugs on an approved CAP vendor's CAP drug list due to unavailability requires a written request and approval as described in paragraphs (f)(3)(i) through (iii) and (f)(4) of this section.

[70 FR 39094, July 6, 2005, as amended at 70 FR 70333, Nov. 21, 2005; 71 FR 9460, Feb. 24, 2006; 74 FR 62012, Nov. 25, 2009]

§ 414.908 Competitive acquisition program.

(a) Participating CAP *physician selection of an approved CAP vendor.* (1) CMS provides the participating CAP physician with a process for the selection of an approved CAP vendor on an annual basis, with exceptions as specified in § 414.908(a)(2). Participating CAP physicians will also receive information about the CAP in the enrollment process for Medicare participation set forth in section 1842(h) of the Act.

(2) A participating CAP physician may select an approved CAP vendor outside the annual selection process or opt out of the CAP for the remainder of the annual selection period when—

(i) The selected approved CAP vendor ceases participation in the CAP;

(ii) The physician leaves a group practice participating in CAP;

(iii) The participating CAP physician relocates to another competitive acquisition area; or

(iv) The approved CAP vendor refuses to ship to the participating CAP physician because the conditions of § 414.914(i) have been met (if this subparagraph (a)(2)(iv) applies, the physician can withdraw from the CAP category for the remainder of the year immediately upon notice to CMS and the approved CAP vendor); or

(v) Other exigent circumstances defined by CMS are present, including—

(A) If, up to and including 60 days after the effective date of the physician's CAP election agreement, the participating CAP physician submits a

written request to the designated carrier to terminate the CAP election agreement because CAP participation imposes a burden on the physician's practice. The written request must document the burden. The designated carrier will process the participating CAP physician's request and CMS will approve or deny the request under the dispute resolution process as specified under § 414.917 of this subpart.

(B) If, more than 60 days after the effective date of the physician's CAP election agreement, the participating CAP physician submits a written request to the designated carrier to terminate the CAP election agreement because, based on a change in circumstances of which the participating CAP physician was not previously aware, CAP participation imposes a burden on the physician's practice. The written request must document the burden. The designated carrier will process the participating CAP physician's request and CMS will approve or deny the request under the dispute resolution process as specified under § 414.917 of this subpart.

(3) The physician participating in the CAP—

(i) Elects to use an approved CAP vendor for the drug category and area as set forth in § 414.908(b);

(ii) Completes and signs the CAP election agreement;

(iii) Submits a written prescription order to the approved CAP vendor with complete patient information for patients new to the approved CAP vendor or when information changes. Abbreviated information may be sent on all subsequent orders for a patient for which the approved CAP vendor has previously received complete information and that has no changes to the original information. Prescription orders may be initiated by telephone, with a follow-up written order provided within 8 hours for routine deliveries and immediately for emergency deliveries;

(iv) Does not receive payment for the CAP drug;

(v) Except where applicable State pharmacy law prohibits it, provides the following information to the approved CAP vendor to facilitate collection of applicable deductible and coinsurance as described in § 414.906(a)(3):

(A) Date of order.

(B) Beneficiary name, address, and phone number.

(C) Physician identifying information:

Name, practice location/shipping address, group practice information (if applicable), PIN, and UPIN.

(D) Drug name.

(E) Strength.

(F) Quantity ordered.

(G) Dose.

(H) Frequency/instructions.

(I) Anticipated date of administration.

(J) Beneficiary Medicare information/Health insurance (HIC) number.

(K) Supplementary insurance information (if applicable).

(L) Medicaid information (if applicable).

(M) Additional patient information: date of birth, allergies, height/weight, ICD–9–CM (if necessary).

(vi) Agrees to accept the particular National Drug Codes (NDCs) supplied by the approved CAP vendor for the duration of the participating CAP physician's enrollment with the approved CAP vendor, subject to paragraphs (a)(3)(vii) and (a)(3)(xiv) of this section. By electing to participate with an approved CAP vendor, the participating CAP physician also agrees to accept the changes to the approved CAP vendor's CAP drug list that have been approved in accordance with § 414.906(f).

(vii) Agrees to place routine orders for CAP drugs at the HCPCs level, except when medical necessity requires a particular formulation on the approved CAP vendor's CAP drug list. Medical necessity must be documented. When the conditions of this paragraph are met, the participating CAP physician may submit a prescription order to the approved CAP vendor that specifies the NDC.

(viii) Notifies the approved CAP vendor when a drug is not administered or a smaller amount was administered than was originally ordered. The participating CAP physician and the approved CAP vendor agree on how to handle the unused CAP drug. If it is agreed that the participating CAP physician will maintain the CAP drug in

his inventory for administration at a later date, the participating CAP physician submits a new prescription order at that time. This prescription order specifies that the CAP drug is being obtained from the participating CAP physician's CAP inventory and shipment should not occur;

(ix) Maintains a separate electronic or paper inventory for each CAP drug obtained;

(x) Agrees to file the Medicare claim within 30 calendar days of the date of drug administration.

(xi) Agrees to submit documentation such as medical records or certification, as necessary, to support payment for a CAP drug;

(xii) Agrees not to transport CAP drugs from one practice location or place of service to another location except in accordance with a written agreement between the participating CAP physician and the approved CAP vendor that requires that drugs are not subjected to conditions that will jeopardize their integrity, stability, and/or sterility while being transported.

(xiii) Agrees to provide the CMS-developed CAP fact sheet to beneficiaries; and

(xiv) May receive payment under the ASP system when medical necessity requires a certain brand or formulation of a drug that the approved CAP vendor has not been contracted to furnish under the CAP.

(4) Physician group practices. If a physician group practice using a group billing number(s) elects to participate in the CAP, all physicians in the group are considered to be participating CAP physicians when using the group's billing number(s).

(b) *Program requirements.* (1) CMS selects approved CAP vendors through a competition among entities based on the following:

(i) Submission of the bid prices using the OMB-approved Vendor Application and Bid Form for CAP drugs within the category and competitive acquisition area that—

(A) Places the vendor among the qualified bidders with the lowest five composite bids; and

(B) Does not exceed the weighted payment amount established under section 1847A of the Act across all drugs in that category.

(ii) Ability to ensure product integrity.

(iii) Customer service/Grievance process.

(iv) At least 3 years experience in furnishing Part B injectable drugs.

(v) Financial performance and solvency.

(vi) Record of integrity and the implementation of internal integrity measures.

(vii) Internal financial controls.

(viii) Acquisition of all CAP drugs directly from the manufacturer or from a distributor that has acquired the products directly from the manufacturer.

(ix) Maintenance of appropriate licensure to supply CAP drugs in States in which they are supplying CAP drugs.

(x) Cost-sharing assistance as described in § 414.914(g).

(xi) Other factors as determined by CMS.

(2) Approved CAP vendors must also meet the contract requirements under § 414.914.

(c) *Additional considerations.* CMS may refuse to award a contract or terminate an approved CAP vendor contract based upon the following:

(1) Suspension or revocation by the Federal or State government of the entity's license for distribution of drugs, including controlled substances.

(2) Exclusion of the entity under section 1128 of the Act from participation in Medicare or other Federal health care programs. These considerations are in addition to CMS' ability to terminate the approved CAP vendor for cause as specified in § 414.914(a).

(3) Past violations or misconduct related to the pricing, marketing, distribution, or handling of drugs provided incident to a physician's service.

(d) *Multiple source drugs.* In the case of multiple source drugs, there must be a competition among entities for the acquisition of at least one CAP drug within each billing and payment code within each category for each competitive acquisition area.

(e) *Multiple contracts for a category and area.* The number of bidding qualified entities that are awarded a contract for a given category and area may be limited to no fewer than two.

[70 FR 39094, July 6, 2005, as amended at 70 FR 70333, Nov. 21, 2005; 72 FR 66402, Nov. 27, 2007; 74 FR 62013, Nov. 25, 2009]

§414.910 Bidding process.

(a) Entities may bid to furnish CAP drugs in all competitive acquisition areas of the United States, or one or more specific competitive acquisition areas.

(b) The amount of the bid for any CAP drug for a specific competitive acquisition area must be uniform for all portions of that competitive acquisition area.

(c) A submitted bid price must include the following:

(1) All costs related to the delivery of the drug to the participating CAP physician.

(2) The costs of dispensing (including shipping) of the drug and management fees. The costs related to the administration of the drug or wastage, spillage, or spoilage may not be included.

[70 FR 39095, July 6, 2005]

§414.912 Conflicts of interest.

(a) Approved CAP vendors and applicants that bid to participate in the CAP are subject to the following:

(1) The conflict of interest standards and requirements of the Federal Acquisition Regulation (FAR) organizational conflict of interest guidance, found under FAR subpart 9.5.

(2) Those requirements and standards contained in each individual contract awarded to perform functions under section 1847B of the Act.

(b) *Post-award conflicts of interest.* Approved CAP vendors must have a code of conduct that establishes policies and procedures for recognizing and resolving conflicts of interest between the approved CAP vendor and any entity, including the Federal Government, with whom it does business. The code of conduct which is submitted as part of the application must—

(1) State the need for management, employees, contractors, and agents to comply with the approved CAP vendor's code of conduct, and policies and procedures for conflicts of interest; and

(2) State the approved CAP vendor's expectations for management, employees, contractors, and agents to comply with the approved CAP vendor's code of conduct, and policies and procedures for detecting, preventing, and resolving conflicts of interest.

[70 FR 39094, July 6, 2005]

§414.914 Terms of contract.

(a) The contract between CMS and the approved CAP vendor will be for a term of 3 years, unless terminated or suspended earlier as provided in this section or provided in §414.917. The contract may be terminated—

(1) By CMS for default if the approved CAP vendor violates any term of the contract; or

(2) In the absence of a contract violation, by either CMS or the approved CAP vendor, if the terminating party notifies the other party by June 30 for an effective date of termination of December 31 of that year.

(b) The contract will provide for a code of conduct for the approved CAP vendor that includes standards relating to conflicts of interest standards as set forth at §414.912.

(c) The approved CAP vendor will have and implement a compliance plan that contains policies and procedures that control program fraud, waste, and abuse, and consists of the following minimum elements:

(1) Written policies, procedures, and standards of conduct articulating the organization's commitment to comply with all applicable Federal and State laws, regulations, and guidance, including, but not limited to, the Prescription Drug Marketing Act (PDMA), the physician self-referral (''Stark'') prohibition, the Anti-Kickback statute and the False Claims Act.

(2) The designation of a compliance officer and compliance committee accountable to senior management.

(3) Effective training and education of the compliance officer and organization employees, contractors, agents, and directors.

(4) Enforcement of standards through well publicized disciplinary guidelines.

(5) Procedures for effective internal monitoring and auditing.

(6) Procedures for ensuring prompt responses to detected offenses and development of corrective action initiatives relating to the organization's contract as an approved CAP vendor.

(i) If the approved CAP vendor discovers evidence of misconduct related to payment or delivery of drugs or biologicals under the contract, it will conduct a timely and reasonable inquiry into that conduct.

(ii) The approved CAP vendor will conduct appropriate corrective actions including, but not limited to, repayment of overpayments and disciplinary actions against responsible individuals, in response to potential violations referenced at paragraph (c)(6)(i) of this section.

(7) Procedures to voluntarily self-report potential fraud or misconduct related to the CAP to the appropriate government agency.

(d) The contract must provide for disclosure of the approved CAP vendor's reasonable, net acquisition costs for a specified period of time, not to exceed quarterly.

(e) The contract must provide for appropriate adjustments as described in § 414.906(c)(1).

(f) Under the terms of the contract, the approved CAP vendor must also—

(1) Have sufficient arrangements to acquire and deliver CAP drugs within the category in the competitive acquisition area specified by the contract;

(2) Have arrangements in effect for shipment at least 5 weekdays each week of CAP drugs under the contract, including the ability to comply with the routine and emergency delivery timeframes defined in § 414.902;

(3) Have procedures in place to address and resolve complaints of participating CAP physicians and individuals and inquiries regarding shipment of CAP drugs;

(4) Have a grievance and appeals process for dispute resolution;

(5) Respond within 2 business days to any inquiry, or sooner if the inquiry is related to drug quality;

(6) Staff a toll-free telephone line from 8:30 a.m. or earlier and until 5 p.m. or later for all time zones served in the continental United States by the CAP vendor on business days (Monday through Friday excluding Federal holidays) to provide customer assistance, and establish reasonable hours of operation for Hawaii, Alaska, Puerto Rico, and the other U.S. territories;

(7) Staff an emergency toll-free telephone line for weekend and evening access when the call center is closed, and determine what hours on Saturday and Sunday the call center is staffed and which hours a toll-free emergency line is activated; and

(8) Include assistance for the disabled, the hearing impaired, and Spanish-speaking inquirers in all customer service operations.

(9) Meet applicable licensure requirements in each State in which it supplies drugs under the CAP;

(10) Be enrolled in Medicare as a participating supplier;

(11) Comply with all applicable Federal and State laws, regulations and guidance related to the prevention of fraud and abuse;

(12) Supply CAP drugs upon receipt of a prescription order to all participating CAP physicians who have selected the approved CAP vendor, except when the conditions of paragraph (h) of this section or § 414.916(b) of this subpart are met;

(13) Provide direct notification to participating CAP physicians enrolled with them of updates to the approved CAP vendor's CAP drug list on a quarterly basis. Changes must be disseminated at least 30 days before the approved changes are due to take effect, unless immediate notification as described in § 414.906(f)(4) is required. The approved CAP vendor's entire CAP drug list must be disseminated at least once yearly; and approved CAP vendors must make a complete list that incorporates the most recent updates available to physicians on an ongoing basis. CMS posts on its web site the updated CAP drug lists for each approved CAP vendor.

(14) Ensure that subcontractors who are involved in providing services under the approved CAP contractor's CAP contract meet all requirements and comply with all laws and regulations relating to the services they provide under the CAP program. Notwithstanding any relationship the CAP vendor may have with any subcontractor,

the approved CAP vendor maintains ultimate responsibility for adhering to and otherwise fully complying with all terms and conditions of its contract with CMS;

(15) Comply with product integrity and record keeping requirements including but not limited to drug acquisition, handling, storage, shipping, drug waste, and return processes; and

(16) Comply with such other terms and conditions as CMS may specify in the CAP contract consistent with section 1847B of the Act.

(g) Under the terms of the contract, the approved CAP vendor must provide assistance to beneficiaries experiencing financial difficulty in paying their cost-sharing amounts through any one or all of the following:

(1) Referral to a bona fide and independent charitable organization.

(2) Implementation of a reasonable payment plan.

(3) A full or partial waiver of the cost-sharing amount after determining in good faith that the individual is in financial need or the failure of reasonable collection efforts, provided that the waiver meets all of the requirements of section 1128A(i)(6)(A) of the Act and the corresponding regulations at paragraph (1) of the definition of ''Remuneration'' in §1003.101 of this title. The availability of waivers may not be advertised or be made as part of a solicitation. Approved CAP vendors must inform beneficiaries that they generally make available the categories of assistance described in paragraphs (g)(1), (g)(2), and (g)(3) of this section. In no event may the approved CAP vendor include or make any statements or representations that promise or guarantee that beneficiaries receive cost-sharing waivers.

(h) The approved CAP vendor must verify drug administration prior to collection of any applicable cost sharing amount.

(1) The approved CAP vendor documents, in writing, the following information necessary to verify drug administration:

(i) Beneficiary name.

(ii) Health insurance number.

(iii) Expected date of administration.

(iv) Actual date of administration.

(v) Identity of the participating CAP physician.

(vi) Prescription order number.

(vii) Identity of the individuals who supply and receive the information.

(viii) Dosage supplied.

(ix) Dosage administered.

(2) If the information is obtained verbally, the approved CAP vendor must also maintain the following information:

(i) The identities of individuals who exchanged the information.

(ii) The date and time that the information was obtained.

(3) The approved CAP vendor must provide this information to CMS or the beneficiary upon request.

(i) The approved CAP vendor must comply with the following procedures before it may refuse to make further shipments of CAP drugs to a participating CAP physician on behalf of a beneficiary:

(1) Subsequent to receipt of payment by Medicare, or the verification of drug administration by the participating CAP physician, the approved CAP vendor must bill any applicable supplemental insurance policies.

(2) An approved CAP vendor that has received payment from the designated carrier for CAP drugs that have not been administered must promptly refund payment for such drugs to the designated carrier and must refund any coinsurance and deductible collected from the beneficiary and his or her supplemental insurer.

(3) At the time of billing the beneficiary, or the participating CAP physician's presentation of the bill on behalf of the approved CAP vendor, the approved CAP vendor must inform the beneficiary of any types of cost-sharing assistance that may be available consistent with the requirements of section 1128A(a)(5) of the Act and §414.914(g).

(4) If the beneficiary demonstrates a financial need, the approved CAP vendor must follow the conditions outlined in paragraph (g) of this section.

(5) For purposes of paragraph (i) of this section delivery means postmark date, or the date the coinsurance bill

or notice was presented to the beneficiary by the participating CAP physician on behalf of the approved CAP vendor.

(i) Except as specified in paragraph (i)(5)(ii) of this section, if after 45 days from delivery of the approved CAP vendor's bill to the beneficiary, the beneficiary's cost-sharing obligation remains unpaid, the approved CAP vendor may refuse further shipments to the participating CAP physician for that beneficiary.

(ii) If the beneficiary has requested cost-sharing assistance within 45 days of receiving delivery of the approved CAP vendor's bill, provisions of paragraphs (i)(6), (i)(7), or (i)(8) of this section, apply.

(6) If the approved CAP vendor implements a reasonable payment plan, as specified in § 414.914(g)(2), the approved CAP vendor must continue to ship CAP drugs for the beneficiary, as long as the beneficiary remains in compliance with the payment plan and makes an initial payment under the plan within 15 days after the delivery of the approved CAP vendor's written notice to the beneficiary offering the payment plan.

(7) If the approved CAP vendor has waived the cost-sharing obligations in accordance with section 1128A of the Act and § 414.914(g)(3), the approved CAP vendor may not refuse to ship drugs for that beneficiary.

(8) If the approved CAP vendor refers the beneficiary to a bona fide and independent charity in accordance with § 414.914(g)(1), the approved CAP vendor may refuse to ship drugs if the past due balance is not paid 15 days after the date of delivery of the approved CAP vendor's written notice to the beneficiary containing the referral for cost-sharing assistance.

(9) The approved CAP vendor may refuse to make further shipments to that participating CAP physician on behalf of the beneficiary for the lesser of the end of the calendar year or until the beneficiary's balance is paid in full.

[70 FR 39096, July 6, 2005, as amended at 70 FR 70333, Nov. 21, 2005; 72 FR 66403, Nov. 27, 2007; 74 FR 62013, Nov. 25, 2009]

§ 414.916 Dispute resolution for vendors and beneficiaries.

(a) *General rule.* Cases of an approved CAP vendor's dissatisfaction with denied drug claims are resolved through a voluntary alternative dispute resolution process delivered by the designated carrier, and a reconsideration process provided by CMS.

(b) *Dispute resolution.* (1) When an approved CAP vendor is not paid on claims submitted to the designated carrier, the vendor may appeal to the designated carrier to counsel the responsible participating CAP physician on his or her agreement to file a clean claim and pursue an administrative appeal in accordance with subpart H of part 405 of this chapter. If problems persist, the approved CAP vendor may ask the designated carrier to—

(i) Review the participating CAP physician's performance; and

(ii) Potentially recommend to CMS that CMS suspend the participating CAP physician's CAP election agreement.

(2) The designated carrier—

(i) Gathers information from the local carrier, the participating CAP physician, the beneficiary, and the approved CAP vendor; and

(ii) Makes a recommendation to CMS on whether the participating CAP physician has been filing his or her CAP drug administration claims in accordance with the requirements for physician participation in the CAP as set forth in § 414.908(a)(3). The recommendation will include numbered findings of fact.

(3) CMS will review the recommendation of the designated carrier and gather relevant additional information from the participating CAP physician before deciding whether to suspend the participating CAP physician's CAP election agreement. A suspension commencing before October 1 will conclude on December 31 of the same year. A suspension commencing on or after October 1 will conclude on December 31 of the next year.

(4) Upon notification from CMS of a participating CAP physician's suspension from the program, the approved CAP vendor must cease delivery of

CAP drugs to the suspended participating CAP physician until the suspension has been lifted.

(5) The participating CAP physician may appeal that suspension by requesting a reconsideration of CMS' decision. The reconsideration will address whether the participating CAP physician's denied claims and appeals were the result of the participating CAP physician's failure to participate in accordance with the requirements of §414.908(a)(3).

(c) *Reconsideration*—(1) *Right to a reconsideration.* A participating CAP physician dissatisfied with a determination that his or her CAP election agreement has been suspended by CMS or a determination under §414.917(d) denying the participating CAP physician's request to terminate participation in the CAP under §414.908(a)(v) is entitled to a reconsideration as provided in this subpart.

(2) *Eligibility for reconsideration.* CMS reconsiders any determination to suspend a participating CAP physician's election agreement if the participating CAP physician files a written request for reconsideration in accordance with paragraphs (c)(3) and (c)(4) of this section.

(3) *Manner and timing of request for reconsideration.* A participating CAP physician who is dissatisfied with a CMS decision to suspend his or her CAP election agreement may request a reconsideration of the decision by filing a request with CMS. The request must be filed within 30 days of receipt of the CMS decision letter notifying the participating CAP physician of CMS' decision to suspend his or her CAP election agreement. From the date of receipt of the decision letter until the day the reconsideration determination is final, the ASP payment methodology under section 1847A of the Act applies to the physician.

(4) *Content of request.* The request for reconsideration must specify—

(i) The findings or issues with which the participating CAP physician disagrees;

(ii) The reasons for the disagreement;

(iii) A recital of the facts and law supporting the participating CAP physician's position;

(iv) Any supporting documentation; and

(v) Any supporting statements from approved CAP vendors, local carriers, or beneficiaries.

(5) *Withdrawal of request for reconsideration.* A participating CAP physician may withdraw his or her request for reconsideration at any time before the issuance of a reconsideration determination.

(6) *Discretionary informal hearing.* In response to a request for reconsideration, CMS may, at its discretion, provide the participating CAP physician the opportunity for an informal hearing that—

(i) Is conducted by a hearing officer appointed by the director of the CMS Center for Medicare Management or his or her designee; and

(ii) Provides the participating CAP physician the opportunity to present, by telephone or in person, evidence to rebut CMS' decision to suspend or terminate a participating CAP physician's CAP election agreement.

(7) *Informal hearing procedures.* (i) CMS provides written notice of the time and place of the informal hearing at least 10 days before the scheduled date.

(ii) The informal reconsideration hearing will be conducted in accordance with the following procedures:

(A) The hearing is open to CMS and the participating CAP physician requesting the reconsideration, including—

(*1*) Authorized representatives;

(*2*) Technical advisors (individuals with knowledge of the facts of the case or presenting interpretation of the facts);

(*3*) Representatives from the local carrier;

(*4*) Representatives from the approved CAP vendor; and

(*5*) Legal counsel.

(B) The hearing is conducted by the hearing officer who receives relevant testimony;

(C) Testimony and other evidence may be accepted by the hearing officer even though it would be inadmissible under the rules of evidence applied in Federal courts;

(D) Either party may call witnesses from among those individuals specified

in paragraph (c)(7)(ii)(A) of this section; and

(E) The hearing officer does not have the authority to compel by subpoena the production of witnesses, papers, or other evidence.

(8) *Hearing officer's findings.* (i) Within 30 days of the hearing officer's receipt of the hearing request, the hearing officer presents the findings and recommendations to the participating CAP physician who requested the reconsideration. If the hearing officer decides to conduct an in-person or telephone hearing, the hearing officer will send a hearing notice to the participating CAP physician within 10 days of receipt of the hearing request, and the findings and recommendations are due to the participating CAP physician within 30 days of the hearing's conclusion.

(ii) The written report of the hearing officer includes separate numbered findings of fact and the legal conclusions of the hearing officer.

(9) *Final reconsideration determination.* (i) The hearing officer's decision is final unless the director of the CMS Center for Medicare Management or his or her designee chooses to review that decision within 30 days. If the decision is favorable to the participating CAP physician, then the participating CAP physician may resume his or her participation in CAP. The hearing officer and the CMS official may review decisions that are favorable or unfavorable to the participating CAP physician.

(ii) The CMS official may accept, reject, or modify the hearing officer's findings.

(iii) If the CMS official reviews the hearing officer's decision, the CMS official issues a final reconsideration determination to the participating CAP physician on the basis of the hearing officer's findings and recommendations and other relevant information.

(iv) The reconsideration determination of the CMS official is final. If the final decision is unfavorable to the participating CAP physician, then the participating CAP physician's CAP election agreement is terminated.

(d) The approved CAP vendor may not charge the beneficiary for the full drug coinsurance amount if the designated contractor did not pay the approved CAP vendor in full, unless a properly executed advance beneficiary notice is in place. When a beneficiary receives an inappropriate coinsurance bill, the beneficiary may participate in the approved CAP vendor's grievance process to request correction of the approved CAP vendor's file. If the beneficiary is dissatisfied with the result of the approved CAP vendor's grievance process, the beneficiary may request intervention from the designated carrier. This is in addition to, rather than in place of, any other beneficiary appeal rights. The designated carrier will first investigate the facts and then facilitate correction to the appropriate claim record and beneficiary file.

[70 FR 39097, July 6, 2005, as amended at 72 FR 66403, Nov. 27, 2007; 74 FR 62013, Nov. 25, 2009]

§ 414.917 Dispute resolution and process for suspension or termination of approved CAP contract and termination of physician participation under exigent circumstances.

(a) *General rule.* If a participating CAP physician finds an approved CAP vendor's service, or the quality of a CAP drug supplied by the approved CAP vendor to be unsatisfactory, then the physician may address the issue first through the approved CAP vendor's grievance process, and second through an alternative dispute resolution process administered by the designated carrier and CMS. If CMS suspends an approved CAP vendor's CAP contract for noncompliance or terminates the CAP contract in accordance with § 414.914(a), the approved CAP vendor may request a reconsideration in accordance with paragraph (c) of this section.

(b) *Dispute resolution.* (1) When a participating CAP physician is dissatisfied with an approved CAP vendor's service or the quality of a CAP drug supplied by the approved CAP vendor, then the participating CAP physician may use the approved CAP vendor's grievance process. If the service or quality issues are not resolved through the grievance process to the physician's satisfaction, then the participating CAP physician may ask the designated carrier to—

(i) Review the approved CAP vendor's performance; and

(ii) Potentially recommend termination of the approved CAP vendor's CAP contract.

(2) *Responsibility of the designated carrier*. The designated carrier—

(i) Gathers information from the local carrier, the participating CAP physician, the beneficiary, and the approved CAP vendor; and

(ii) Makes a recommendation to CMS on whether the approved CAP vendor has been meeting the service and quality obligations of its CAP contract. This recommendation will include numbered findings of fact.

(3) CMS will review the recommendation of the designated carrier and, gather relevant additional information from the approved CAP vendor, the participating CAP physician, the local carrier, and the beneficiary before deciding whether to terminate the approved CAP vendor's CAP contract.

(4) The approved CAP vendor may appeal that termination by requesting a reconsideration. A determination must be made as to whether the approved CAP vendor has been meeting the service and quality obligations of its CAP contract. The approved CAP vendor's contract will remain suspended during the reconsideration process.

(c) *Reconsideration*—(1) *Right to reconsideration*. An approved CAP vendor dissatisfied with a determination that its CAP contract has been suspended or terminated by CMS is entitled to a reconsideration as provided in this subpart.

(2) *Eligibility for reconsideration*. CMS will reconsider any determination to suspend or terminate an approved CAP vendor's contract if the approved CAP vendor files a written request for reconsideration in accordance with paragraphs (c)(3) and (c)(4) of this section.

(3) *Manner and timing of request for reconsideration*. An approved CAP vendor that is dissatisfied with a CMS decision to suspend or terminate its CAP contract may request a reconsideration of the decision by filing a request with CMS. The request must be filed within 30 days of receipt of the CMS decision letter notifying the approved CAP vendor of the suspension or termination of its CAP contract.

(4) *Content of request*. The request for reconsideration must specify—

(i) The findings or issues with which the approved CAP vendor disagrees;

(ii) The reasons for the disagreement;

(iii) A recital of the facts and law supporting the approved CAP vendor's position;

(iv) Any supporting documentation; and

(v) Any supporting statements from participating CAP physicians, the local carrier, or beneficiaries.

(5) *Withdrawal of request for reconsideration*. An approved CAP vendor may withdraw its request for reconsideration at any time before the issuance of a reconsideration determination.

(6) *Discretionary informal hearing*. In response to a request for reconsideration, CMS may, at its discretion, provide the approved CAP vendor the opportunity for an informal hearing that—

(i) Is conducted by a hearing officer appointed by the Director of the CMS Center for Medicare Management or his or her designee; and

(ii) Provides the approved CAP vendor the opportunity to present, by telephone or in person, evidence to rebut CMS' decision to suspend or terminate the approved CAP vendor's CAP contract.

(7) *Informal hearing procedures*. (i) CMS will provide written notice of the time and place of the informal hearing at least 10 days before the scheduled date.

(ii) The informal reconsideration hearing will be conducted in accordance with the following procedures:

(A) The hearing is open to CMS and the approved CAP vendor requesting the reconsideration, including—

(*1*) Authorized representatives;

(*2*) Technical advisors (individuals with knowledge of the facts of the case or presenting interpretation of the facts);

(*3*) Representatives from the local carriers and the designated carrier;

(*4*) The participating CAP physician who requested the suspension, if any; and

(*5*) Legal counsel.

(B) The hearing will be conducted by the hearing officer, who will receive relevant testimony;

(C) Testimony and other evidence may be accepted by the hearing officer even though it would be inadmissible under the rules of evidence applied in Federal courts;

(D) Either party may call witnesses from among those individuals specified in the paragraph (c)(7)(ii)(A) of this section; and

(E) The hearing officer does not have the authority to compel by subpoena the production of witnesses, papers, or other evidence.

(8) *Hearing officer's findings.* (i) Within 30 days of the hearing officer's receipt of the hearing request, the hearing officer will present the findings and recommendations to the approved CAP vendor that requested the reconsideration. If the hearing officer conducts a hearing in person or by phone, the hearing officer will send a hearing notice to the approved CAP vendor within 10 days of receipt of the hearing request, and the findings and recommendations are due to the approved CAP vendor within 30 days from of the hearing's conclusion.

(ii) The written report of the hearing officer will include separate numbered findings of fact and the legal conclusions of the hearing officer.

(9) *Final reconsideration determination.* (i) The hearing officer's decision is final unless the Director of the CMS Center for Medicare Management or his or her designee (CMS official) chooses to review that decision within 30 days. If the decision is favorable to the approved CAP vendor, then the approved CAP vendor may resume participation in CAP. The hearing officer and the CMS official may review decisions that are favorable or unfavorable to the approved CAP vendor.

(ii) The CMS official may accept, reject, or modify the hearing officer's findings.

(iii) If the CMS official reviews the hearing officer's decision, the CMS official will issue a final reconsideration determination to the approved CAP vendor on the basis of the hearing officer's findings and recommendations and other relevant information.

(iv) The reconsideration determination of the CMS official is final.

(d) *CAP participating physicians' exigent circumstances provision.* The following process must be completed for participating CAP physicians' requests to terminate their participation in the program under exigent circumstances provisions described in § 414.908(a)(2)(v):

(1) The designated carrier must—

(i) Determine whether a request to terminate CAP participation was related to approved CAP vendor service, and if so, forward the issue to the approved CAP vendor's grievance process within 1 business day of the receipt of the request; or

(ii) Continue to investigate, consistent with § 414.916(b)(2) of this chapter, and within 2 business days of receipt, do any of the following:

(A) Request a single, 2-business day extension. No later than the end of any 2-business day extension, the designated carrier must make findings and a recommendation as provided in subparagraph (B) or (C).

(B) Submit a recommendation and relevant findings to CMS that the requesting participating CAP physician be permitted to terminate his or her participation in the CAP.

(C) Submit a recommendation and relevant findings to CMS that the requesting participating CAP physician not be permitted to terminate his or her participation in the CAP.

(ii) In the case of a request made under § 414.908(a)(2)(v)(B), the designated carrier also shall include in its recommendation its finding with respect to whether the request is based on a change in circumstances of which the participating CAP physician was previously unaware.

(2) CMS will consider the carrier's findings and recommendation and may also make its own findings. As a result, CMS will—

(i) Approve or deny the request to terminate participation in the CAP within 2 business days of receipt of the recommendation.

(ii) Communicate the decision to the appropriate Medicare contractors and the participating CAP physician.

(3) A denial of the participating CAP physician's request to terminate participation in the CAP must include written notification of the right to request reconsideration under § 414.916(c).

(4) Upon termination of participation in the CAP a physician must—

(i) Continue to submit claims for drugs supplied and administered under the CAP prior to the effective date of the physician's termination from the CAP consistent with §414.908(a) until all such claims are timely submitted.

(ii) Return any unused CAP drugs that had not been administered to the beneficiary prior to the effective date of the physician's termination from the CAP to the approved CAP vendor consistent with applicable law and regulation and any agreement with the approved CAP vendor.

(iii) Cooperate in any post-payment review activities on claims submitted under the CAP, as required under section 1847B(a)(3) of the Act.

(5) An approved CAP vendor that has billed and been paid for CAP drugs that have not been administered must refund any payments made by CMS or the beneficiary and his or her supplemental insurer in accordance with §414.914(h)(3)(i)(2) of this chapter.

[70 FR 39098, July 6, 2005, as amended at 72 FR 66403, Nov. 27, 2007; 74 FR 62013, Nov. 25, 2009]

EDITORIAL NOTE: At 72 FR 66222, November 27, 2007, §414.917 was amended by adding paragraph (d), which contained two paragraphs labeled (d)(1)(ii).

§414.918 Assignment.

Payment for a CAP drug may be made only on an assignment-related basis.

[70 FR 39099, July 6, 2005]

§414.920 Judicial review.

The following areas under the CAP are not subject to administrative or judicial review:

(a) The establishment of payment amounts.

(b) The awarding of vendor contracts.

(c) The establishment of competitive acquisition areas.

(d) The selection of CAP drugs.

(e) The bidding structure.

(f) The number of vendors selected.

[70 FR 39099, July 6, 2005]

§414.930 Compendia for determination of medically-accepted indications for off-label uses of drugs and biologicals in an anti-cancer chemotherapeutic regimen.

(a) *Definitions.* For the purposes of this section:

Compendium means a comprehensive listing of FDA-approved drugs and biologicals or a comprehensive listing of a specific subset of drugs and biologicals in a specialty compendium, for example a compendium of anti-cancer treatment. A compendium—

(i) Includes a summary of the pharmacologic characteristics of each drug or biological and may include information on dosage, as well as recommended or endorsed uses in specific diseases.

(ii) Is indexed by drug or biological.

(iii) Has a publicly transparent process for evaluating therapies and for identifying potential conflicts of interests.

Publicly transparent process for evaluating therapies means that the process provides that the following information from an internal or external request for inclusion of a therapy in a compendium are available to the public for a period of not less than 5 years, which includes availability on the compendium's Web site for a period of not less than 3 years, coincident with the compendium's publication of the related recommendation:

(i) The internal or external request for listing of a therapy recommendation including criteria used to evaluate the request.

(ii) A listing of all the evidentiary materials reviewed or considered by the compendium pursuant to the request.

(iii) A listing of all individuals who have substantively participated in the review or disposition of the request.

(iv) Minutes and voting records of meetings for the review and disposition of the request.

Publicly transparent process for identifying potential conflicts of interests means that process provides that the following information is identified and made timely available in response to a public request for a period of not less than 5 years, coincident with the compendium's publication of the related recommendation:

(i) Direct or indirect financial relationships that exist between individuals or the spouse or minor child of individuals who have substantively participated in the development or disposition of compendia recommendations and the manufacturer or seller of the drug or biological being reviewed by the compendium. This may include, for example, compensation arrangements such as salary, grant, contract, or collaboration agreements between individuals or the spouse or minor child of individuals who have substantively participated in the review and disposition of the request and the manufacturer or seller of the drug or biological being reviewed by the compendium.

(ii) Ownership or investment interests between individuals or the spouse or minor child of individuals who have substantively participated in the development or disposition of compendia recommendations and the manufacturer or seller of the drug or biological being reviewed by the compendium.

(b) *Process for listing compendia for determining medically-accepted uses of drugs and biologicals in anti-cancer treatment.* (1) The CMS process—

(i) Receives formal written requests for changes to the list of compendia during a 30 day window beginning January 15 each year.

(ii) Publishes a listing of the timely, complete requests by March 15th and solicits public comment on the requests for 30 days. The listing identifies the requestor and the requested action.

(iii) Considers a compendium's attainment of the MedCAC (Medicare Evidence Development and Coverage Advisory Committee, previously known as the MCAC—Medicare Coverage Advisory Committee) recommended desirable characteristics of compendia (including explicit listing and recommendations) in reviewing requests. CMS may consider additional reasonable factors.

(iv) Considers a compendium's grading of evidence used in making recommendations regarding off-label uses and the process by which the compendium grades the evidence.

(v) Considers whether the publication that is the subject of the request meets the definition of a compendium in this section.

(vi) Publishes its decision no later than 90 days after the close of the public comment period.

(2) *Exception.* In addition to the annual process outlined in paragraph (b)(1) of this section, CMS may internally generate a request for changes to the list of compendia at any time.

(c) *Written request for review.* (1) CMS will review a complete, written request that is submitted in writing, electronically or via hard copy (no duplicate submissions) and includes the following:

(i) The full name and contact information of the requestor.

(ii) The full identification of the compendium that is the subject of the request, including name, publisher, edition if applicable, date of publication, and any other information needed for the accurate and precise identification of the specific compendium.

(iii) A complete written copy of the compendium that is the subject of the request.

(iv) The specific action that is requested of CMS.

(v) Materials that the requestor must submit for CMS review in support of the requested action.

(vi) A single compendium as its subject.

(d) CMS may at its discretion combine and consider multiple requests that refer to the same compendium.

(e) For the purposes of this section, publication by CMS may be accomplished by posting on the CMS Web site.

[72 FR 66404, Nov. 27, 2007, as amended at 74 FR 62013, Nov. 25, 2009]

§ 414.940 Refund for certain discarded single-dose container or single-use package drugs.

(a) *Provision of information to manufacturers*—(1) *In general.* For each calendar quarter beginning on or after January 1, 2023, CMS reports to each manufacturer (as defined in § 414.802) of a refundable single-dose container or single-use package drug the following for the calendar quarter:

(i) Information on the total number of billing units of the billing and payment code of such drug, if any, that

were discarded during such quarter, as determined by the JW modifier (or any successor modifier that includes the same data).

(ii) The refund amount that the manufacturer is liable for pursuant to paragraph (a)(3) of this section.

(iii) Reports will include information in paragraphs (a)(1)(i) and (ii) of this section for new refund quarters and updated refund quarters (as defined at §414.902).

(iv) For purposes of this section, the term billing unit means the identifiable quantity associated with a billing and payment code, as established by CMS.

(2) *Exclusion of units of packaged drugs.* The total number of billing units of the billing and payment code of a refundable single-dose container or single-use package drug of a manufacturer furnished during a calendar quarter for purposes of paragraph (a)(1) of this section, and the determination of the estimated total allowed charges for the drug in the quarter for purposes of paragraph (c)(2) of this section, shall not include such units that are packaged into the payment amount for an item or service and are not separately payable.

(3) *Report Timing.* Reports are sent once annually.

(b) *Manufacturer requirement.* For each calendar quarter beginning on or after January 1, 2023, the manufacturer of a refundable single-dose container or single-use package drug shall, for such drug, pay a refund that is equal to the amount determined in accordance with paragraph (c) of this section for such drug for such quarter.

(1) Refund amounts for which the manufacturer is liable, pursuant to this paragraph, must be paid by December 31 of the year in which the report described in paragraph (a) of this section is sent, except that refund amounts for which the manufacturer is liable, pursuant to this paragraph, for amounts in the initial report for calendar quarters in 2023 must be paid no later than February 28, 2025.

(2) In the case that a disputed report results in a refund amount due, refund amounts that the manufacturer is liable for pursuant to this paragraph shall be paid no later than the dates specified in paragraph (b)(1) of this section or 30 days following the resolution of the dispute, whichever is later.

(3) Amounts paid as refunds pursuant to this paragraph shall be deposited into the Federal Supplementary Medical Insurance Trust Fund established under section 1841 of the Act.

(c) *Refund amount.* The amount of the refund specified in this paragraph is with respect to a refundable single-dose container or single-use package drug of a manufacturer assigned to a billing and payment code (except as provided in paragraph (c)(4) of this section) for:

(1) A new refund quarter (as defined at §414.902) beginning on or after January 1, 2023, an amount equal to the estimated amount (if any) by which:

(i) The product of the total number of units of the billing and payment code for such drug that were discarded during such new refund quarter; and the amount of payment determined for such drug or biological under section 1847A(b)(1)(B) or (C) of the Act, as applicable, for such new refund quarter;

(ii) Exceeds an amount equal to the applicable percentage of the estimated total allowed charges for such drug for the new refund quarter.

(2) The refund amount owed by a manufacturer for an updated refund quarter (as defined at §414.902) beginning on or after January 1, 2023, an amount equal to the estimated amount (if any) by which:

(i) The product of the total number of units of the billing and payment code for such drug that were discarded during such updated refund quarter; and the amount of payment determined for such drug or biological under section 1847A(b)(1)(B) or (C) of the Act, as applicable, for such quarter.

(ii) Exceeds the difference of:

(A) An amount equal to the applicable percentage of the estimated total allowed charges for such a drug during the updated refund quarter; and

(B) The refund amount already paid for such refundable drug for such quarter.

(3) Negative refund amount for an updated refund quarter. If the refund amount described in paragraph (c)(2) of this section is negative, the amount will be netted from refunds owed for other updated and new refund quarters

included in the same report as such updated refund quarter.

(4) Exception when there are multiple manufacturers. If there is more than one manufacturer of a refundable single-dose container or single-use package drug for a quarter, the refund amount for which a manufacturer is liable is an amount equal to the estimated amount (if any) by which—

(i) The product of the amount calculated in paragraph (c)(1) of this section and the percentage of billing unit sales (of the applicable billing and payment code attributed to the National Drug Code; exceeds:

(ii) The product of the amount in paragraph (c)(2) of this section and percentage of billing unit sales of the applicable billing and payment code attributed to the National Drug Code.

(iii) The number of billing unit sales for each NDC is the reported number of NDCs sold (as submitted in the ASP report to CMS each quarter) multiplied by the billing units per package for such NDC.

(d) *Applicable percentage.* For purposes of paragraph (c) of this section, and except as provided in paragraph (e) of this section, the applicable percentage is:

(1) 10 percent, unless specified otherwise in this section.

(2) 35 percent for a drug that is reconstituted with a hydrogel and has variable dosing based on patient-specific characteristics.

(3) 90 percent for a drug with a low volume dose (as defined at §414.902) contained within 0.1 mL or less.

(4) 45 percent for a drug with a low volume dose (as defined in §414.902) contained within 0.11 mL up to 0.4 mL.

(5) 26 percent for a drug designated an orphan drug under section 526 of the Federal Food, Drug, and Cosmetic Act for a rare disease or condition (or diseases or conditions) and approved by the FDA only for one or more indications within such designated rare disease or condition (or diseases or conditions) and is furnished to fewer than 100 unique beneficiaries per calendar year. A drug is furnished to fewer than 100 unique beneficiaries per calendar year when one of the following two conditions is met:

(i) The number of unique beneficiaries to whom the drug is furnished is less than 100 during the calendar year in which the refund quarter occurs; or

(ii) Either:

(A) In the case of a drug for which 3 or more years of data is available, the average of unique beneficiaries per year to whom the drug is furnished during the calendar year in which the refund quarter occurs and the 2 previous calendar years is less than 100; or

(B) In the case of a drug for which at least 2 but less than 3 years of data is available, the average of unique beneficiaries per year to whom the drug is furnished during the calendar year in which the refund quarter occurs and the previous calendar year is less than 100.

(e) *Application process for increased applicable percentage.* Manufacturers may submit an application to CMS requesting consideration of an increased applicable percentage for purposes of paragraph (c) of this section because of the drug's unique circumstances. The process for submitting such an application is as follows:

(1) *Application.* An application must include:

(i) A written request that a drug be considered for an increased applicable percentage based on its unique circumstances;

(ii) FDA-approved labeling for the drug, or, if the drug is not approved by the February 1 application deadline described in paragraph (e)(2) of this section, documentation of FDA acceptance of the application for review;

(iii) Justification for the consideration of an increased applicable percentage based on such unique circumstances; and

(iv) Justification for the requested applicable percentage.

(2) *Application timeline.* An application must be submitted in a form and manner specified by CMS by February 1 of the calendar year prior to the year the increased applicable percentage would apply. An application for a drug that is not FDA-approved by February 1 must have FDA approval by August 1 and the manufacturer must notify and submit the FDA-approved label to CMS by September 1 of the calendar year

prior to the year the increased applicable percentage would apply.

(3) *Application processing.* Following a review of timely applications, CMS will summarize its analyses of applications and propose appropriate increases in rulemaking. If adopted, the increased applicable percentage will be the applicable percentage for purposes of paragraph (c) of this section beginning as of the following January 1.

(f) *Dispute resolution.* Each manufacturer has an opportunity to dispute information in the report described in paragraph (a) of this section by submitting an error report as described in this paragraph.

(1) *Error report information.* To assert that there have been one or more errors in the report, a manufacturer must submit a dispute with each asserted error and provide the following information—

(i) Manufacturer name and address;

(ii) The name, telephone number, and email address of one or more employees or representatives of the manufacturer.

(iii) For a mathematical calculation error, the specific calculation element(s) that the manufacturer disputes and its proposed corrected calculation;

(iv) For any other asserted error, an explanation of the nature of the error, how the error affects the refund calculation, an explanation of why the manufacturer believes that an error occurred, the proposed correction to the error, and an explanation of why CMS should use the proposed corrected data.

(2) *Form, manner, and timing of submission.* Each manufacturer asserting an error must submit its error report(s), in the form and manner specified by CMS, within 30-days after the issuance of the report.

(g) *Enforcement*—(1) *Manufacturer audit*s. Each manufacturer of a refundable single-dose container or single-use package drug that is required to provide a refund under this section shall be subject to periodic audit with respect to such drug and such refunds.

(2) *Civil money penalty.* The Secretary shall impose a civil money penalty on a manufacturer of a refundable single-dose container or single-use package drug who has failed to comply with the requirement under paragraph (b) of this section for such drug for a calendar quarter in an amount equal to the sum of—

(i) The amount that the manufacturer would have paid under such paragraph with respect to such drug for such quarter; and

(ii) 25 percent of such amount.

[87 FR 70226, Nov. 18, 2022, as amended at 88 FR 15920, Mar. 15, 2023; 88 FR 79532, Nov. 16, 2023]

Subpart L—Supplying and Dispensing Fees

§414.1000 Purpose.

This subpart implements section 1842(o)(2) and section 1842(o)(6) of the Act, as added by section 303(e)(2) of the MMA, by specifying a supplying fee for drugs and biologicals covered under Part B of Title XVIII of the Act that are described in sections 1861(s)(2)(J), 1861(s)(2)(Q), and 1861(s)(2)(T) of the Act.

[69 FR 66425, Nov. 15, 2004]

§414.1001 Basis of payment.

(a) *Supplying fees.* Beginning in CY 2006—

(1) A supplying fee of $24 is paid to a pharmacy (no more often than once every 30 days) for the first prescription of drugs and biologicals described in sections 1861(s)(2)(J), 1861(s)(2)(Q), and 1861(s)(2)(T) of the Act, that the pharmacy provided to a beneficiary, except as provided in paragraph (a)(2) of this section.

(2) A supplying fee of $50 is paid to pharmacy for the initial supplied prescription of drugs and biologicals described in section 1861(s)(2)(J) of the Act, that the pharmacy provided to a patient during the first 30-day period following a transplant.

(3) A supplying fee of $16 is paid to a pharmacy (no more often than once every 30 days) for each prescription following the first prescription (as specified in paragraphs (a)(1) and (2) of this section) of drugs and biologicals described in sections 1861(s)(2)(J), 1861(s)(2)(Q), and 1861(s)(2)(T) of the Act, that the pharmacy provided to a beneficiary.

(4) A separate supplying fee is paid to a pharmacy for each prescription of

drugs and biologicals described in sections 1861(s)(2)(J), 1861(s)(2)(Q), and 1861(s)(2)(T) of the Act.

(b) *30-day dispensing fees.* Beginning CY 2006—(1) A dispensing fee of $57 is paid to a supplier to the extent that the prescription is for the initial dispensed 30-day supply of inhalation drugs furnished through durable medical equipment covered under section 1861(n) of the Act, regardless of the number of partial shipments of that 30-day supply.

(2) Except for supplied inhalation drugs that meet criteria described in paragraph (b)(1) of this section, a dispensing fee of $33 is paid for each dispensed 30-day supply of inhalation drugs furnished through durable medical equipment covered under section 1861(n) of the Act, regardless of the number of partial shipments of that 30-day supply.

(c) *90-day dispensing fee.* Beginning CY 2006, a dispensing fee of $66 is paid to a supplier for each dispensed 90-day supply of inhalation drugs furnished through durable medical equipment covered under section 1861(n) of the Act, regardless of the number of partial shipments of that 90-day supply.

[70 FR 70334, Nov. 21, 2005, as amended at 89 FR 98560, Dec. 9, 2024]

Subpart M—Payment for Comprehensive Outpatient Rehabilitation Facility (CORF) Services

SOURCE: 72 FR 66404, Nov. 27, 2007, unless otherwise noted.

§ 414.1100 Basis and scope.

This subpart implements sections 1834(k)(1) and (k)(3) of the Act by specifying the payment methodology for comprehensive outpatient rehabilitation facility services covered under Part B of Title XVIII of the Act that are described at section 1861(cc)(1) of the Act.

§ 414.1105 Payment for Comprehensive Outpatient Rehabilitation Facility (CORF) services.

(a) *Payment under the physician fee schedule.* Except as otherwise specified under paragraphs (b), (c), (d), and (e) of this section payment for CORF services, as defined under § 410.100 of this chapter, is paid the lesser of 80 percent of the following:

(1) The actual charge for the item or service; or

(2) The nonfacility amount determined under the physician fee schedule established under section 1848(b) of the Act for the item or service.

(b) *Payment for physician services.* No separate payment for physician services that are CORF services under § 410.100(a) of this chapter will be made.

(c) *Payment for supplies and durable medical equipment, prosthetic and orthotic devices, and drugs and biologicals.* Supplies and durable medical equipment that are CORF services under § 410.100(l) of this chapter, prosthetic device services that are CORF services under § 410.100(f), orthotic devices that are CORF services under § 410.100(g) of this chapter and drugs and biologicals that are CORF services under § 410.100(k) of this chapter are paid the lesser of 80 percent of the following:

(1) The actual charge for the service provided that payment for such item is not included in the payment amount for other CORF services paid under paragraphs (a) or (d); or

(2) The amount determined under the DMEPOS fee schedule established under part 414 subparts D and F for the item or the single payment amount established under the DMEPOS competitive bidding program provided that payment for such item is not included in the payment amount for other CORF services paid under paragraphs (a) or (d).

(d) *Payment for drugs and biologicals.* Drugs and biologicals that are CORF services under § 410.100(j) of this chapter, are paid the lesser of 80 percent of the following:

(1) The actual charge for the service provided that payment for such item is not included in the payment amount for other CORF services paid under paragraphs (a) or (c); or

(2) The amount determined using the same methodology for drugs (as defined in § 414.704 of this chapter) described in section 1842(o)(1) of the Act provided that payment for such *drug* is not included in the payment amount for

other CORF services paid under paragraphs (a) or (c).

(e) *Payment for CORF services when no fee schedule amount for the service.* If there is no fee schedule amount established for a CORF service, payment for the item or service will be the lesser of 80 percent of:

(i) The actual charge for the service provided that payment for such item or service is not included in the payment amount for other CORF services paid under paragraphs (a), (c), or (d) of this section.

(ii) The amount determined under the fee schedule established for a comparable service as specified by the Secretary provided that payment for such item or service is not included in the payment amount for other CORF services paid under paragraphs (a), (c), or (d) of this section.

Subpart N—Value-Based Payment Modifier Under the Physician Fee Schedule

SOURCE: 77 FR 69368, Nov. 16, 2012, unless otherwise noted.

§ 414.1200 Basis and scope.

(a) *Basis.* This subpart implements section 1848(p) of the Act by establishing a payment modifier that provides for differential payment starting in 2015 to a group of physicians and starting in 2017 to a group and a solo practitioner under the Medicare Physician Fee Schedule based on the quality of care furnished compared to cost during a performance period.

(b) *Scope.* This subpart sets forth the following:

(1) The application of the value-based payment modifier.

(2) Performance and payment adjustment periods.

(3) Reporting mechanisms for the value-based payment modifier.

(4) Alignment of PQRS quality of care measures with the quality measures for the value-based payment modifier.

(5) Additional measures for groups and solo practitioners.

(6) Cost measures.

(7) Attribution for quality of care and cost measures.

(8) Scoring methods for the value-based payment modifier.

(9) Benchmarks for quality of care measures.

(10) Benchmarks for cost measures.

(11) Composite scores.

(12) Reliability of measures.

(13) Payment adjustments.

(14) Value-based payment modifier quality-tiering scoring methodology.

(15) Limitation of review.

(16) Inquiry process.

[77 FR 69368, Nov. 16, 2012, as amended at 79 FR 68005, Nov. 13, 2014]

§ 414.1205 Definitions.

As used in this subpart, unless otherwise indicated—

Accountable care organization (ACO) has the same meaning given this term under § 425.20 of this chapter.

Certified registered nurse anesthetist (CRNA) has the same meaning given this term under section 1861(bb)(2) of the Act.

Critical access hospital has the same meaning given this term under § 400.202 of this chapter.

Electronic health record (EHR) has the same meaning given this term under § 414.92 of this chapter.

Eligible professional has the same meaning given this term under section 1848(k)(3)(B) of the Act.

Federally Qualified Health Center has the same meaning given this term under § 405.2401(b) of this chapter.

Group of physicians (Group) means a single Taxpayer Identification Number (TIN) with 2 or more eligible professionals, as identified by their individual National Provider Identifier (NPI), who have reassigned their Medicare billing rights to the TIN.

Performance period means the calendar year that will be used to assess the quality of care furnished compared to cost.

Performance rate mean the calculated rate for each quality or cost measure such as the percent of times that a particular clinical quality action was reported as being performed, or a particular outcome was attained, for the applicable persons to whom a measure applies as described in the denominator for the measure.

Physician has the same meaning given this term under section 1861(r) of the Act.

Physician assistant (PA), nurse practitioner (NP), and clinical nurse specialist (CNS) have the same meanings given these terms under section 1861(aa)(5) of the Act.

Physician Fee Schedule has the same meaning given this term under part 410 of this chapter.

Physician Quality Reporting System means the system established under section 1848(k) of the Act.

Risk score means the beneficiary risk score derived from the CMS Hierarchical Condition Categories (HCC) model.

Solo practitioner means a single Taxpayer Identification Number (TIN) with one eligible professional who is identified by an individual National Provider Identifier (NPI) billing under the TIN.

Taxpayer Identification Number (TIN) has the same meaning given this term under § 425.20 of this chapter.

Value-based payment modifier means the percentage as determined under § 414.1270 by which amounts paid to a group or solo practitioner under the Medicare Physician Fee Schedule established under section 1848 of the Act are adjusted based upon a comparison of the quality of care furnished to cost as determined by this subpart.

[77 FR 69368, Nov. 16, 2012, as amended at 79 FR 68005, Nov. 13, 2014; 80 FR 71382, Nov. 16, 2015]

§ 414.1210 Application of the value-based payment modifier.

(a) The value-based payment modifier is applicable:

(1) For the CY 2015 payment adjustment period, to physicians in groups with 100 or more eligible professionals based on the performance period described at § 414.1215(a).

(2) For the CY 2016 payment adjustment period, to physicians in groups with 10 or more eligible professionals based on the performance period described at § 414.1215(b).

(3) For the CY 2017 payment adjustment period and each subsequent calendar year payment adjustment period, to physicians in groups with 2 or more eligible professionals and to physicians who are solo practitioners based on the performance period for the payment adjustment period as described at § 414.1215.

(4) For the CY 2018 payment adjustment period, to nonphysician eligible professionals who are physician assistants, nurse practitioners, clinical nurse specialists, and certified registered nurse anesthetists in groups with 2 or more eligible professionals and to physician assistants, nurse practitioners, clinical nurse specialists, and certified registered nurse anesthetists who are solo practitioners based on the performance period for the payment adjustment period as described at § 414.1215.

(b) *Exceptions.* (1) Groups of physicians that are participating in the Medicare Shared Savings Program, the testing of the Pioneer ACO model, or other similar Innovation Center or CMS initiatives shall not be subject to any adjustments under the value-based payment modifier for CY 2015 and CY 2016.

(2) *Application of the value-based payment modifier to participants in the Shared Savings Program.*

(i) For the CY 2017 payment adjustment period and each subsequent calendar year payment adjustment period, the value-based payment modifier is applicable to physicians in groups with 2 or more eligible professionals and to physicians who are solo practitioners that participate in an ACO under the Shared Savings Program during the performance period for the payment adjustment period as described at § 414.1215. The value-based payment modifier for a group or solo practitioner that participates in an ACO under the Shared Savings Program during the performance period is determined based on paragraphs (b)(2)(i)(A) through (D) of this section.

(A) The cost composite is classified as ''average'' under § 414.1275(b).

(B) For groups and solo practitioners that participate in a Shared Savings Program ACO that successfully reports quality data as required by the Shared Savings Program under § 425.504 of this chapter, the quality composite score is calculated under § 414.1260(a) using quality data reported by the ACO for the performance period through the

ACO GPRO Web interface as required under §425.504(a)(1) of this chapter or another mechanism specified by CMS and the ACO all-cause readmission measure. Groups and solo practitioners that participate in two or more ACOs during the applicable performance period receive the quality composite score of the ACO that has the highest numerical quality composite score. For the CY 2018 payment adjustment period, the CAHPS for ACOs survey also will be included in the quality composite score. For the CY 2017 and 2018 payment adjustment periods, for groups and solo practitioners who participate in a Shared Savings Program ACO that does not successfully report quality data as required by the Shared Savings Program under §425.504 and who meet the requirements to avoid the PQRS payment adjustment for CY 2018 by reporting to the PQRS outside the ACO, the quality composite is classified as ''average'' under §414.1275(b).

(C) For the CY 2017 payment adjustment period, the value-based payment modifier adjustment will be equal to the amount determined under §414.1275 for the payment adjustment period, except that if the ACO (or groups and solo practitioners that participate in the ACO) does not successfully report quality data as described in paragraph (b)(2)(i)(B) of this section for the performance period, such adjustment will be equal to –4% for groups of physicians with 10 or more eligible professionals and equal to –2% for groups of physicians with two to nine eligible professionals and for physician solo practitioners. If the ACO has an assigned beneficiary population during the performance period with an average risk score in the top 25 percent of the risk scores of beneficiaries nationwide, and a group of physician or physician solo practitioner that participates in the ACO during the performance period is classified as high quality/average cost under quality-tiering for the CY 2017 payment adjustment period, the group or solo practitioner receives an upward adjustment of +3 × (rather than +2 ×) if the group has 10 or more eligible professionals or +2 × (rather than +1 ×) for a solo practitioner or the group has two to nine eligible professionals.

(D) For the CY 2018 payment adjustment period, the value-based payment modifier adjustment will be equal to the amount determined under §414.1275 for the payment adjustment period, except that if the ACO (or groups and solo practitioners that participate in the ACO) does not successfully report quality data as described in paragraph (b)(2)(i)(B) of this section for the performance period, such adjustment will be equal to the downward payment adjustment amounts described at §414.1270(d)(1). If the ACO has an assigned beneficiary population during the performance period with an average risk score in the top 25 percent of the risk scores of beneficiaries nationwide, and a group or solo practitioner that participates in the ACO during the performance period is classified as high quality/average cost under quality-tiering for the CY 2018 payment adjustment period, the group or solo practitioner receives an upward adjustment of +3 × (rather than +2 ×) if the group of physicians has 10 or more eligible professionals, +2 × (rather than +1 ×) for a physician solo practitioner or if the group of physicians has two to nine eligible professionals, or +2 × (rather than +1 ×) for a solo practitioner who is a nonphysician eligible professional or if the group consists of nonphysician eligible professionals.

(E) For the CY 2017 payment adjustment period and each subsequent calendar year payment adjustment period, the value-based payment modifier for groups and solo practitioners that participate in an ACO under the Shared Savings Program during the applicable performance period is determined as described under paragraph (b)(2) of this section, regardless of whether any eligible professionals in the group or the solo practitioner also participate in an Innovation Center model during the performance period.

(F) For groups and solo practitioners that participate in a Shared Savings Program ACO that successfully reports quality data as required by the Shared Savings Program under §425.504 of this chapter, the same value-based payment modifier adjustment will be applied in the payment adjustment period to all groups based on size as specified under §414.1275 and solo practitioners that

participated in the ACO during the performance period.

(ii) For the CY 2018 payment adjustment period and each subsequent calendar year payment adjustment period, the value-based payment modifier is applicable to nonphysician eligible professionals in groups with 2 or more eligible professionals and to nonphysician eligible professionals who are solo practitioners that participate in an ACO under the Shared Savings Program during the performance period for the payment adjustment period as described at § 414.1215. The value-based payment modifier for nonphysician eligible professionals is determined in the same manner as for physicians as described under paragraphs (b)(2)(i)(A) through (D) of this section.

(3) *Application of the value-based payment modifier to participants in the Pioneer ACO Model and the Comprehensive Primary Care Initiative.* (i) For the CY 2017 payment adjustment period, the value-based payment modifier is waived under section 1115A(d)(1) of the Act for physicians in groups with 2 or more eligible professionals and for physicians who are solo practitioners that participate in the Pioneer ACO Model or the Comprehensive Primary Care (CPC) Initiative during the performance period for the payment adjustment period as described at § 414.1215.

(ii) For the CY 2018 payment adjustment period, the value-based payment modifier is waived under section 1115A(d)(1) of the Act for physicians and nonphysician eligible professionals in groups with 2 or more eligible professionals and for physicians and nonphysician eligible professionals who are solo practitioners that participate in the Pioneer ACO Model or the Comprehensive Primary Care (CPC) Initiative during the performance period for the payment adjustment period as described at § 414.1215.

(iii) For purposes of the value-based payment modifier, a group or solo practitioner is considered to be participating in the Pioneer ACO Model or CPC Initiative if at least one eligible professional billing under the TIN in the performance period for the payment adjustment period as described at § 414.1215 is participating in the Pioneer ACO Model or CPC Initiative in the performance period.

(4) *Application of the value-based payment modifier to participants in other similar Innovation Center models.* (i) For the CY 2017 payment adjustment period, the value-based payment modifier is waived under section 1115A(d)(1) of the Act for physicians in groups with 2 or more eligible professionals and for physicians who are solo practitioners that participate in other similar Innovation Center models during the performance period for the payment adjustment period as described at § 414.1215.

(ii) For the CY 2018 payment adjustment period, the value-based payment modifier is waived under section 1115A(d)(1) of the Act for physicians and nonphysician eligible professionals in groups with 2 or more eligible professionals and for physicians and nonphysician eligible professionals who are solo practitioners that participate in other similar Innovation Center models during the performance period for the payment adjustment period as described at § 414.1215.

(iii) For purposes of the value-based payment modifier, a group or solo practitioner is considered to be participating in a similar Innovation Center model if at least one eligible professional billing under the TIN in the performance period for the payment adjustment period as described at § 414.1215 is participating in the similar model in the performance period.

(c) *Group size and composition determination.* (1) The list of groups of physicians subject to the value-based payment modifier for the CY 2015 payment adjustment period is based on a query of PECOS on October 15, 2013. For each subsequent calendar year payment adjustment period, the list of groups and solo practitioners subject to the value-based payment modifier is based on a query of PECOS that occurs within 10 days of the close of the Physician Quality Reporting System group registration process during the applicable performance period described at § 414.1215. Groups are removed from the PECOS-generated list if, based on a claims analysis, the group did not have the required number of eligible professionals,

as defined in paragraph (a) of this section, that submitted claims during the performance period for the applicable calendar year payment adjustment period. Solo practitioners are removed from the PECOS-generated list if, based on a claims analysis, the solo practitioner did not submit claims during the performance period for the applicable calendar year payment adjustment period.

(2) Beginning with the CY 2016 payment adjustment period, the size of a group during the applicable performance period will be determined by the lower number of eligible professionals as indicated by the PECOS-generated list or claims analysis.

(3) For the CY 2018 payment adjustment period, the composition of a group during the applicable performance period will be determined based on whether the group includes physicians, physician assistants, nurse practitioners, clinical nurse specialists, certified registered nurse anesthetists, and/or other types of nonphysician eligible professionals as indicated by the PECOS-generated list or claims analysis.

[77 FR 69368, Nov. 16, 2012, as amended at 78 FR 74820, Dec. 10, 2013; 79 FR 68005, Nov. 13, 2014; 80 FR 71382, Nov. 16, 2015; 81 FR 80555, Nov. 15, 2016]

§ 414.1215 Performance and payment adjustment periods for the value-based payment modifier.

(a) The performance period is calendar year 2013 for value-based payment modifier adjustments made in the calendar year 2015 payment adjustment period.

(b) The performance period is calendar year 2014 for value-based payment modifier adjustments made in the calendar year 2016 payment adjustment period.

(c) The performance period is calendar year 2015 for value-based payment modifier adjustments made in the calendar year 2017 payment adjustment period.

(d) The performance period is calendar year 2016 for value-based payment modifier adjustments made in the calendar year 2018 payment adjustment period.

[77 FR 69368, Nov. 16, 2012, as amended at 78 FR 74820, Dec. 10, 2013; 80 FR 71383, Nov. 16, 2015]

§ 414.1220 Reporting mechanisms for the value-based payment modifier.

Solo practitioners and groups subject to the value-based payment modifier (or individual eligible professionals within such groups) may submit data on quality measures as specified under the Physician Quality Reporting System using the reporting mechanisms for which they are eligible.

[78 FR 74820, Dec. 10, 2013, as amended at 79 FR 68006, Nov. 13, 2014]

§ 414.1225 Alignment of Physician Quality Reporting System quality measures and quality measures for the value-based payment modifier.

All of the quality measures for which solo practitioners and groups (or individual eligible professionals within such groups) are eligible to report under the Physician Quality Reporting System in a given calendar year are used to calculate the value-based payment modifier for the applicable payment adjustment period, as defined in § 414.1215, to the extent a solo practitioner or a group (or individual eligible professionals within such group) submit data on such measures.

[79 FR 68006, Dec. 13, 2014]

§ 414.1230 Additional measures for groups and solo practitioners.

The value-based payment modifier includes the following additional quality measures (outcome measures) as applicable for all groups and solo practitioners subject to the value-based payment modifier:

(a) A composite of rates of potentially preventable hospital admissions for heart failure, chronic obstructive pulmonary disease, and diabetes. The rate of potentially preventable hospital admissions for diabetes is a composite measure of uncontrolled diabetes, short term diabetes complications, long term diabetes complications and lower extremity amputation for diabetes.

(b) A composite of rates of potentially preventable hospital admissions

for dehydration, urinary tract infections, and bacterial pneumonia.

(c) Rates of an all-cause hospital readmissions measure, except for groups with between two to nine eligible professionals and solo practitioners starting with the CY 2017 payment adjustment period.

[77 FR 69368, Nov. 16, 2012, as amended at 79 FR 68007, Nov. 13, 2014; 80 FR 71383, Nov. 16, 2015]

§ 414.1235 Cost measures.

(a) *Included measures.* Beginning with the CY 2016 payment adjustment period, costs for groups and solo practitioners subject to the value-based payment modifier are assessed based on a cost composite comprised of the following 6 cost measures (only the measures identified in paragraphs (a)(1) through (5) of this section are included for the value-based payment modifier for the CY 2015 payment adjustment period):

(1) Total per capita costs for all attributed beneficiaries.

(2) Total per capita costs for all attributed beneficiaries with diabetes.

(3) Total per capita costs for all attributed beneficiaries with coronary artery disease.

(4) Total per capita costs for all attributed beneficiaries with chronic obstructive pulmonary disease.

(5) Total per capita costs for all attributed beneficiaries with heart failure.

(6) Medicare Spending per Beneficiary associated with an acute inpatient hospitalization.

(b) *Included payments.* Cost measures enumerated in paragraph (a) of this section include all fee-for-service payments made under Medicare Part A and Part B.

(c) *Cost measure adjustments.* (1) Payments under Medicare Part A and Part B will be adjusted using CMS' payment standardization methodology to ensure fair comparisons across geographic areas.

(2) The CMS–HCC model (and adjustments for ESRD status) is used to adjust standardized payments for the measures listed at paragraphs (a)(1) through (5) of this section.

(3) The beneficiary's age and severity of illness are used to adjust the Medicare Spending per Beneficiary measure as specified in paragraph (a)(6) of this section.

(4) Beginning with the CY 2016 payment adjustment period, the cost measures of a group and solo practitioner subject to the value-based payment modifier are adjusted to account for the group's and solo practitioner's specialty mix, by computing the weighted average of the national specialty specific expected costs and comparing this to the group's actual risk adjusted costs. Each national specialty-specific expected cost is weighted by the proportion of Part B payments incurred by each specialty within the group.

(5) The national specialty-specific expected costs referenced in paragraph (c)(4) of this section are derived by calculating, for each specialty, the weighted average of the risk-adjusted costs computed across all groups, where the weight for each group is equal to the number of beneficiaries attributed to the group, times the number of eligible professionals in the group with the relevant specialty, times the proportion of eligible professionals in the group with the relevant specialty.

[78 FR 74821, Dec. 10, 2013, as amended at 79 FR 68007, Nov. 13, 2014; 80 FR 71383, Nov. 16, 2015]

§ 414.1240 Attribution for quality of care and cost measures.

(a) Beneficiaries are attributed to groups and solo practitioners subject to the value-based payment modifier using a method generally consistent with the method of assignment of beneficiaries under § 425.402 of this chapter, for measures other than the Medicare Spending per Beneficiary measure.

(b) For the Medicare Spending per Beneficiary (MSPB) measure, an MSPB episode is attributed to the group or the solo practitioner subject to the value-based payment modifier whose eligible professionals submitted the plurality of claims (as measured by allowable charges) under the group's or solo practitioner's TIN for Medicare Part B services, rendered during an inpatient hospitalization that is an index

admission for the MSPB measure during the applicable performance period described at § 414.1215.

[79 FR 68007, Nov. 13, 2014]

§ 414.1245 Scoring methods for the value-based payment modifier using the quality-tiering approach.

For each quality of care and cost measure, a standardized score is calculated for each group and solo practitioner subject to the value-based payment modifier by dividing—

(a) The difference between their performance rate and the benchmark, by

(b) The measure's standard deviation.

[77 FR 69368, Nov. 16, 2012, as amended at 79 FR 68007, Nov. 13, 2014]

§ 414.1250 Benchmarks for quality of care measures.

(a) The benchmark for quality of care measures reported through the PQRS using the claims, registries, QCDR, or web interface is the national mean for that measure's performance rate (regardless of the reporting mechanism) during the year prior to the performance period. In calculating the national benchmark, solo practitioners' and groups' (or individual eligible professionals' within such groups) performance rates are weighted by the number of beneficiaries used to calculate the solo practitioners' or groups' (or individual eligible professionals' within such groups) performance rate. Beginning with the CY 2016 performance period, eCQMs reported via EHRs are excluded from the overall benchmark for quality of care measures and separate eCQM benchmarks will be developed. The eCQM benchmark is the national mean for the measure's performance rate during the year prior to the performance period. In calculating the national benchmark, solo practitioners' and groups' (or individual eligible professionals' within such groups) performance rates are weighted by the number of beneficiaries used to calculate the solo practitioners' or groups' (or individual eligible professionals' within such groups) performance rate.

(b) The benchmark for each outcome measure under § 414.1230, is the national mean for that measure's performance rate during the year prior to the performance period. In calculating the national benchmark, solo practitioners' and groups' (or individual eligible professionals' within such groups) performance rates are weighted by the number of beneficiaries used to calculate the solo practitioners' or groups' (or individual eligible professionals' within such groups) performance rate.

[79 FR 68007, Nov. 13, 2014, as amended at 80 FR 71384, Nov. 16, 2015]

§ 414.1255 Benchmarks for cost measures.

(a) For the CY 2015 payment adjustment period, the benchmark for each cost measure is the national mean of the performance rates calculated among all groups of physicians for which beneficiaries are attributed to the group of physicians that are subject to the value-based payment modifier. In calculating the national benchmark, groups of physicians' performance rates are weighted by the number of beneficiaries used to calculate the group of physician's performance rate.

(b) Beginning with the CY 2016 payment adjustment period, the benchmark for each cost measure is the national mean of the performance rates calculated among all groups and solo practitioners that meet the minimum number of cases for that measure under § 414.1265(a). In calculating the national benchmark, groups and solo practitioners' performance rates are weighted by the number of beneficiaries used to calculate the group or solo practitioner's performance rate.

[78 FR 74821, Dec. 10, 2013, as amended at 79 FR 68007, Nov. 13, 2014; 80 FR 71384, Nov. 16, 2015]

§ 414.1260 Composite scores.

(a)(1) The standardized score for each quality of care measure is classified into one of the following equally weighted domains to determine the quality composite:

(i) Patient safety.

(ii) Patient experience.

(iii) Care coordination.

(iv) Clinical care.

(v) Population/community health.

(vi) Efficiency.

(2) If a domain includes no measure or does not reach the minimum case

size in § 414.1265, the remaining domains are equally weighted to form the quality of care composite.

(b)(1) The standardized score for each cost measure is grouped into two separate and equally weighted domains to determine the cost composite:

(i) Total per capita costs for all attributed beneficiaries: Total per capita costs measure and Medicare Spending per Beneficiary measure; and

(ii) Total per capita costs for all attributed beneficiaries with specific conditions: Diabetes, coronary artery disease, chronic obstructive pulmonary disease, or heart failure (four measures).

(2) Measures within each domain are equally weighted.

[77 FR 69368, Nov. 16, 2012, as amended at 78 FR 74821, Dec. 10, 2013]

§ 414.1265 Reliability of measures.

To calculate a composite score for a quality measure or a cost measure, a group or solo practitioner subject to the value-based payment modifier must have 20 or more cases for that measure.

(a) In a performance period, if a group or solo practitioner has fewer than 20 cases for a measure, that measure is excluded from its domain and the remaining measures in the domain are given equal weight.

(1) Starting with the CY 2017 payment adjustment period, the exception to this paragraph (a) is the all-cause hospital readmissions measure described at § 414.1230(c). In a performance period, if a group has fewer than 200 cases for this all-cause hospital readmissions measure, that measure is excluded from its domain and the remaining measures in the domain are given equal weight.

(2) Starting with the CY 2017 payment adjustment period, the Medicare Spending Per Beneficiary measure described at § 414.1235(a)(6) is an exception to this paragraph (a). In a performance period, if a group or a solo practitioner has fewer than 125 episodes for this MSPB measure, that measure is excluded from its domain and the remaining measures in the domain are given equal weight.

(b)(1) For the CY 2015 payment adjustment period, if a reliable quality of care composite or cost composite cannot be calculated, payments will not be adjusted under the value-based payment modifier.

(2) Beginning with the CY 2016 payment adjustment period, a group and a solo practitioner subject to the value-based payment modifier will receive a quality composite score that is classified as ''average'' under § 414.1275(b)(1) if such group and solo practitioner do not have at least one quality measure that meets the minimum number of cases under paragraph (a) of this section.

(3) Beginning with the CY 2016 payment adjustment period, a group and a solo practitioner subject to the value-based payment modifier will receive a cost composite score that is classified as ''average'' under § 414.1275(b)(2) if such group and solo practitioner do not have at least one cost measure that meets the minimum number of cases under paragraph (a) of this section.

[77 FR 69368, Nov. 16, 2012, as amended at 79 FR 68007, Nov. 13, 2014; 80 FR 71384, Nov. 16, 2015]

§ 414.1270 Determination and calculation of Value-Based Payment Modifier adjustments.

(a) For the CY 2015 payment adjustment period:

(1) *Downward payment adjustments.* A downward payment adjustment will be applied to a group of physicians subject to the value-based payment modifier if—

(i) Such group neither self-nominates for the PQRS GPRO and reports at least one measure, nor elects the PQRS administrative claims option for CY 2013 as defined in § 414.90(h).

(A) Such adjustment will be −1.0 percent.

(B) [Reserved]

(ii) Such group elects that its value-based payment modifier be calculated using a quality-tiering approach, and is determined to have poor performance (low quality and high costs; low quality and average costs; or average quality and high costs).

(A) Such adjustment will not exceed −1.0 percent as specified in § 414.1275(c)(1).

(B) [Reserved]

(2) *No payment adjustments.* There will be no value-based payment modifier adjustment applied to a group of physicians subject to the value-based payment modifier if such group either:

(i) Self-nominates for the PQRS GPRO and reports at least one measure; or

(ii) Elects the PQRS administrative claims option for CY 2013 as defined in §414.90(h).

(3) *Upward payment adjustments.* If a group of physicians subject to the value-based payment modifier elects that the value-based payment modifier be calculated using a quality-tiering approach, upward payment adjustments are determined based on the projected aggregate amount of downward payment adjustments determined under paragraph (a)(1) of this section and applied as specified in §414.1275(c)(1).

(b) For the CY 2016 payment adjustment period:

(1) A downward payment adjustment of −2.0 percent will be applied to a group of physicians subject to the value-based payment modifier if, during the applicable performance period as defined in §414.1215, the following apply:

(i) Such group does not self-nominate for the PQRS GPRO and meet the criteria as a group to avoid the PQRS payment adjustment for CY 2016 as specified by CMS; and

(ii) Fifty percent of the eligible professionals in such group do not meet the criteria as individuals to avoid the PQRS payment adjustment for CY 2016 as specified by CMS.

(2) For a group of physicians comprised of 100 or more eligible professionals that is not included in paragraph (b)(1) of this section, the value-based payment modifier adjustment will be equal to the amount determined under §414.1275(c)(2).

(3) For a group of physicians comprised of between 10 and 99 eligible professionals that is not included in paragraph (b)(1) of this section, the value-based payment modifier adjustment will be equal to the amount determined under §414.1275(c)(2), except that such adjustment will be 0.0 percent if the group of physicians is determined to be low quality/high cost, low quality/average cost, or average quality/high cost.

(4) If at least fifty percent of the eligible professionals in the group meet the criteria as individuals to avoid the PQRS payment adjustment for CY 2016 as specified by CMS, and all of those eligible professionals use a qualified clinical data registry and CMS is unable to receive quality performance data for them, the quality composite score for such group will be classified as ''average'' under §414.1275(b)(1).

(c) For the CY 2017 payment adjustment period:

(1) A downward payment adjustment of −2.0 percent will be applied to a group with two to nine eligible professionals and a solo practitioner and a downward payment adjustment of −4.0 percent will be applied to a group with 10 or more eligible professionals subject to the value-based payment modifier if, during the applicable performance period as defined in §414.1215, the following apply:

(i) Such group does not meet the criteria as a group to avoid the PQRS payment adjustment for CY 2017 as specified by CMS; and

(ii) Fifty percent of the eligible professionals in such group do not meet the criteria as individuals to avoid the PQRS payment adjustment for CY 2017 as specified by CMS; or

(iii) Such solo practitioner does not meet the criteria as an individual to avoid the PQRS payment adjustment for CY 2017 as specified by CMS.

(2) For a group comprised of 10 or more eligible professionals that is not included in paragraph (c)(1) of this section, the value-based payment modifier adjustment will be equal to the amount determined under §414.1275(c)(3)(i).

(3) For a group comprised of between two to nine eligible professionals and a solo practitioner that are not included in paragraph (c)(1) of this section, the value-based payment modifier adjustment will be equal to the amount determined under §414.1275(c)(3)(ii).

(4) If at least fifty percent of the eligible professionals in the group meet the criteria as individuals to avoid the PQRS payment adjustment for CY 2017 as specified by CMS, and all of those eligible professionals use a qualified clinical data registry and CMS is unable to

receive quality performance data for them, the quality composite score for such group will be classified as ''average'' under § 414.1275(b)(1).

(d) For the CY 2018 payment adjustment period:

(1) A downward payment adjustment of −1.0 percent will be applied to a solo practitioner, a group with two to nine eligible professionals, and a group consisting only of nonphysician eligible professionals subject to the value-based payment modifier and no physicians; and a downward payment adjustment of −2.0 percent will be applied to a group with 10 or more eligible professionals and at least one physician if, during the applicable performance period as defined in § 414.1215, the following apply:

(i) For groups:

(A) Such group does not meet the criteria as a group to avoid the PQRS payment adjustment for CY 2018 as specified by CMS; and

(B) Fifty percent of the eligible professionals in such group do not meet the criteria as individuals to avoid the PQRS payment adjustment for CY 2018 as specified by CMS.

(ii) For solo practitioners, such solo practitioner does not meet the criteria as an individual to avoid the PQRS payment adjustment for CY 2018 as specified by CMS.

(2) For a group composed of 10 or more eligible professionals that is not included in paragraph (d)(1) of this section, the value-based payment modifier adjustment will be equal to the amount determined under § 414.1275(c)(4)(i).

(3) For a group composed of between two to nine eligible professionals and a solo practitioner that are not included in paragraph (d)(1) of this section, the value-based payment modifier adjustment will be equal to the amount determined under § 414.1275(c)(4)(ii).

(4) For a group and a solo practitioner consisting of nonphysician eligible professionals that are not included in paragraph (d)(1) of this section, the value-based payment modifier adjustment will be equal to the amount determined under § 414.1275(c)(4)(iii).

(5) If at least 50 percent of the eligible professionals in the group meet the criteria as individuals to avoid the PQRS payment adjustment for CY 2018 as specified by CMS, and all of those eligible professionals use a qualified clinical data registry and CMS is unable to receive quality performance data for them, the quality composite score for such group will be classified as ''average'' under § 414.1275(b)(1).

[78 FR 74821, Dec. 10, 2013, as amended at 79 FR 68007, Nov. 13, 2014; 80 FR 71384, Nov. 16, 2015; 82 FR 53363, Nov. 15, 2017]

§ 414.1275 Value-based payment modifier quality-tiering scoring methodology.

(a) The value-based payment modifier amount for a group and a solo practitioner subject to the value-based payment modifier is based upon a comparison of the composite of quality of care measures and a composite of cost measures.

(b) Quality composite and cost composite are classified into high, average, and low categories based on whether the composites are statistically above, not different from, or below the mean composite scores.

(1) Quality composites that are one or more standard deviations above the mean are classified into the high category. Quality composites that are one or more standard deviations below the mean are classified into the low category.

(2) Cost composites that are one or more standard deviations below the mean are classified into the low category. Cost composites that are one or more standard deviations above the mean are classified into the high category.

(c)(1) The following value-based payment modifier percentages apply to the CY 2015 payment adjustment period:

CY 2015 VALUE-BASED PAYMENT MODIFIER AMOUNTS FOR THE QUALITY-TIERING APPROACH

Quality/cost	Low cost	Average cost	High cost (percent)
High quality	+ 2.0x*	+ 1.0x*	+ 0.0
Average quality	+ 1.0x*	+ 0.0%	–0.5

CY 2015 VALUE-BASED PAYMENT MODIFIER AMOUNTS FOR THE QUALITY-TIERING APPROACH—Continued

Quality/cost	Low cost	Average cost	High cost (percent)
Low quality	+ 0.0%	–0.5%	–1.0

*Groups of physicians eligible for an additional + 1.0x if (1) reporting Physician Quality Reporting System quality measures through the GPRO web-interface or CMS-qualified registry, and (2) average beneficiary risk score is in the top 25 percent of all beneficiary risk scores.

(2) The following value-based payment modifier percentages apply to the CY 2016 payment adjustment period:

CY 2016 VALUE-BASED PAYMENT MODIFIER AMOUNTS FOR THE QUALITY-TIERING APPROACH

Quality/cost	Low cost	Average cost	High cost (percent)
High quality	+ 2.0x*	+ 1.0x*	+ 0.0
Average quality	+ 1.0x*	+ 0.0%	–1.0
Low quality	+ 0.0%	–1.0%	–2.0

*Groups of physicians eligible for an additional + 1.0x if reporting Physician Quality Reporting System quality measures and average beneficiary risk score is in the top 25 percent of all beneficiary risk scores.

(3) The following value-based payment modifier percentages apply to the CY 2017 payment adjustment period:

(i) For groups with 10 or more eligible professionals:

CY 2017 VALUE-BASED PAYMENT MODIFIER AMOUNTS FOR THE QUALITY-TIERING APPROACH FOR GROUPS WITH 10 OR MORE ELIGIBLE PROFESSIONALS

Cost/quality	Low quality	Average quality	High quality
Low Cost	+ 0.0%	*+ 2.0x	*+ 4.0x
Average Cost	−2.0%	+ 0.0%	*+ 2.0x
High Cost	−4.0%	−2.0%	+ 0.0%

*Groups eligible for an additional + 1.0x if reporting Physician Quality Reporting System quality measures and average beneficiary risk score is in the top 25 percent of all beneficiary risk scores, where 'x' represents the upward payment adjustment factor.

(ii) For groups with two to nine eligible professionals and solo practitioners:

CY 2017 VALUE-BASED PAYMENT MODIFIER AMOUNTS FOR THE QUALITY-TIERING APPROACH FOR GROUPS WITH TWO TO NINE ELIGIBLE PROFESSIONALS AND SOLO PRACTITIONERS

Cost/quality	Low quality	Average quality	High quality
Low Cost	+ 0.0%	*+ 1.0x	*+ 2.0x
Average Cost	+ 0.0%	+ 0.0%	*+ 1.0x
High Cost	+ 0.0%	+ 0.0%	+ 0.0%

*Groups and solo practitioners eligible for an additional + 1.0x if reporting Physician Quality Reporting System quality measures and average beneficiary risk score is in the top 25 percent of all beneficiary risk scores, where 'x' represents the upward payment adjustment factor.

(4) The following value-based payment modifier percentages apply to the CY 2018 payment adjustment period, for physicians, physician assistants, nurse practitioners, clinical nurse specialists, and certified registered nurse anesthetists who are solo practitioners or who are in groups of any size:

CY 2018 VALUE-BASED PAYMENT MODIFIER AMOUNTS FOR THE QUALITY-TIERING APPROACH FOR PHYSICIANS, PHYSICIAN ASSISTANTS, NURSE PRACTITIONERS, CLINICAL NURSE SPECIALISTS, AND CERTIFIED REGISTERED NURSE ANESTHETISTS

Cost/quality	Low quality	Average quality	High quality
Low Cost	+0.0%	*+1.0x	*+2.0x
Average Cost	+0.0%	+0.0%	*+1.0x

CY 2018 VALUE-BASED PAYMENT MODIFIER AMOUNTS FOR THE QUALITY-TIERING APPROACH FOR PHYSICIANS, PHYSICIAN ASSISTANTS, NURSE PRACTITIONERS, CLINICAL NURSE SPECIALISTS, AND CERTIFIED REGISTERED NURSE ANESTHETISTS—Continued

Cost/quality	Low quality	Average quality	High quality
High Cost	+0.0%	+0.0%	+0.0%

* Eligible for an additional +1.0x if reporting Physician Quality Reporting System quality measures and average beneficiary risk score is in the top 25 percent of all beneficiary risk scores, where 'x' represents the upward payment adjustment factor.

(d)(1) Groups of physicians subject to the value-based payment modifier that have an attributed beneficiary population with an average risk score in the top 25 percent of the risk scores of beneficiaries nationwide and for the CY 2015 payment adjustment period elect the quality-tiering approach or for the CY 2016 payment adjustment period are subject to the quality-tiering approach, receive a greater upward payment adjustment as follows:

(i) Classified as high quality/low cost receive an upward adjustment of + 3x (rather than + 2x); and

(ii) Classified as either high quality/average cost or average quality/low cost receive an upward adjustment of + 2x (rather than + 1x).

(2) Groups and solo practitioners subject to the value-based payment modifier that have an attributed beneficiary population with an average risk score in the top 25 percent of the risk scores of beneficiaries nationwide and for the CY 2017 payment adjustment period are subject to the quality-tiering approach, receive a greater upward payment adjustment as follows:

(i) Classified as high quality/low cost receive an upward adjustment of + 5x (rather than + 4x) if the group has 10 or more eligible professionals or + 3x (rather than + 2x) if a solo practitioner or the group has two to nine eligible professionals; and

(ii) Classified as either high quality/average cost or average quality/low cost receive an upward adjustment of + 3x (rather than + 2x) if the group has 10 or more eligible professionals or + 2x (rather than + 1x) if a solo practitioner or the group has two to nine eligible professionals.

(3) Groups and solo practitioners subject to the value-based payment modifier that have an attributed beneficiary population with an average risk score in the top 25 percent of the risk scores of beneficiaries nationwide and for the CY 2018 payment adjustment period are subject to the quality-tiering approach, receive a greater upward payment adjustment as follows:

(i) Classified as high quality/low cost receive an upward adjustment of +3x (rather than +2x); and

(ii) Classified as either high quality/average cost or average quality/low cost receive an upward adjustment of +2x (rather than +1x).

[77 FR 69368, Nov. 16, 2012, as amended at 78 FR 74822, Dec. 10, 2013; 79 FR 68008, Nov. 13, 2014; 80 FR 71385, Nov. 16, 2015; 82 FR 53363, Nov. 15, 2017]

§ 414.1280 Limitation on review.

(a) There shall be no administrative or judicial review under section 1869 of the Act, section 1878 of the Act, or otherwise of all of the following:

(1) The establishment of the value-based payment modifier.

(2) The evaluation of the quality of care composite, including the establishment of appropriate measure of the quality of care.

(3) The evaluation of costs composite, including establishment of appropriate measures of costs.

(4) The dates of implementation of the value-based payment modifier.

(5) The specification of the initial performance period and any other performance period.

(6) The application of the value-based payment modifier.

(7) The determination of costs.

(b) [Reserved]

§ 414.1285 Informal inquiry process.

After the dissemination of the annual Physician Feedback reports, a group and a solo practitioner may contact CMS to inquire about its report and

the calculation of the value-based payment modifier.

[77 FR 69368, Nov. 16, 2012, as amended at 79 FR 68008, Nov. 13, 2014]

Subpart O—Merit-Based Incentive Payment System and Alternative Payment Model Incentive

SOURCE: 81 FR 77537, Nov. 4, 2016, unless otherwise noted.

§ 414.1300 Basis and scope.

(a) *Basis.* This subpart implements the following provisions of the Act:

(1) Section 1833(z)—Incentive Payments for Participation in Eligible Alternative Payment Models.

(2) Section 1848(k)—Quality Reporting System.

(3) Section 1848(m)—Incentive Payments for Quality Reporting.

(4) Section 1848(q)—Merit-based Incentive Payment System.

(b) *Scope.* This subpart part sets forth the following:

(1) The circumstances under which eligible clinicians are not considered MIPS eligible clinicians with respect to a year.

(2) How individual MIPS eligible clinicians can have their performance assessed as a group.

(3) The data submission methods and data submission criteria for each of the MIPS performance categories.

(4) Methods for calculating a performance category score for each of the MIPS performance categories.

(5) Methods for calculating a MIPS final score and applying the MIPS payment adjustment to MIPS eligible clinicians.

(6) Requirements for an APM to be designated an ''Advanced APM.''

(7) Methods for eligible clinicians and entities participating in Advanced APMs to meet the participation thresholds to become Qualifying APM Participants (QPs) and Partial QPs.

(8) Methods and processes for counting participation in Other Payer Advanced APMs in making QP and Partial QP determinations.

(9) Methods for calculating and paying the APM Incentive Payment to QPs.

(10) Criteria for Physician-Focused Payment Models (PFPMs).

[81 FR 77537, Nov. 4, 2016, as amended at 86 FR 65669, Nov. 19, 2021]

§ 414.1305 Definitions.

As used in this section, unless otherwise indicated—

Additional performance threshold means the numerical threshold for a MIPS payment year against which the final scores of MIPS eligible clinicians are compared to determine the additional MIPS payment adjustment factors for exceptional performance.

Advanced Alternative Payment Model (Advanced APM) means an APM that CMS determines meets the criteria set forth in § 414.1415.

Affiliated practitioner means an eligible clinician identified by a unique APM participant identifier on a CMS-maintained list who has a contractual relationship with the APM Entity for the purposes of supporting the APM Entity's quality or cost goals under the Advanced APM.

Affiliated practitioner list means the list of Affiliated Practitioners of an APM Entity that is compiled from a CMS-maintained list.

Aligned Other Payer Medical Home Model means an aligned other payer payment arrangement (not including a Medicaid payment arrangement) operated by a payer formally partnering in a CMS Multi-Payer Model that is a Medical Home Model through a written expression of alignment and cooperation, such as a memorandum of understanding (MOU) with CMS, and is determined by CMS to have the following characteristics:

(1) The other payer payment arrangement has a primary care focus with participants that primarily include primary care practices or multispecialty practices that include primary care physicians and practitioners and offer primary care services. For the purposes of this provision, primary care focus means the inclusion of specific design elements related to eligible clinicians practicing under one or more of the following Physician Specialty Codes: 01 General Practice; 08 Family Medicine; 11 Internal Medicine; 16 Obstetrics and Gynecology; 37 Pediatric Medicine; 38

Geriatric Medicine; 50 Nurse Practitioner; 89 Clinical Nurse Specialist; and 97 Physician Assistant;

(2) Empanelment of each patient to a primary clinician; and

(3) At least four of the following:

(i) Planned coordination of chronic and preventive care.

(ii) Patient access and continuity of care.

(iii) Risk-stratified care management.

(iv) Coordination of care across the medical neighborhood.

(v) Patient and caregiver engagement.

(vi) Shared decision-making.

(vii) Payment arrangements in addition to, or substituting for, fee-for-service payments (for example, shared savings or population-based payments).

Alternative Payment Model (APM) means any of the following:

(1) A model under section 1115A of the Act (other than a health care innovation award).

(2) The shared savings program under section 1899 of the Act.

(3) A demonstration under section 1866C of the Act.

(4) A demonstration required by Federal law.

Ambulatory Surgical Center (ASC)-based MIPS eligible clinician means:

(1) For the 2019 and 2020 MIPS payment years, a MIPS eligible clinician who furnishes 75 percent or more of his or her covered professional services in sites of service identified by the Place of Service (POS) codes used in the HIPAA standard transaction as an ambulatory surgical center setting based on claims for a period prior to the performance period as specified by CMS; and

(2) Beginning with the 2021 MIPS payment year, a MIPS eligible clinician who furnishes 75 percent or more of his or her covered professional services in sites of service identified by the POS codes used in the HIPAA standard transaction as an ambulatory surgical center setting based on claims for the MIPS determination period.

APM Entity means an entity that participates in an APM or other payer arrangement through a direct agreement with CMS or an other payer or through Federal or State law or regulation.

APM Entity group means the group of eligible clinicians participating in an APM Entity, as identified by a combination of the APM identifier, APM Entity identifier, Taxpayer Identification Number (TIN), and National Provider Identifier (NPI) for each participating eligible clinician.

APM Incentive Payment means the lump sum incentive payment for a year paid to an eligible clinician who is a QP for the year from 2019 through 2024.

Attestation means a secure mechanism, specified by CMS, with respect to a particular performance period, whereby a MIPS eligible clinician, subgroup, or group may submit the required data for the Promoting Interoperability or the improvement activities performance categories of MIPS in a manner specified by CMS.

Attributed beneficiary means a beneficiary attributed to the APM Entity under the terms of the Advanced APM as indicated on the most recent available list of attributed beneficiaries at the time of a QP determination.

Attribution-eligible beneficiary means a beneficiary who during the QP Performance Period:

(1) Is not enrolled in Medicare Advantage or a Medicare cost plan;

(2) Does not have Medicare as a secondary payer;

(3) Is enrolled in both Medicare Parts A and B;

(4) Is at least 18 years of age;

(5) Is a United States resident; and

(6) Has a minimum of one claim for evaluation and management services furnished by an eligible clinician who is in the APM Entity for any period during the QP Performance Period or, for an Advanced APM that does not base attribution on evaluation and management services and for which attributed beneficiaries are not a subset of the attribution-eligible beneficiary population based on the requirement to have at least one claim for evaluation and management services furnished by an eligible clinician who is in the APM Entity for any period during the QP Performance Period, the attribution basis determined by CMS based upon the methodology the Advanced APM uses for attribution, which may include a combination of evaluation and management and/or other services.

Certified Electronic Health Record Technology (CEHRT) means the following:

(1) For any calendar year before 2019, EHR technology (which could include multiple technologies) certified under the ONC Health IT Certification Program that meets one of the following:

(i) The 2014 Edition Base EHR definition (as defined at 45 CFR 170.102) and that has been certified to the certification criteria that are necessary to report on applicable objectives and measures specified for the MIPS advancing care information performance category, including the applicable measure calculation certification criterion at 45 CFR 170.314(g)(1) or (2) for all certification criteria that support an objective with a percentage-based measure.

(ii) Certification to—

(A) The following certification criteria:

(*1*) CPOE at—

(*i*) 45 CFR 170.314(a)(1), (18), (19) or (20); or

(*ii*) 45 CFR 170.315(a)(1), (2) or (3).

(*2*)(*i*) Record demographics at 45 CFR 170.314(a)(3); or

(*ii*) 45 CFR 170.315(a)(5).

(*3*)(*i*) Problem list at 45 CFR 170.314(a)(5); or

(*ii*) 45 CFR 170.315(a)(6).

(*4*)(*i*) Medication list at 45 CFR 170.314(a)(6); or

(*ii*) 45 CFR 170.315(a)(7).

(*5*)(*i*) Medication allergy list 45 CFR 170.314(a)(7); or

(*ii*) 45 CFR 170.315(a)(8).

(*6*)(*i*) Clinical decision support at 45 CFR 170.314(a)(8); or

(*ii*) 45 CFR 170.315(a)(9).

(*7*) Health information exchange at transitions of care at one of the following:

(*i*) 45 CFR 170.314(b)(1) and (2).

(*ii*) 45 CFR 170.314(b)(1), (b)(2), and (h)(1).

(*iii*) 45 CFR 170.314(b)(1), (b)(2), and (b)(8).

(*iv*) 45 CFR 170.314(b)(1), (b)(2), (b)(8), and (h)(1).

(*v*) 45 CFR 170.314(b)(8) and (h)(1).

(*vi*) 45 CFR 170.314(b)(1), (b)(2), and 170.315(h)(2).

(*vii*) 45 CFR 170.314(b)(1), (b)(2), (h)(1), and 170.315(h)(2).

(*viii*) 45 CFR 170.314(b)(1), (b)(2), (b)(8), and 170.315(h)(2).

(*ix*) 45 CFR 170.314(b)(1), (b)(2), (b)(8), (h)(1), and 170.315(h)(2).

(*x*) 45 CFR 170.314(b)(8), (h)(1), and 170.315(h)(2).

(*xi*) 45 CFR 170.314(b)(1), (b)(2), and 170.315(b)(1).

(*xii*) 45 CFR 170.314(b)(1), (b)(2), (h)(1), and 170.315(b)(1).

(*xiii*) 45 CFR 170.314(b)(1), (b)(2), (b)(8), and 170.315(b)(1).

(*xiv*) 45 CFR 170.314(b)(1), (b)(2), (b)(8), (h)(1), and 170.315(b)(1).

(*xv*) 45 CFR 170.314(b)(8), (h)(1), and 170.315(b)(1).

(*xvi*) 45 CFR 170.314(b)(1), (b)(2), (b)(8), (h)(1), 170.315(b)(1), and 170.315(h)(1).

(*xvii*) 45 CFR 170.314(b)(1), (b)(2), (b)(8), (h)(1), 170.315(b)(1), and 170.315(h)(2).

(*xviii*) 45 CFR 170.314(h)(1) and 170.315(b)(1).

(*xix*) 45 CFR 170.315(b)(1) and (h)(1).

(*xx*) 45 CFR 170.315(b)(1) and (h)(2).

(*xxi*) 45 CFR 170.315(b)(1), (h)(1), and (h)(2); and

(B) Clinical quality measures at—

(*1*) 45 CFR 170.314(c)(1) or 170.315(c)(1);

(*2*) 45 CFR 170.314(c)(2) or 170.315(c)(2);

(*3*) Clinical quality measure certification criteria that support the calculation and reporting of clinical quality measures at 45 CFR 170.314(c)(2) and (3) and optionally (4); or 45 CFR 170.315(c)(3)(i) and (ii) and optionally (c)(4); and can be electronically accepted by CMS if the data is submitted electronically.

(C) Privacy and security at—

(*1*) 45 CFR 170.314(d)(1) or 170.315(d)(1);

(*2*) 45 CFR 170.314(d)(2) or 170.315(d)(2);

(*3*) 45 CFR 170.314(d)(3) or 170.315(d)(3);

(*4*) 45 CFR 170.314(d)(4) or 170.315(d)(4);

(*5*) 45 CFR 170.314(d)(5) or 170.315(d)(5);

(*6*) 45 CFR 170.314(d)(6) or 170.315(d)(6);

(*7*) 45 CFR 170.314(d)(7) or 170.315(d)(7);

(*8*) 45 CFR 170.314(d)(8) or 170.315(d)(8); and

(D) The certification criteria that are necessary to report on applicable objectives and measures specified for the MIPS Promoting Interoperability performance category, including the applicable measure calculation certification criterion at 45 CFR 170.314(g)(1) or (2) or 45 CFR 170.315(g)(1) or (2) for all certification criteria that support an objective with a percentage-based measure.

(iii) The definition for 2019 and subsequent years specified in paragraph (2) of this definition.

(2) For 2019 and subsequent years, EHR technology (which could include multiple technologies) certified under the ONC Health IT Certification Program that meets the 2015 Edition Base EHR definition, or subsequent Base EHR definition (as defined in 45 CFR 170.102), and has been certified to the ONC health IT certification criteria as adopted and updated in 45 CFR 170.315—

(i) At 45 CFR 170.315(a)(12) (family health history) and 45 CFR 170.315(e)(3) (patient health information capture); and

(ii) Necessary to report on applicable objectives and measures specified for MIPS including the following:

(A) The applicable measure calculation certification criterion at 45 CFR 170.315(g)(1) or (2) for all certification criteria that support an objective with a percentage-based measure.

(B) Clinical quality measure certification criteria that support the calculation and reporting of clinical quality measures at 45 CFR 170.315(c)(2) and (c)(3)(i) and (ii) and optionally (c)(4), and can be electronically accepted by CMS.

(3) For purposes of determinations under §§ 414.1415 and 414.1420, beginning for CY 2024, EHR technology (which could include multiple technologies) certified under the ONC Health IT Certification Program that meets—

(i) The 2015 Edition Base EHR definition, or subsequent Base EHR definition (as defined in 45 CFR 170.102); and

(ii) Any such ONC health IT certification criteria adopted or updated in 45 CFR 170.315 that are determined applicable for the APM, for the year, considering factors such as clinical practice area, promotion of interoperability, relevance to reporting on applicable quality measures, clinical care delivery objectives of the APM, or any other factor relevant to documenting and communicating clinical care to patients or their health care providers in the APM.

CMS-approved survey vendor means a survey vendor that is approved by CMS for a particular performance period to administer the CAHPS for MIPS survey and to transmit survey measures data to CMS.

CMS Multi-Payer Model means an Advanced APM that CMS determines, per the terms of the Advanced APM, has at least one other payer arrangement that is designed to align with the terms of that Advanced APM.

CMS Web Interface means a web product developed by CMS that is used by groups that have elected to utilize the CMS Web Interface to submit data on the MIPS measures and activities.

Collection type means a set of quality measures with comparable specifications and data completeness criteria, as applicable, including, but not limited to: Electronic clinical quality measures (eCQMs); MIPS clinical quality measures (MIPS CQMs); QCDR measures; Medicare Part B claims measures; CMS Web Interface measures (except as provided in paragraph (1) of this definition, for the CY 2017 through CY 2022 performance periods/2019 through 2024 MIPS payment years); the CAHPS for MIPS survey measure; administrative claims measures; and Medicare Clinical Quality Measures for Accountable Care Organizations Participating in the Medicare Shared Savings Program (Medicare CQMs).

Covered professional services has the meaning given by section 1848(k)(3)(A) of the Act.

Eligible clinician means ''eligible professional'' as defined in section 1848(k)(3) of the Act, as identified by a unique TIN and NPI combination and, includes any of the following:

(1) A physician.

(2) A practitioner described in section 1842(b)(18)(C) of the Act.

(3) A physical or occupational therapist or a qualified speech-language pathologist.

(4) A qualified audiologist (as defined in section 1861(ll)(3)(B) of the Act).

Episode payment model means an APM or other payer arrangement designed to improve the efficiency and quality of care for an episode of care by bundling payment for services furnished to an individual over a defined period of time for a specific clinical condition or conditions.

Estimated aggregate payment amounts means the total payments to a QP for Medicare Part B covered professional

services for the incentive payment base period, estimated by CMS as described in §414.1450(b).

Facility-based group means a group that CMS determines meets the criteria specified in §414.1380(e)(2)(ii).

Facility-based MIPS eligible clinician means an individual MIPS eligible clinician who CMS determines meets the criteria specified in §414.1380(e)(2)(i).

Final score means a composite assessment (using a scoring scale of 0 to 100) for each MIPS eligible clinician for a performance period determined using the methodology for assessing the total performance of a MIPS eligible clinician according to performance standards for applicable measures and activities for each performance category.

Group means a single TIN with two or more eligible clinicians (including at least one MIPS eligible clinician), as identified by their individual NPI, who have reassigned their billing rights to the TIN.

Health IT vendor means an entity that supports the health IT requirements on behalf of a MIPS eligible clinician (including obtaining data from a MIPS eligible clinician's CEHRT).

Health Professional Shortage Areas (HPSA) means areas as designated under section 332(a)(1)(A) of the Public Health Service Act.

High priority measure means an outcome (including intermediate-outcome and patient-reported outcome), appropriate use, patient safety, efficiency, patient experience, care coordination, opioid, or health equity-related quality measure.

Hospital-based MIPS eligible clinician means:

(1) For the 2019 and 2020 MIPS payment years, a MIPS eligible clinician who furnishes 75 percent or more of his or her covered professional services in sites of service identified by the Place of Service (POS) codes used in the HIPAA standard transaction as an inpatient hospital, on-campus outpatient hospital, off campus-outpatient hospital, or emergency room setting based on claims for a period prior to the performance period as specified by CMS; and

(2) For the 2021 MIPS payment year, a MIPS eligible clinician who furnishes 75 percent or more of his or her covered professional services in sites of service identified by the POS codes used in the HIPAA standard transaction as an inpatient hospital, on-campus outpatient hospital, off campus outpatient hospital, or emergency room setting based on claims for the MIPS determination period; and

(3) Beginning with the 2022 MIPS payment year, an individual MIPS eligible clinician who furnishes 75 percent or more of his or her covered professional services in sites of service identified by the POS codes used in the HIPAA standard transaction as an inpatient hospital, on-campus outpatient hospital, off campus outpatient hospital, or emergency room setting based on claims for the MIPS determination period, and a group or virtual group provided that more than 75 percent of the NPIs billing under the group's TIN or virtual group's TINs, as applicable, meet the definition of a hospital-based individual MIPS eligible clinician during the MIPS determination period.

Improvement activities means an activity that relevant MIPS eligible clinician, organizations and other relevant stakeholders identify as improving clinical practice or care delivery and that the Secretary determines, when effectively executed, is likely to result in improved outcomes.

Improvement scoring means an assessment measuring improvement for each MIPS eligible clinician or group for a performance period using a methodology that compares improvement from one performance period to another performance period.

Incentive payment base period means the calendar year prior to the year in which CMS disburses the APM Incentive Payment.

Low-volume threshold means:

(1) For the 2019 MIPS payment year, the low-volume threshold that applies to an individual eligible clinician, group, or APM Entity group that, during the low-volume threshold determination period described in paragraph (4) of this definition, has Medicare Part B allowed charges less than or equal to $30,000 or provides care for 100 or fewer Medicare Part B-enrolled individuals.

(2) For the 2020 MIPS payment year, the low-volume threshold that applies to an individual eligible clinician,

group, or APM Entity group that, during the low-volume threshold determination period described in paragraph (4) of this definition, has allowed charges for covered professional services less than or equal to $90,000 or furnishes covered professional services to 200 or fewer Medicare Part B-enrolled individuals.

(3) For the 2021 and 2022 MIPS payment years, the low-volume threshold that applies to an individual eligible clinician, group, or APM Entity group that, during the MIPS determination period, has allowed charges for covered professional services less than or equal to $90,000, furnishes covered professional services to 200 or fewer Medicare Part B-enrolled individuals, or furnishes 200 or fewer covered professional services to Medicare Part B-enrolled individuals.

(4) For the 2019 and 2020 MIPS payment years, the low-volume threshold determination period is a 24-month assessment period consisting of:

(i) An initial 12-month segment that spans from the last 4 months of the calendar year 2 years prior to the performance period through the first 8 months of the calendar year preceding to the performance period; and

(ii) A second 12-month segment that spans from the last 4 months of the calendar year 1 year prior to the performance period through the first 8 months of the calendar year performance period. An individual eligible clinician, group, or APM Entity group that is identified as not exceeding the low-volume threshold during the initial 12-month segment will continue to be excluded under §414.1310(b)(1)(iii) for the applicable year regardless of the results of the second 12-month segment analysis. For the 2019 MIPS payment year, each segment of the low-volume threshold determination period includes a 60-day claims run out. For the 2020 MIPS payment year, each segment of the low-volume threshold determination period includes a 30-day claims run out.

(5) Beginning with the 2023 MIPS payment year, the low-volume threshold that applies to an individual eligible clinician, or group that, during the MIPS determination period, has allowed charges for covered professional services less than or equal to $90,000, furnishes covered professional services to 200 or fewer Medicare Part B-enrolled individuals, or furnishes 200 or fewer covered professional services to Medicare Part B-enrolled individuals.

Meaningful EHR user for MIPS means a MIPS eligible clinician that possesses CEHRT, uses the functionality of CEHRT, reports on applicable objectives and measures specified for the Promoting Interoperability performance category for a performance period in the form and manner specified by CMS, does not knowingly and willfully take action (such as to disable functionality) to limit or restrict the compatibility or interoperability of CEHRT, and engages in activities related to supporting providers with the performance of CEHRT. In addition, a MIPS eligible clinician (other than a qualified audiologist) is not a meaningful EHR user for a performance period if the HHS Inspector General refers a determination that the MIPS eligible clinician committed information blocking as defined at 45 CFR 171.103 during the calendar year of the performance period. The term ''information blocking,'' with respect to an individual MIPS eligible clinician or group, shall not include an act or practice other than an act or practice committed by such individual MIPS eligible clinician or group.

Measure benchmark means the level of performance that the MIPS eligible clinician is assessed on for a specific performance period at the measures and activities level.

Medicaid APM means a payment arrangement authorized by a State Medicaid program that meets the Other Payer Advanced APM criteria set forth in §414.1420.

Medical Home Model means an APM under section 1115A of the Act that is determined by CMS to have the following characteristics:

(1) The APM has a primary care focus with participants that primarily include primary care practices or multispecialty practices that include primary care physicians and practitioners and offer primary care services. For the purposes of this provision, primary care focus means the inclusion of specific design elements related to eligible

clinicians practicing under one or more of the following Physician Specialty Codes: 01 General Practice; 08 Family Medicine; 11 Internal Medicine; 16 Obstetrics and Gynecology; 37 Pediatric Medicine; 38 Geriatric Medicine; 50 Nurse Practitioner; 89 Clinical Nurse Specialist; and 97 Physician Assistant;

(2) Empanelment of each patient to a primary clinician; and

(3) At least four of the following:

(i) Planned coordination of chronic and preventive care.

(ii) Patient access and continuity of care.

(iii) Risk-stratified care management.

(iv) Coordination of care across the medical neighborhood.

(v) Patient and caregiver engagement.

(vi) Shared decision-making.

(vii) Payment arrangements in addition to, or substituting for, fee-for-service payments (for example, shared savings or population-based payments).

Medicaid Medical Home Model means a payment arrangement under title XIX that CMS determines to have the following characteristics:

(1) The payment arrangement has a primary care focus with participants that primarily include primary care practices or multispecialty practices that include primary care physicians and practitioners and offer primary care services. For the purposes of this provision, primary care focus means the inclusion of specific design elements related to eligible clinicians practicing under one or more of the following Physician Specialty Codes: 01 General Practice; 08 Family Medicine; 11 Internal Medicine; 16 Obstetrics and Gynecology; 37 Pediatric Medicine; 38 Geriatric Medicine; 50 Nurse Practitioner; 89 Clinical Nurse Specialist; and 97 Physician Assistant;

(2) Empanelment of each patient to a primary clinician; and

(3) At least four of the following:

(i) Planned coordination of chronic and preventive care.

(ii) Patient access and continuity.

(iii) Risk-stratified care management.

(iv) Coordination of care across the medical neighborhood.

(v) Patient and caregiver engagement.

(vi) Shared decision-making.

(vii) Payment arrangements in addition to, or substituting for, fee-for-service payments (for example, shared savings or population-based payments).

Merit-based Incentive Payment System (MIPS) means the program required by section 1848(q) of the Act.

MIPS APM means:

(1) For the 2019 through 2022 MIPS payment years, an APM that meets the criteria specified under §414.1370(b).

(2) Beginning with the 2023 MIPS payment year, an APM that meets the criteria as set forth in §414.1367(b).

MIPS determination period means:

(1) Beginning with the 2021 MIPS payment year, a 24-month assessment period consisting of:

(i) An initial 12-month segment beginning on October 1 of the calendar year 2 years prior to the applicable performance period and ending on September 30 of the calendar year preceding the applicable performance period, and that includes a 30-day claims run out; and

(ii) A second 12-month segment beginning on October 1 of the calendar year preceding the applicable performance period and ending on September 30 of the calendar year in which the applicable performance period occurs.

(2) Subject to §414.1310(b)(1)(iii), an individual eligible clinician, group, or APM Entity group that is identified as not exceeding the low-volume threshold or as having special status, as applicable, during the first segment of the MIPS determination period will be identified as such for the applicable MIPS payment year regardless of the results of the second segment of the MIPS determination period. An individual eligible clinician, group, or APM Entity group for which the unique billing TIN and NPI combination is established during the second segment of the MIPS determination period will be assessed based solely on the results of such segment.

MIPS eligible clinician as identified by a unique billing TIN and NPI combination used to assess performance, means any of the following (except as excluded under §414.1310(b)):

(1) For the 2019 and 2020 MIPS payment years:

(i) A physician (as defined in section 1861(r) of the Act);

(ii) A physician assistant, a nurse practitioner, and clinical nurse specialist (as such terms are defined in section 1861(aa)(5) of the Act);

(iii) A certified registered nurse anesthetist (as defined in section 1861(bb)(2) of the Act); and

(iv) A group that includes such clinicians.

(2) For the 2021 through 2023 MIPS payment years:

(i) A clinician described in paragraph (1) of this definition;

(ii) A physical therapist or occupational therapist;

(iii) A qualified speech-language pathologist;

(iv) A qualified audiologist (as defined in section 1861(ll)(3)(B) of the Act);

(v) A clinical psychologist (as defined by the Secretary for purposes of section 1861(ii) of the Act);

(vi) A registered dietician or nutrition professional; and

(vii) A group that includes such clinicians.

(3) For the 2024 MIPS payment year and future years:

(i) A clinician described in paragraph (2) of this definition;

(ii) A clinical social worker (as defined in section 1861(hh)(1) of the Act);

(iii) A certified nurse midwife (as defined in section 1861(gg)(2) of the Act); and

(iv) A group that includes such clinicians.

MIPS payment year means a calendar year in which the MIPS payment adjustment factor, and if applicable the additional MIPS payment adjustment factor, are applied to Medicare Part B payments.

MIPS Value Pathway means a subset of measures and activities established through rulemaking.

Multispecialty group means a group as defined at § 414.1305 that consists of two or more specialty types as determined by CMS using Medicare Part B claims.

MVP participant means an individual MIPS eligible clinician, multispecialty group, single-specialty group, subgroup, or APM Entity that is assessed on an MVP in accordance with § 414.1365 for all MIPS performance categories. For the CY 2026 performance period/2028 MIPS payment year and future years, MVP Participant means an individual MIPS eligible clinician, single-specialty group, subgroup, or APM Entity that is assessed on an MVP in accordance with § 414.1365 for all MIPS performance categories.

New Medicare-Enrolled MIPS eligible clinician means an eligible clinician who first becomes a Medicare-enrolled eligible clinician within the Provider Enrollment, Chain and Ownership System (PECOS) during the performance period for a year and had not previously submitted claims under Medicare as an individual, an entity, or a part of a physician group or under a different billing number or tax identifier.

Non-patient facing MIPS eligible clinician means:

(1) For the 2019 and 2020 MIPS payment year, an individual MIPS eligible clinician who bills 100 or fewer patient facing encounters (including Medicare telehealth services defined in section 1834(m) of the Act), as described in paragraph (3) of this definition, during the non-patient facing determination period described in paragraph (4) of this definition, and a group or virtual group provided that more than 75 percent of the NPIs billing under the group's TIN or virtual group's TINs, as applicable, meet the definition of a non-patient facing individual MIPS eligible clinician.

(2) Beginning with the 2021 MIPS payment year, an individual MIPS eligible clinician who bills 100 or fewer patient facing encounters (including Medicare telehealth services defined in section 1834(m) of the Act), as described in paragraph (3) of this definition, during the MIPS determination period, and a group or virtual group provided that more than 75 percent of the NPIs billing under the group's TIN or virtual group's TINs, as applicable, meet the definition of a non-patient facing individual MIPS eligible clinician.

(3) For purposes of this definition, a patient-facing encounter is an instance in which the individual MIPS eligible clinician or group bills for items and

services furnished such as general office visits, outpatient visits, and procedure codes under the PFS, as specified by CMS.

(4) For the 2019 and 2020 MIPS payment year, the non-patient facing determination period is a 24-month assessment period consisting of:

(i) An initial 12-month segment that spans from the last 4 months of the calendar year 2 years prior to the performance period through the first 8 months of the calendar year preceding the performance period; and

(ii) A second 12-month segment that spans from the last 4 months of the calendar year 1 year prior to the performance period through the first 8 months of the calendar year performance period. An individual eligible MIPS clinician, group, or virtual group that is identified as non-patient facing during the initial 12-month segment will continue to be considered non-patient facing for the applicable year regardless of the results of the second 12-month segment analysis. For the 2019 MIPS payment year, each segment of the non-patient facing determination period includes a 60-day claims run out. For the 2020 MIPS payment year and future years, each segment of the non-patient facing determination period includes a 30-day claims run out.

Other MIPS APM means a MIPS APM that does not require reporting through the CMS Web Interface.

Other Payer Advanced APM means an other payer arrangement that meets the Other Payer Advanced APM criteria set forth in §414.1420.

Other payer arrangement means a payment arrangement with any payer that is not an APM.

Partial Qualifying APM Participant (Partial QP) means an eligible clinician determined by CMS to have met the relevant Partial QP threshold under §414.1430(a)(2) and (4) and (b)(2) and (4) for a year.

Partial QP patient count threshold means the minimum threshold score specified in §414.1430(a)(4) and (b)(4) that an eligible clinician must attain through a patient count methodology described in §§414.1435(b) and 414.1440(c) to become a Partial QP for a year.

Partial QP payment amount threshold means the minimum threshold score specified in §414.1430(a)(2) and (b)(2) that an eligible clinician must attain through a payment amount methodology described §§414.1435(a) and 414.1440(b) to become a Partial QP for a year.

Participation List means the list of participants in an APM Entity that is compiled from a CMS-maintained list.

Performance category score means the assessment of each MIPS eligible clinician's performance on the applicable measures and activities for a performance category for a performance period based on the performance standards for those measures and activities.

Performance standards means the level of performance and methodology that the MIPS eligible clinician is assessed on for a MIPS performance period at the measures and activities level for all MIPS performance categories.

Performance threshold means the numerical threshold for a MIPS payment year against which the final scores of MIPS eligible clinicians are compared to determine the MIPS payment adjustment factors.

Physician Compare means the Physician Compare internet website of the Centers for Medicare & Medicaid Services (or a successor website).

Population health measure means a quality measure that indicates the quality of a population or cohort's overall health and well-being, such as access to care, clinical outcomes, coordination of care and community services, health behaviors, preventive care and screening, health equity, or utilization of health services.

Primary care services for purposes of CMS Web Interface and CAHPS for MIPS survey beneficiary assignment means the set of services identified by the following:

(1) CPT codes:

(i) 99201 through 99215 (codes for office or other outpatient visit for the evaluation and management of a patient); 99304 through 99318 (codes for professional services furnished in a nursing facility, excluding professional services furnished in a SNF for claims identified by place of service (POS) modifier 31); 99319 through 99340 (codes for patient domiciliary, rest home, or custodial care visit); 99341 through

99350 (codes for evaluation and management services furnished in a patient's home for claims identified by POS modifier 12); 99487, 99489, and 99490 (codes for chronic care management); and 99495 and 99496 (codes for transitional care management services); and

(ii) Beginning with the 2023 MIPS payment year, 99421, 99422, and 99423 (codes for online digital evaluation and management services (e-visit)); 99441, 99442, and 99443 (codes for telephone evaluation and management services); and 96160 and 96161 (codes for administration of health risk assessment).

(2) HCPCS codes:

(i) G0402 (code for the Welcome to Medicare visit); and G0438 and G0439 (codes for the annual wellness visits); and

(ii) Beginning with the 2023 MIPS payment year, G2010 (code for remote evaluation of patient video/images); and G2012 (code for virtual check-in).

QCDR measure means a quality measure that is submitted by a QCDR and approved by CMS under § 414.1400. QCDR measures consist of:

(1) Measures that are not included in the MIPS final list of quality measures described in § 414.1330(a)(1) for the applicable MIPS payment year; and

(2) Measures that are included in the MIPS final list of quality measures described in § 414.1330(a)(1) for the applicable MIPS payment year, but have undergone substantive changes, as determined by CMS.

QP patient count threshold means the minimum threshold score specified in § 414.1430(a)(3) and (b)(3) that an eligible clinician must attain through a patient count methodology described in §§ 414.1435(b) and 414.1440(c) to become a QP for a year.

QP payment amount threshold means the minimum threshold score specified in § 414.1430(a)(1) and (b)(1) that an eligible clinician must attain through the payment amount methodology described in §§ 414.1435(a) and 414.1440(b) to become a QP for a year.

QP Performance Period means the time period that CMS will use to assess the level of participation by an eligible clinician in Advanced APMs and Other Payer Advanced APMs for purposes of making a QP determination for the eligible clinician for the year as specified in § 414.1425. The QP Performance Period begins on January 1 and ends on August 31 of the calendar year that is 2 years prior to the payment year.

Qualified clinical data registry (QCDR) means:

(1) For the 2019, 2020 and 2021 MIPS payment year, a CMS-approved entity that has self-nominated and successfully completed a qualification process to determine whether the entity may collect medical or clinical data for the purpose of patient and disease tracking to foster improvement in the quality of care provided to patients.

(2) Beginning with the 2022 MIPS payment year, an entity that demonstrates clinical expertise in medicine and quality measurement development experience and collects medical or clinical data on behalf of a MIPS eligible clinician for the purpose of patient and disease tracking to foster improvement in the quality of care provided to patients.

Qualified posting means the document made available that lists qualified registries or QCDRs available by CMS for use by MIPS eligible clinicians, groups, subgroups, virtual groups, and APM Entities.

Qualified registry means a medical registry, a maintenance of certification program operated by a specialty body of the American Board of Medical Specialties or other data intermediary that, with respect to a particular performance period, has self-nominated and successfully completed a vetting process (as specified by CMS) to demonstrate its compliance with the MIPS qualification requirements specified by CMS for that performance period. The registry must have the requisite legal authority to submit MIPS data (as specified by CMS) on behalf of a MIPS eligible clinician or group to CMS.

Qualifying APM participant (QP) means an eligible clinician determined by CMS to have met or exceeded the relevant QP payment amount or QP patient count threshold under § 414.1430(a)(1), (a)(3), (b)(1), or (b)(3) for a year based on participation in an APM Entity that is also participating in an Advanced APM.

Rural area means a ZIP code designated as rural by the Federal Office of Rural Health Policy (FORHP), using

the most recent FORHP Eligible ZIP Code file available.

Single specialty group means a group as defined at §414.1305 that consists of one specialty type as determined by CMS using Medicare Part B claims.

Small practice means:

(1) For the 2019 MIPS payment year, a TIN consisting of 15 or fewer eligible clinicians.

(2) For the 2020 MIPS payment year, a TIN consisting of 15 or fewer eligible clinicians during a 12-month assessment period that spans from the last 4 months of the calendar year 2 years prior to the performance period through the first 8 months of the calendar year preceding the performance period and includes a 30-day claims run out.

(3) Beginning with the 2021 MIPS payment year, a TIN consisting of 15 or fewer eligible clinicians during the MIPS determination period.

Solo practitioner means a practice consisting of 1 eligible clinician (who is also a MIPS eligible clinician).

Special status means that a MIPS eligible clinician:

(1) Meets the definition of an ASC-based MIPS eligible clinician, facility-based MIPS eligible clinician, hospital-based MIPS eligible clinician, non-patient facing MIPS eligible clinician, or is in a small practice; or

(2) Is located in an HPSA or rural area.

Subgroup means a subset of a group which contains at least one MIPS eligible clinician and is identified by a combination of the group TIN, subgroup identifier, and each eligible clinician's NPI.

Submission type means the mechanism by which the submitter type submits data to CMS, including, but not limited to:

(1) Direct;

(2) Log in and upload;

(3) Log in and attest;

(4) Medicare Part B claims; and

(5) CMS Web Interface (except as provided in paragraph (5)(i) of this definition, for the CY 2017 through CY 2022 performance periods/2019 through 2024 MIPS payment years).

(i) For the CY 2021 through CY 2024 performance periods/2023 through 2026 MIPS payment years, submission types include the CMS Web Interface for APM Entities reporting through the APM Performance Pathway in accordance with §414.1367.

(ii) [Reserved]

Submitter type means the MIPS eligible clinician, group, Virtual Group, subgroup, APM Entity, or third party intermediary acting on behalf of a MIPS eligible clinician, group, Virtual Group, subgroup, APM Entity, as applicable, that submits data on measures and activities under MIPS.

Third party intermediary means an entity that CMS has approved under §414.1400 to submit data on behalf of a MIPS eligible clinician, group, virtual group, subgroup, or APM Entity for one or more of the quality, improvement activities, and Promoting Interoperability performance categories.

Threshold Score means the percentage value that CMS determines for an eligible clinician based on the calculations described in §414.1435 or §414.1440.

Topped out non-process measure means a measure where the Truncated Coefficient of Variation is less than 0.10 and the 75th and 90th percentiles are within 2 standard errors.

Topped out process measure means a measure with a median performance rate of 95 percent or higher.

Virtual group means a combination of two or more TINs assigned to one or more solo practitioners or to one or more groups consisting of 10 or fewer eligible clinicians, or both, that elect to form a virtual group for a performance period for a year.

[81 FR 77537, Nov. 4, 2016, as amended at 82 FR 53950, Nov. 16, 2017; 83 FR 60075, Nov. 23, 2018; 84 FR 63194, Nov. 15, 2019; 85 FR 54872, Sept. 2, 2020; 85 FR 85029, Dec. 28, 2020; 86 FR 65670, Nov. 19, 2021; 86 FR 73159, Dec. 27, 2021; 87 FR 70227, Nov. 18, 2022; 88 FR 79533, Nov. 16, 2023; 89 FR 54716, July 1, 2024]

§414.1310 Applicability.

(a) *Program implementation.* Except as specified in paragraph (b) of this section, MIPS applies to payments for covered professional services furnished by MIPS eligible clinicians on or after January 1, 2019.

(b) *Exclusions.* (1) For a year, a MIPS eligible clinician does not include an eligible clinician who:

(i) Is a Qualifying APM Participant (as defined at § 414.1305);

(ii) Is a Partial Qualifying APM Participant and does not elect to participate in MIPS as a MIPS eligible clinician; or

(iii) Does not exceed the low volume threshold.

(A) Beginning with the 2021 MIPS payment year, if an individual eligible clinician or group exceeds at least one, but not all, of the low-volume threshold criteria and elects to participate in MIPS as a MIPS eligible clinician, the individual eligible clinician or group is treated as a MIPS eligible clinician for the applicable MIPS payment year. For such solo practitioners and groups that elect to participate in MIPS as a virtual group (except for APM Entity groups in MIPS APMs), the virtual group election under § 414.1315 constitutes an election under this paragraph (b)(1)(iii)(A) and results in the solo practitioners and groups being treated as MIPS eligible clinicians for the applicable MIPS payment year.

(B) For the 2021 and 2022 MIPS payment years, if an APM Entity group in a MIPS APM exceeds at least one, but not all, of the low-volume threshold criteria and elects to participate in MIPS as a MIPS eligible clinician, the APM Entity group is treated as a MIPS eligible clinician for the applicable MIPS payment year. For such APM Entity groups in MIPS APMs, only the APM Entity group election can result in the APM Entity group being treated as MIPS eligible clinicians for the applicable MIPS payment year.

(2) Eligible clinicians, as defined at § 414.1305, who are not MIPS eligible clinicians, as defined at § 414.1305, have the option to voluntarily report measures and activities for MIPS.

(c) *Treatment of new Medicare-enrolled eligible clinicians.* New Medicare-enrolled eligible clinician, as defined at § 414.1305, will not be treated as a MIPS eligible clinician until the subsequent year and the performance period for such subsequent year.

(d) *Clarification.* In no case will a MIPS payment adjustment factor (or additional MIPS payment adjustment factor) apply to payments for items and services furnished during a year by a eligible clinician, including an eligible clinician described in paragraph (b) or (c) of this section, who is not a MIPS eligible clinician, including an eligible clinician who voluntarily reports on applicable measures and activities under MIPS.

(e) *Requirements for groups.* (1) Except as provided under §§ 414.1315(a)(2), 414.1317(b), 414.1318(b), and 414.1370(f)(2) each MIPS eligible clinician in the group receives a final score based on the group's combined performance assessment.

(2) For individual MIPS eligible clinicians to participate in MIPS as a group, all of the following requirements must be met:

(i) Groups must meet the definition of a group at all times during the applicable performance period.

(ii) Individual eligible clinicians that elect to participate in MIPS as a group must aggregate their performance data across the group's TIN, and for the Promoting Interoperability performance category, must aggregate the performance data of all of the MIPS eligible clinicians in the group's TIN for whom the group has data in CEHRT.

(iii) Individual eligible clinicians that elect to participate in MIPS as a group will have their performance assessed at the group level across all four MIPS performance categories.

(iv) Groups must adhere to an election process established by CMS, as applicable.

[81 FR 77537, Nov. 4, 2016, as amended at 83 FR 60076, Nov. 23, 2018; 84 FR 63195, Nov. 15, 2019; 85 FR 85030, Dec. 28, 2020; 86 FR 65670, Nov. 19, 2021]

§ 414.1315 Virtual groups.

(a) *Eligibility.* (1) For a MIPS payment year, a solo practitioner or a group of 10 or fewer eligible clinicians may elect to participate in MIPS as a virtual group with at least one other such solo practitioner or group. The election must be made prior to the start of the applicable performance period and cannot be changed during the performance period. A solo practitioner or group may elect to be in no more than one virtual group for a performance period, and, in the case of a group, the election applies to all MIPS eligible clinicians in the group.

(2) Except as provided under §414.1370(f)(2), each MIPS eligible clinician in the virtual group receives a MIPS payment adjustment factor and, if applicable, an additional MIPS payment adjustment factor based on the virtual group's combined performance assessment.

(b) *Election deadline.* The election deadline is December 31 of the calendar year preceding the applicable performance period.

(c) *Election process.* For the 2020 MIPS payment year and future years, the virtual group election process is as follows:

(1) *Stage 1: Virtual group eligibility determination.* (i) For the 2020 MIPS payment year, the virtual group eligibility determination period is an assessment period of up to 5 months beginning on July 1 and ending as late as November 30 of the calendar year preceding the applicable performance period, and that includes a 30-day claims run out.

(ii) Beginning with the 2021 MIPS payment year, the virtual group eligibility determination period is the first segment of the MIPS determination period.

(2) *Stage 2: Virtual group formation.* (i) Solo practitioners and groups that elect to participate in MIPS as a virtual group must establish a formal written agreement that satisfies paragraph (c)(3) of this section prior to the election.

(ii) A designated virtual group representative must submit an election, on behalf of the solo practitioners and groups that compose a virtual group, to participate in MIPS as a virtual group for a performance period in a form and manner specified by CMS by the election deadline specified in paragraph (b) of this section. The virtual group election must include each TIN and NPI associated with the virtual group and contact information for the virtual group representative.

(iii) After an election is made, the virtual group representative must contact their designated CMS contact to update any election information that changed during a performance period at least one time prior to the start of data submission.

(3) *Virtual group agreement.* The virtual group arrangement must be set forth in a formal written agreement among the parties, consisting of each solo practitioner and group that composes a virtual group. The agreement must comply with the following requirements:

(i) Identifies each party by name, TIN, and each NPI under the TIN, and includes as parties only the solo practitioners and groups that compose the virtual group.

(ii) Is for a term of at least one performance period.

(iii) Requires each party to notify each NPI under the party's TIN regarding their participation in the MIPS as a virtual group.

(iv) Sets forth each NPI's rights and obligations in, and representation by, the virtual group, including, but not limited to, the reporting requirements and how participation in the MIPS as a virtual group affects the NPI's ability to participate in the MIPS outside of the virtual group.

(v) Describes how the opportunity to receive payment adjustments will encourage each member of the virtual group (and each NPI under each TIN in the virtual group) to adhere to quality assurance and improvement.

(vi) Requires each party to update its Medicare enrollment information, including the addition or removal of NPIs billing under its TIN, on a timely basis in accordance with Medicare program requirements and to notify the other parties of any such changes within 30 days of the change.

(vii) Requires completion of a closeout process upon termination or expiration of the agreement that requires each party to furnish all data necessary for the parties to aggregate their data across the virtual group's TINs.

(viii) Expressly requires each party to participate in the MIPS as a virtual group and comply with the requirements of the MIPS and all other applicable laws (including, but not limited to, Federal criminal law, the Federal False Claims Act, the Federal anti-kickback statute, the Federal civil monetary penalties law, the Federal physician self-referral law, and the Health Insurance Portability and Accountability Act of 1996).

(ix) Is executed on behalf of each party by an individual who is authorized to bind the party.

(d) *Virtual group reporting requirements.* For solo practitioners and groups of 10 or fewer eligible clinicians to participate in MIPS as a virtual group, all of the following requirements must be met:

(1) Virtual groups must meet the definition of a virtual group at all times during the applicable performance period.

(2) Solo practitioners and groups of 10 or fewer eligible clinicians that elect to participate in MIPS as a virtual group must aggregate their performance data across the virtual group's TINs, and for the Promoting Interoperability performance category, must aggregate the performance data of all of the MIPS eligible clinicians in the virtual group's TINs for whom the virtual group has data in CEHRT.

(3) Solo practitioners and groups of 10 or fewer eligible clinicians that elect to participate in MIPS as a virtual group will have their performance assessed at the virtual group level across all four MIPS performance categories.

(4) Virtual groups must adhere to the election process described in paragraph (c) of this section.

[83 FR 60077, Nov. 23, 2018, as amended at 84 FR 63195, Nov. 15, 2019]

§ 414.1317 APM Entity groups.

(a) *APM entity group determination.* The APM Entity group will be determined according to the requirements set forth in § 414.1425(b)(1).

(1) In addition to the dates set forth in § 414.1425(b)(1), for purposes of MIPS, the APM Entity group includes an eligible clinician who is on a Participation List on December 31 of the MIPS performance period.

(2) For purposes of MIPS scoring, the APM Entity group will be comprised only of those eligible clinicians within the APM Entity group who are determined to be MIPS eligible at the individual or group level.

(3) For purposes of calculating the APM Entity group score, MIPS scores submitted by virtual groups will not be included.

(b) *APM Entity group scoring.* The MIPS final score calculated for the APM Entity is applied to each MIPS eligible clinician in the APM Entity group. The MIPS payment adjustment is applied at the TIN/NPI level for each of the MIPS eligible clinicians in the APM Entity group.

(1) *Determination of performance category score for each MIPS eligible clinician in an APM Entity.* For APM Entities, where a performance category is not reported by the APM Entity, CMS uses one score for each MIPS eligible clinician in an APM Entity group to derive a single average APM Entity score for the performance category. The applicable score for each MIPS eligible clinician is the higher of either:

(i) A group score based on the measure data for the performance category reported by a TIN for the MIPS eligible clinician according to MIPS submission and reporting requirements for groups.

(ii) An individual score based on the measure data for the performance category reported by the MIPS eligible clinician according to MIPS submission and reporting requirements for individuals.

(iii) In the event that a MIPS eligible clinician in an APM Entity receives an exception from the reporting requirements, such eligible clinician will be assigned a null score when CMS calculates the APM Entity's performance category score.

(2) *Performance category weights.* The cost performance category weight is zero percent of the final score for an APM Entity. The performance category reweighting scenarios under § 414.1380(c)(2) apply to an APM Entity.

(3) *Improvement scoring for APM Entity groups.* For an APM Entity for which CMS calculated a total performance category score for one or more participants in the APM Entity for the preceding MIPS performance period, CMS calculates an improvement score for each performance category for which a previous year's total performance category score is available as specified in § 414.1380(b).

(4) *Extreme and uncontrollable circumstances.* Beginning with the 2022 MIPS payment year, an APM Entity may submit to CMS an application described at § 414.1380(c)(2)(i)(A)(*6*) and (c)(2)(i)(C)(2) requesting reweighting of

all four MIPS performance categories and for all MIPS eligible clinicians in the APM Entity group, based on extreme and uncontrollable circumstances.

(i) An APM Entity must demonstrate in its application to CMS that greater than 75 percent of its participant MIPS eligible clinicians would be eligible for reweighting the Promoting Interoperability performance category for the applicable performance period.

(ii) If CMS approves the request for reweighting based on an APM Entity's application, and if MIPS data are submitted for the APM Entity for the applicable performance period, all four of the MIPS performance categories will be reweighted for the APM Entity group notwithstanding the data submission.

[85 FR 85030, Dec. 28, 2020, as amended at 86 FR 65671, Nov. 19, 2021]

§ 414.1318 Subgroups.

(a) *Eligibility and special status*—(1) *General.* Except as provided under paragraph (a)(2) of this section and subject to paragraph (a)(4) of this section, for a MIPS payment year, determinations of meeting the low-volume threshold criteria and special status for a subgroup is determined at the group level in accordance with §§ 414.1305 and 414.1310.

(2) *Exclusions.* An individual eligible clinician or group that elects to participate in MIPS as a MIPS eligible clinician in accordance with § 414.1310(b)(1)(iii)(A) or (b)(2) is not eligible to participate in a subgroup.

(3) *Single subgroup per eligible clinician.* An individual eligible clinician (as represented by a TIN–NPI combination) may register for no more than one subgroup within a group's TIN.

(4) *Subgroup determination period.* CMS will apply the low-volume threshold criteria for a subgroup as described under paragraph (a)(1) of this section using information from the initial 12-month segment of the applicable MIPS determination period.

(b) *Final score.* Except as provided under § 414.1317(b) and paragraph (b)(1) of this section, each MIPS eligible clinician in the subgroup receives a final score based on the subgroup's combined performance.

(1) CMS will not assign a final score for a subgroup that registers and does not submit data as a subgroup for the applicable performance period.

(2) [Reserved]

(c) *Subgroup reporting requirements.* For individual eligible clinicians to participate in MIPS as a subgroup, all of the following requirements must be met:

(1) Individual eligible clinicians that elect to participate in MIPS as a subgroup must aggregate their quality and improvement activities performance data across the subgroup's identifier.

(2) Individual eligible clinicians that elect to participate in MIPS as a subgroup will have their performance assessed at the subgroup level across all the MIPS performance categories based on an MVP in accordance with § 414.1365. Subgroups that are MVP Participants must adhere to an election process described in § 414.1365(b).

[86 FR 65671, Nov. 19, 2021; as amended at 87 FR 70227, Nov. 18, 2022]

§ 414.1320 MIPS performance period.

(a) For purposes of the 2019 MIPS payment year, the performance period for all performance categories and submission mechanisms except for the cost performance category and data for the quality performance category reported through the CMS Web Interface, for the CAHPS for MIPS survey, and for the all-cause hospital readmission measure, is a minimum of a continuous 90-day period within CY 2017, up to and including the full CY 2017 (January 1, 2017 through December 31, 2017). For purposes of the 2019 MIPS payment year, for data reported through the CMS Web Interface or the CAHPS for MIPS survey and administrative claims-based cost and quality measures, the performance period under MIPS is CY 2017 (January 1, 2017 through December 31, 2017).

(b) For purposes of the 2020 MIPS payment year, the performance period for:

(1) The quality and cost performance categories is CY 2018 (January 1, 2018 through December 31, 2018).

(2) Promoting Interoperability and improvement activities performance categories is a minimum of a continuous 90-day period within CY 2018, up

to and including the full CY 2018 (January 1, 2018 through December 31, 2018).

(c) For purposes of the 2021 MIPS payment year, the performance period for:

(1) The quality and cost performance categories is CY 2019 (January 1, 2019 through December 31, 2019).

(2) Promoting Interoperability and improvement activities performance categories is a minimum of a continuous 90-day period within CY 2019, up to and including the full CY 2019 (January 1, 2019 through December 31, 2019).

(d) For purposes of the CY 2020 performance period/2022 MIPS payment year, the performance period for:

(1) The quality and cost performance categories are the full calendar year (January 1 through December 31) that occurs 2 years prior to the applicable MIPS payment year.

(2) The improvement activities performance categories are a minimum of a continuous 90-day period within the calendar year that occurs 2 years prior to the applicable MIPS payment year, up to and including the full calendar year.

(e) Beginning with the 2023 MIPS payment year, the performance period for:

(1) The quality and cost performance categories is the full calendar year (January 1 through December 31) that occurs 2 years prior to the applicable MIPS payment year, except as otherwise specified for administrative claims-based measures in the MIPS final list of quality measures described in § 414.1330(a)(1).

(2) The improvement activities performance categories is a minimum of a continuous 90-day period within the calendar year that occurs 2 years prior to the applicable MIPS payment year, up to and including the full calendar year.

(f) For purposes of the 2022 MIPS payment year, the performance period for:

(1) The Promoting Interoperability performance category is a minimum of a continuous 90-day period within the calendar year that occurs 2 years prior to the applicable MIPS payment year, up to and including the full calendar year.

(2) [Reserved]

(g) For purposes of the 2023 MIPS payment year, the performance period for:

(1) The Promoting Interoperability performance category is a minimum of a continuous 90-day period within the calendar year that occurs 2 years prior to the applicable MIPS payment year, up to and including the full calendar year.

(2) [Reserved]

(h) For purposes of the 2024 MIPS payment year and the 2025 MIPS payment year, the performance period for:

(1) The Promoting Interoperability performance category is a minimum of a continuous 90-day period within the calendar year that occurs 2 years prior to the applicable MIPS payment year, up to and including the full calendar year.

(2) [Reserved]

(i) For purposes of the 2026 MIPS payment year and each subsequent payment year, the performance period for:

(1) The Promoting Interoperability performance category is a minimum of a continuous 180-day period within the calendar year that occurs 2 years prior to the applicable MIPS payment year, up to and including the full calendar year.

(2) [Reserved]

[81 FR 77537, Nov. 4, 2016, as amended at 82 FR 53953, Nov. 16, 2017; 83 FR 60078, Nov. 23, 2018; 84 FR 63195, Nov. 15, 2019; 85 FR 85030, Dec. 28, 2020; 86 FR 65671, Nov. 19, 2021; 88 FR 79534, Nov. 16, 2023]

§ 414.1325 Data submission requirements.

(a) *Applicable performance categories.* (1) Except as provided in paragraph (a)(2) of this section, or under § 414.1370 or § 414.1365(c), as applicable, individual MIPS eligible clinicians, groups, virtual groups, subgroups, and APM Entities must submit data on measures and activities for the quality, improvement activities, and Promoting Interoperability performance categories in accordance with this section. Except for the Medicare Part B claims submission type, the data may also be submitted on behalf of the individual MIPS eligible clinician, group, virtual group, subgroup, or APM Entity by a third party intermediary described at § 414.1400.

(i) For the quality performance category, a data submission must include numerator and denominator data for at least one MIPS quality measure from the final list of MIPS quality measures.

(ii) For the improvement activities performance category, a data submission must include a response of ''yes'' for at least one activity in the MIPS improvement activities inventory.

(iii) For the Promoting Interoperability performance category, a data submission must include all of the following elements:

(A) Performance data, including any claim of an applicable exclusion, for the measures in each objective, as specified by CMS;

(B) Required attestation statements, as specified by CMS;

(C) CMS EHR Certification ID (CEHRT ID) from the Certified Health IT Product List (CHPL); and

(D) The start date and end date for the applicable performance period as set forth in §414.1320.

(2) There are no data submission requirements for:

(i) The cost performance category or administrative claims-based quality measures. Performance in the cost performance category and on such measures is calculated by CMS using administrative claims data, which includes claims submitted with dates of service during the applicable performance period that are processed no later than 60 days following the close of the applicable performance period.

(ii) The quality and cost performance categories, as applicable, for MIPS eligible clinicians and groups that are scored under the facility-based measurement scoring methodology described in §414.1380(e).

(b) *Data submission types for individual MIPS eligible clinicians.* An individual MIPS eligible clinician may submit their MIPS data using:

(1) For the quality performance category, the direct, login and upload, and Medicare Part B claims (beginning with the 2021 MIPS payment year for small practices only) submission types.

(2) For the improvement activities or Promoting Interoperability performance categories, the direct, login and upload, or login and attest submission types.

(c) *Data submission types for groups, virtual groups, subgroups, and APM Entities.* Groups, virtual groups, subgroups, and APM Entities may submit their MIPS data using:

(1) For the quality performance category, the direct; login and upload; Medicare Part B claims (beginning with the CY 2019 MIPS performance period/2021 MIPS payment year, for small practices only); and CMS Web Interface (for groups consisting of 25 or more eligible clinicians, a third party intermediary submitting on behalf of a group) submission type.

(2) For the improvement activities or Promoting Interoperability performance categories, the direct, login and upload, or login and attest submission types.

(d) *Use of multiple data submission types.* Beginning with the 2021 MIPS payment year as applicable to MIPS eligible clinicians, groups, and virtual groups, beginning with the 2023 MIPS payment year as applicable to APM Entities, and beginning with the 2025 MIPS payment year as applicable to subgroups, MIPS eligible clinicians, groups, virtual groups, APM Entities, and subgroups may submit their MIPS data using multiple data submission types for any performance category described in paragraph (a)(1) of this section, as applicable; provided, however, that the MIPS eligible clinician, group, virtual group, APM Entity, or subgroup uses the same identifier for all performance categories and all data submissions.

(e) *Data submission deadlines.* The data submission deadlines are as follows:

(1) For the direct, login and upload, login and attest, and CMS Web Interface submission types, March 31 following the close of the applicable performance period or a later date as specified by CMS.

(2) For the Medicare Part B claims submission type, data must be submitted on claims with dates of service during the applicable performance period that must be processed no later than 60 days following the close of the applicable performance period.

(f) *Treatment of multiple data submissions.* (1) For multiple data submissions received in the quality and improvement activities performance categories in accordance with paragraphs (a)(1)(i) and (ii) of this section for an individual MIPS eligible clinician, group, subgroup, or virtual group from submitters in multiple organizations (for example, qualified registry, practice administrator, or EHR vendor), CMS will calculate and score each submission received and assign the highest of the scores. For multiple data submissions received for an individual MIPS eligible clinician, group, subgroup, or virtual group from one or multiple submitters in the same organization, CMS will score the most recent submission.

(2) For multiple data submissions received for the Promoting Interoperability performance category, CMS will calculate a score for each data submission received and assign the highest of the scores.

[83 FR 60078, Nov. 23, 2018, as amended at 85 FR 85031, Dec. 28, 2020; 86 FR 65671, Nov. 19, 2021; 88 FR 79534, Nov. 16, 2023; 89 FR 98560, Dec. 9, 2024]

§ 414.1330 Quality performance category.

(a) For a MIPS payment year, CMS uses the following quality measures, as applicable, to assess performance in the quality performance category:

(1) Measures included in the MIPS final list of quality measures established by CMS through rulemaking;

(2) QCDR measures approved by CMS under § 414.1400;

(3) Facility-based measures described in § 414.1380; and

(4) MIPS APM measures described in § 414.1370.

(b) Unless a different scoring weight is assigned by CMS, performance in the quality performance category comprises:

(1) 60 percent of a MIPS eligible clinician's final score for MIPS payment year 2019.

(2) 50 percent of a MIPS eligible clinician's final score for MIPS payment year 2020.

(3) 45 percent of a MIPS eligible clinician's final score for MIPS payment years 2021 and 2022.

(4) 40 percent of a MIPS eligible clinician's final score for the MIPS payment year 2023.

(5) 30 percent of a MIPS eligible clinician's final score for the MIPS payment year 2024 and future years.

(c)(1) CMS uses the following criteria to determine the removal of a quality measure:

(i) If the Secretary determines that the quality measure is no longer meaningful, such as measures that are topped out.

(ii) If a measure steward is no longer able to maintain the quality measure.

(iii) If the quality measure reached extremely topped out status.

(iv) If the quality measure does not meet case minimum and reporting volumes required for benchmarking after being in the program for 2 consecutive CY performance periods.

(v) If the quality measure is duplicative.

(vi) If the quality measure is not updated to reflect current clinical guidelines, which are not reflective of a clinician's scope of practice.

(vii) If the quality measure is a process measure.

(viii) If the quality measure addresses a measurement gap.

(ix) If the quality measure is a patient-reported outcome.

(x) If the quality measure is not available for MIPS quality reporting by or on behalf of all MIPS eligible clinicians.

(xi) The robustness of the quality measure.

(xii) Consideration of the quality measure in developing MIPS Value Pathways (MVPs).

(2) A quality measure that otherwise meets the criteria for removal in paragraph (c)(1) of this section may nonetheless be retained based on the following considerations:

(i) Whether the removal of the process measure impacts the number of measures available for a specific specialty.

(ii) Whether the quality measure addresses a priority area.

(iii) Whether the quality measure promotes positive outcomes in patients.

(iv) Whether the quality measure is designated as high priority or not.

(v) Whether the quality measure has reached extremely topped out status.

(vi) Evaluation of the quality measure's performance data.

[83 FR 60078, Nov. 23, 2018, as amended at 84 FR 63195, Nov. 15, 2019; 85 FR 85031, Dec. 28, 2020; 89 FR 98561, Dec. 9, 2024]

§414.1335 Data submission criteria for the quality performance category.

(a) *Criteria.* Except as provided in paragraph (b) of this section, a MIPS eligible clinician, group, virtual group, subgroup, or APM Entity must submit data on MIPS quality measures in one of the following manners, as applicable:

(1) *For Medicare Part B claims measures, MIPS CQMs, eCQMs, or QCDR measures.* (i) Except as provided in paragraph (a)(1)(ii) of this section, submits data on at least six measures, including at least one outcome measure. If an applicable outcome measure is not available, reports one other high priority measure. If fewer than six measures apply to the MIPS eligible clinician, group, virtual group, or APM Entity, reports on each measure that is applicable.

(A) For eCQMs, the submission of data requires the utilization of CEHRT, as defined at §414.1305.

(B) [Reserved]

(ii) A MIPS eligible clinician, group, virtual group, and APM Entity that report on a specialty or subspecialty measure set, as designated in the MIPS final list of quality measures established by CMS through rulemaking, must submit data on at least six measures within that set, including at least one outcome measure. If an applicable outcome measure is not available, report one other high priority measure. If the set contains fewer than six measures or if fewer than six measures within the set apply to the MIPS eligible clinician, group, virtual group, or APM Entity, report on each measure that is applicable.

(A) For eCQMs, the submission of data requires the utilization of CEHRT, as defined at §414.1305.

(B) [Reserved]

(2) *For CMS Web Interface measures.* (i) Report on all measures included in the CMS Web Interface. The group is required to report on at least one measure for which there is Medicare patient data.

(ii) [Reserved]

(3) *For the CAHPS for MIPS survey measure.* (i) For the 12-month performance period, a group, virtual group, subgroup, or APM Entity that participates in the CAHPS for MIPS survey must use a survey vendor that is approved by CMS for the applicable performance period to transmit survey measures data to CMS.

(ii) [Reserved]

(4) *For Medicare CQMs.* (i) A MIPS eligible clinician, group, and APM Entity reporting on the Medicare CQMs (reporting quality data on beneficiaries eligible for Medicare CQMs as defined at §425.20) within the APP measure set and administering the CAHPS for MIPS Survey as required under the APP.

(ii) [Reserved]

(b) *Special rule for the APM Performance Pathway (APP) Plus measure set.* A MIPS eligible clinician, group, or APM Entity that reports the APP Plus measure set via the APP must report on all measures included in the APP Plus measure set, except for administrative claims-based quality measures as provided in §414.1325(a)(2)(i).

[81 FR 77537, Nov. 4, 2016, as amended at 82 FR 53953, Nov. 16, 2017; 83 FR 60079, Nov. 23, 2018; 84 FR 63195, Nov. 15, 2019; 88 FR 79534, Nov. 16, 2023; 89 FR 98561, Dec. 9, 2024]

§414.1340 Data completeness criteria for the quality performance category.

(a) MIPS eligible clinicians, groups, virtual groups, subgroups, and APM Entities submitting quality measures data on QCDR measures, MIPS CQMs, or eCQMs must submit data on:

(1) At least 50 percent of the MIPS eligible clinician or group's patients that meet the measure's denominator criteria, regardless of payer for MIPS payment year 2019.

(2) At least 60 percent of the MIPS eligible clinician, group, and virtual group's patients that meet the measure's denominator criteria, regardless of payer for MIPS payment years 2020 and 2021.

(3) At least 70 percent of the MIPS eligible clinician, group, and virtual

group's patients that meet the measure's denominator criteria, regardless of payer for MIPS payment years 2022, 2023, 2024, and 2025.

(i) Applicable to an APM Entity for MIPS payment years 2023, 2024, and 2025.

(ii) Applicable to a subgroup for MIPS payment year 2025.

(4) At least 75 percent of the MIPS eligible clinician, group, virtual group, subgroup, and APM Entity's patients that meet the measure's denominator criteria, regardless of payer for MIPS payment years 2026, 2027, 2028, 2029, and 2030.

(b) MIPS eligible clinicians, groups, virtual groups, subgroups, and APM Entities submitting quality measure data on Medicare Part B claims measures must submit data on:

(1) At least 50 percent of the applicable Medicare Part B patients seen during the performance period to which the measure applies for MIPS payment years 2019.

(2) At least 60 percent of the applicable Medicare Part B patients seen during the performance period to which the measure applies for MIPS payment years 2020 and 2021.

(i) Applicable to virtual groups starting with MIPS payment year 2020.

(ii) [Reserved]

(3) At least 70 percent of the applicable Medicare Part B patients seen during the performance period to which the measure applies for MIPS payment years 2022, 2023, 2024, and 2025.

(i) Applicable to APM Entities starting with MIPS payment year 2023 and subgroups starting with MIPS payment year 2025.

(ii) [Reserved].

(4) At least 75 percent of the applicable Medicare Part B patients seen during the performance period to which the measure applies for MIPS payment years 2026, 2027, 2028, 2029, and 2030.

(c) Groups submitting quality measures data on CMS Web Interface measures or the CAHPS for MIPS survey must submit data on the sample of the Medicare Part B patients CMS provides, as applicable.

(1) *For CMS Web Interface measures.* (i) The group must report on the first 248 consecutively ranked beneficiaries in the sample for each measure or module. If the sample of eligible assigned beneficiaries is less than 248, then the group must report on 100 percent of assigned beneficiaries.

(ii) [Reserved]

(2) [Reserved]

(d) APM Entities, specifically Medicare Shared Savings Program Accountable Care Organizations that meet reporting requirements under the APP, submitting quality measure data on Medicare CQMs must submit data on:

(1) At least 75 percent of the applicable beneficiaries eligible for the Medicare CQM, as defined at § 425.20 of this chapter, who meet the measure's denominator criteria for MIPS payment years 2026, 2027, 2028, 2029, and 2030.

(2) [Reserved]

(e) If quality data are submitted selectively such that the submitted data are unrepresentative of a MIPS eligible clinician, group, virtual group, subgroup, or APM Entity's performance, any such data would not be true, accurate, or complete for purposes of § 414.1390(b) or § 414.1400(a)(5).

[81 FR 77537, Nov. 4, 2016, as amended at 82 FR 53953, Nov. 16, 2017; 83 FR 60079, Nov. 23, 2018; 84 FR 63195, Nov. 15, 2019; 86 FR 65671, Nov. 19, 2021; 87 FR 70227, Nov. 18, 2022; 88 FR 79534, Nov. 16, 2023; 89 FR 98561, Dec. 9, 2024]

§ 414.1350 Cost performance category.

(a) *Specification of cost measures.* For purposes of assessing performance of MIPS eligible clinicians on the cost performance category, CMS specifies cost measures for a performance period.

(b) *Attribution.* (1) Cost measures are attributed at the TIN/NPI level for the 2017 thorough 2019 performance periods.

(2) For the total per capita cost measure specified for the 2017 through 2019 performance periods, beneficiaries are attributed using a method generally consistent with the method of assignment of beneficiaries under § 425.402 of this chapter.

(3) For the Medicare Spending per Beneficiary clinician (MSPB clinician) measure specified for the 2017 through 2019 performance periods, an episode is attributed to the MIPS eligible clinician who submitted the plurality of claims (as measured by allowed charges) for Medicare Part B services

rendered during an inpatient hospitalization that is an index admission for the MSPB clinician measure during the applicable performance period.

(4) For the acute condition episode-based measures specified for the 2017 performance period, an episode is attributed to each MIPS eligible clinician who bills at least 30 percent of inpatient evaluation and management (E/M) visits during the trigger event for the episode.

(5) For the procedural episode-based measures specified for the 2017 performance period, an episode is attributed to each MIPS eligible clinician who bills a Medicare Part B claim with a trigger code during the trigger event for the episode.

(6) For the acute inpatient medical condition episode-based measures specified for the 2019 performance period, an episode is attributed to each MIPS eligible clinician who bills inpatient E/M claim lines during a trigger inpatient hospitalization under a TIN that renders at least 30 percent of the inpatient E/M claim lines in that hospitalization.

(7) For the procedural episode-based measures specified for the 2019 performance period, an episode is attributed to each MIPS eligible clinician who renders a trigger service as identified by HCPCS/CPT procedure codes.

(8) Beginning with the 2020 performance period, each cost measure is attributed according to the measure specifications for the applicable performance period.

(c) *Case minimums.* (1) For the total per capita cost measure, the case minimum is 20.

(2) For the Medicare spending per beneficiary clinician measure, the case minimum is 35.

(3) For the episode-based measures specified for the 2017 performance period, the case minimum is 20.

(4) For the procedural episode-based measures specified beginning with and after the CY 2019 performance period/2021 MIPS payment year, the case minimum is 10, unless otherwise specified for individual measures. Beginning with the CY 2022 performance period/2024 MIPS payment year, the case minimum for Colon and Rectal Resection procedural episode-based measure is 20 episodes.

(5) For the acute inpatient medical condition episode-based measures specified beginning with and after CY 2019 performance period/2021 MIPS payment year, the case minimum is 20, unless otherwise specified for individual measures.

(6) For the chronic condition episode-based measures specified beginning with and after the CY 2022 performance period/2024 MIPS payment year, the case minimum is 20, unless otherwise specified for individual measures.

(7) For the care setting episode-based measures specified beginning with and after the CY 2024 performance period/2026 MIPS payment year, the case minimum is 20, unless otherwise specified for individual measures.

(d) *Scoring weight.* Unless a different scoring weight is assigned by CMS under section 1848(q)(5)(F) of the Act, performance in the cost performance category comprises:

(1) Zero percent of a MIPS eligible clinician's final score for MIPS payment year 2019.

(2) 10 percent of a MIPS eligible clinician's final score for MIPS payment year 2020.

(3) 15 percent of a MIPS eligible clinician's final score for MIPS payment years 2021 and 2022.

(4) 20 percent of the MIPS final score for MIPS payment year 2023.

(5) 30 percent of the MIPS final score for MIPS payment year 2024 and each subsequent MIPS payment year.

(e) *Cost measure removal criteria.* CMS may remove a cost measure from MIPS based on one or more of the following factors, provided however CMS may retain a cost measure that meets one or more of the following factors if CMS determines the benefit of retaining the measure outweighs the benefit of removing it.

(1) It is not feasible to implement the measure specifications.

(2) A measure steward is no longer able to maintain the cost measure.

(3) The implementation costs or negative unintended consequences associated with a cost measure outweigh the benefit of its continued use in the MIPS cost performance category.

(4) The measure specifications do not reflect current clinical practice or guidelines.

(5) The availability of a more applicable measure, including a measure that applies across settings, applies across populations, or is more proximal in time to desired patient outcomes for the particular topic.

[83 FR 60079, Nov. 23, 2018, as amended at 84 FR 63195, Nov. 15, 2019, 85 FR 85031, Dec. 28, 2020; 86 FR 65671, Nov. 19, 2021; 88 FR 79535, Nov. 16, 2023; 89 FR 98561, Dec. 9, 2024]

§ 414.1355 Improvement activities performance category.

(a) For a MIPS payment year, CMS uses improvement activities included in the MIPS final inventory of improvement activities established by CMS through rulemaking to assess performance in the improvement activities performance category.

(b) Unless a different scoring weight is assigned by CMS under section 1848(q)(5)(F) of the Act, performance in the improvement activities performance category comprises:

(1) 15 percent of a MIPS eligible clinician's final score for MIPS payment year 2019 and for each MIPS payment year thereafter.

(2) [Reserved]

(c) The following are the list of subcategories, of which, with the exception of Participation in an APM, include activities for selection by a MIPS eligible clinician or group:

(1) Expanded practice access, such as same day appointments for urgent needs and after-hours access to clinician advice.

(2) Population management, such as monitoring health conditions of individuals to provide timely health care interventions or participation in a QCDR.

(3) Care coordination, such as timely communication of test results, timely exchange of clinical information to patients or other clinicians, and use of remote monitoring or telehealth.

(4) Beneficiary engagement, such as the establishment of care plans for individuals with complex care needs, beneficiary self-management assessment and training, and using shared decision making mechanisms.

(5) Patient safety and practice assessment, such as through the use of clinical or surgical checklists and practice assessments related to maintaining certification.

(6) Participation in an APM.

(7) Achieving health equity, such as for MIPS eligible clinicians that achieve high quality for underserved populations, including persons with behavioral health conditions, racial and ethnic minorities, sexual and gender minorities, people with disabilities, people living in rural areas, and people in geographic HPSAs.

(8) Emergency preparedness and response, such as measuring MIPS eligible clinician participation in the Medical Reserve Corps, measuring registration in the Emergency System for Advance Registration of Volunteer Health Professionals, measuring relevant reserve and active duty uniformed services MIPS eligible clinician activities, and measuring MIPS eligible clinician volunteer participation in domestic or international humanitarian medical relief work.

(9) Integrated behavioral and mental health, such as measuring or evaluating such practices as: Co-location of behavioral health and primary care services; shared/integrated behavioral health and primary care records; cross training of MIPS eligible clinicians, and integrating behavioral health with primary care to address substance use disorders or other behavioral health conditions, as well as integrating mental health with primary care.

(d) CMS may remove an improvement activity from MIPS based on one or more of the following factors, provided however CMS may retain an improvement activity that meets one or more of the following factors if CMS determines the benefit of retaining the activity outweighs the benefit of removing it:

(1) *Factor 1:* Activity is duplicative of another activity.

(2) *Factor 2:* There is an alternative activity with a stronger relationship to quality care or improvements in clinical practice.

(3) *Factor 3:* Activity does not align with current clinical guidelines or practice.

(4) *Factor 4:* Activity does not align with at least one meaningful measures area.

(5) *Factor 5:* Activity does not align with the quality, cost, or Promoting Interoperability performance categories.

(6) *Factor 6:* There have been no attestations of the activity for 3 consecutive years.

(7) *Factor 7:* Activity is obsolete.

[81 FR 77537, Nov. 4, 2016, as amended at 83 FR 60079, Nov. 23, 2018; 89 FR 98561, Dec. 9, 2024]

§ 414.1360 Data submission criteria for the improvement activities performance category.

(a) For purposes of the transition year of MIPS and future years, MIPS eligible clinicians, subgroups, or groups must submit data on MIPS improvement activities in one of the following manners:

(1) *Via direct, login and upload, and login and attest.* For the applicable performance period, submit a yes response for each improvement activity that is performed for at least a continuous 90-day period during the applicable performance period.

(i) Submit a yes response for activities within the improvement activities inventory.

(ii) [Reserved]

(2) *Groups and virtual groups.* Beginning with the 2022 performance year, each improvement activity for which groups and virtual groups submit a yes response in accordance with paragraph (a)(1) of this section must be performed by at least 50 percent of the NPIs that are billing under the group's TIN or virtual group's TINs or that are part of the subgroup, as applicable; and the NPIs must perform the same activity during any continuous 90-day period within the same performance year.

(b) [Reserved]

[81 FR 77537, Nov. 4, 2016, as amended at 82 FR 53953, Nov. 16, 2017; 83 FR 60080, Nov. 23, 2018; 84 FR 63196, Nov. 15, 2019; 86 FR 65671, Nov. 19, 2021; 88 FR 79535, Nov. 16, 2023]

§ 414.1365 MIPS Value Pathways.

(a) *General.* (1) Beginning with the CY 2023 MIPS performance period/2025 MIPS payment year, CMS uses MVPs included in the MIPS final inventory of MVPs established by CMS through rulemaking to assess performance for the quality, cost, improvement activities, and Promoting Interoperability performance categories.

(2) [Reserved]

(b) *MVP/Subgroup registration.* (1) To report an MVP, an MVP Participant must register for the MVP, and if applicable, as a subgroup during a period that begins on April 1 and ends on November 30 of the applicable CY performance period or a later date specified by CMS. To report the CAHPS for MIPS survey associated with an MVP, a group, subgroup or APM Entity must complete their registration by June 30 of such performance period or a later date specified by CMS.

(2) At the time of registration, the MVP Participant must submit the following information, as applicable:

(i) For the CY 2023 through 2024 performance periods/2025 through 2026 MIPS payment years, each MVP Participant must select an MVP, one population health measure included in the MVP, and any outcomes-based administrative claims measure on which the MVP Participant intends to be scored. Beginning in the CY 2025 performance period/2027 MIPS payment year, each MVP Participant must select an MVP and any outcomes-based administrative claims measure on which the MVP Participant intends to be scored.

(ii) Each subgroup must submit a list of each TIN/NPI associated with the subgroup and a plain language name for the subgroup.

(iii) TINs must provide a description of each subgroup that is registered.

(c) *MVP reporting requirements*—(1) Quality. Except as provided in paragraph (c)(1)(i) of this section, an MVP Participant must select and report, if applicable, 4 quality measures, including 1 outcome measure (or, if an outcome measure is not available, 1 high priority measure), included in the MVP, excluding the population health measure required under paragraph (c)(4)(ii) of this section.

(i) Paragraph (c)(1) introductory text of this section does not apply to a small practice that reports on an MVP that includes fewer than 4 Medicare Part B claims measures, provided that

the small practice reports each such measure that is applicable.

(ii) [Reserved]

(2) *Cost.* An MVP Participant is scored on the cost measures included in the MVP that they select and report.

(3) *Improvement activities.* An MVP Participant who reports an MVP, must report one of the following:

(i) For the CY 2023 and 2024 performance periods/2025 through 2026 MIPS payment years:

(A) Two medium-weighted improvement activities.

(B) One high-weighted improvement activity.

(C) Participation in a certified or recognized patient-centered medical home (PCMH) or comparable specialty practice, as described at § 414.1380(b)(3)(ii).

(ii) Beginning in the CY 2025 performance period/2027 MIPS payment year:

(A) One improvement activity.

(B) Participation in a certified or recognized patient-centered medical home (PCMH) or comparable specialty practice, as described at § 414.1380(b)(3)(ii).

(iii) Participation in a certified or recognized patient-centered medical home (PCMH) or comparable specialty practice, as described at § 414.1380(b)(3)(ii).

(4) *Foundational layer*—(i) Promoting interoperability. An MVP Participant is required to meet the Promoting Interoperability performance category reporting requirements described at § 414.1375(b).

(A) An MVP Participant that is a subgroup is required to submit its affiliated group's data for the Promoting Interoperability performance category.

(B) [Reserved]

(ii) *Population health measures.* Each MVP Participant is scored on 1 population health measure in accordance with paragraph (d)(1) of this section.

(d) *MVP scoring*—(1) General. An MVP Participant that is not an APM Entity is scored on measures and activities included in the MVP in accordance with paragraphs (d)(1) through (3) of this section. An MVP Participant that is an APM Entity is scored on measures and activities included in the MVP in accordance with § 414.1317(b).

(2) *Performance standards.* Unless otherwise indicated in this paragraph (d), the performance standards described at § 414.1380(a)(1)(i) through (iv) apply to the measures and activities included in the MVP.

(3) *Performance categories.* An MVP Participant is scored under MIPS in four performance categories.

(i) *Quality performance category.* Except as provided in paragraphs (d)(3)(i)(A)(1) and (d)(3)(i)(B) of this section, the quality performance category score for MVP Participants is calculated in accordance with § 414.1380(b)(1) based on measures included in the MVP.

(A) *Population health measures.* Except as provided in paragraph (d)(3)(i)(A)(*1*) of this section, for the CY 2023 through 2024 performance periods/2025 through 2026 MIPS payment years, each selected population health measure that does not have a benchmark or meet the case minimum requirement is excluded from the MVP participant's total measure achievement points and total available measure achievement points. Beginning in the CY 2025 performance period/2027 MIPS payment year, except as provided in paragraph (d)(3)(i)(A)(*1*) of this section, the highest score of all applicable and available population health measures will be used. If no population health measure has a benchmark or meets the case minimum requirement, each such measure is excluded from the MVP participant's total measure achievement points and total available measure achievement points.

(*1*) For the CY 2023 through 2024 performance periods/2025 through 2026 MIPS payment years, a subgroup is scored on each selected population health measure based on its affiliated group score, if available. Beginning in the CY 2025 performance period/2027 MIPS payment year, a subgroup is scored on the highest scoring of all available population health measures based on its affiliated group score, if available. If the subgroup's affiliated group score is not available, each such measure is excluded from the subgroup's total measure achievement points and total available measure achievement points.

(*2*) [Reserved]

(B) *Outcomes-based administrative claims measures.* MVP Participants receive zero measure achievement points for each selected outcomes-based administrative claims measure that does not have a benchmark or meet the case minimum requirement.

(*1*) A subgroup is scored on each selected outcomes-based administrative claims measure based on its affiliated group score, if available. If the subgroup's affiliated group score is not available, each such measure will receive zero measure achievement points.

(*2*) [Reserved]

(ii) *Cost performance category.* The cost performance category score is calculated for an MVP Participant using the methodology at §414.1380(b)(2) and the cost measures included in the MVP that they select and report.

(A) A subgroup is scored on each cost measure included in the MVP that it selects and reports based on its affiliated group score for each such measure, if available. If the subgroup's affiliated group score is not available for a measure, the measure is excluded from the subgroup's total measure achievement points and total available measure achievement points, as described under §414.1380(b)(2).

(B) [Reserved]

(iii) *Improvement activities performance category.* In the CY 2023 through 2024 performance periods/2025 through 2026 MIPS payment years, the improvement activities performance category score is calculated based on the submission of high- and medium-weighted improvement activities. MVP Participants will receive 20 points for each medium-weighted improvement activity and 40 points for each high-weighted improvement activity required under §414.1360 on which data is submitted in accordance with §414.1325 or for participation in a certified or recognized patient-centered medical home (PCMH) or comparable specialty practice, as described at §414.1380(b)(3)(ii). Beginning in the CY 2025 performance period/2027 MIPS payment year, MVP Participants will receive 40 points for each improvement activity required under §414.1360 on which data is submitted in accordance with §414.1325 or for participation in a certified or recognized PCMH or comparable specialty practice, as described at §414.1380(b)(3)(ii).

(iv) *Promoting interoperability performance category.* The Promoting Interoperability performance category score is calculated for an MVP Participant using the methodology at §414.1380(b)(4), except as provided in paragraph (d)(3)(iv)(A) of this section.

(A) If a subgroup does not submit its affiliated group's data for the Promoting Interoperability performance category, the subgroup will receive a score of zero for the Promoting Interoperability performance category.

(B) [Reserved]

(e) *Final score calculation.* The final score is calculated for an MVP Participant using the methodology at §414.1380(c), unless otherwise indicated in this paragraph (e).

(1) *MVP performance category weights.* For an MVP Participant that is not an APM Entity, the final score is calculated using the performance category weights described at §414.1380(c)(1). For an MVP Participant that is an APM Entity, the final score is calculated using the performance category weights described at §414.1317(b).

(2) *Reweighting MVP performance categories*—(i) *General reweighting.* For an MVP Participant that is not an APM Entity, in accordance with paragraph (e)(2)(iii) of this section, a scoring weight different from the weights described at §414.1380(c)(1) will be assigned to a performance category, and its weight as described at §414.1380(c)(1) will be redistributed to another performance category or categories, in the circumstances described at §414.1380(c)(2)(i)(A)(2) through (9) and §414.1380(c)(2)(i)(C). For an MVP Participant that is an APM Entity, the performance category weights will be redistributed in accordance with §414.1317(b).

(ii) *Subgroups.* For an MVP Participant that is a subgroup, any reweighting applied to its affiliated group will also be applied to the subgroup. In addition, for the CY 2023 performance period/2025 MIPS payment year, if reweighting is not applied to the affiliated group, the subgroup may receive reweighting in the following

circumstances independent of the affiliated group:

(A) A subgroup may submit an application to CMS demonstrating that it was subject to extreme and uncontrollable circumstances and receive reweighting in accordance with § 414.1380(c)(2)(i)(A)(6) and (c)(2)(i)(C)(2). In the event that a subgroup submits data for a performance category, the scoring weight described at § 414.1380(c)(1) would be applied and its weight would not be redistributed.

(B) A subgroup will receive reweighting if CMS determines, based on information known to the agency prior to the beginning of the relevant MIPS payment year, that data for the subgroup are inaccurate, unusable or otherwise compromised due to circumstances outside of the control of the subgroup and its agents, in accordance with § 414.1380(c)(2)(i)(A)(9) and (c)(2)(i)(C)(10).

(iii) *Reweighting scenarios.* For an MVP Participant that is not an APM Entity, a scoring weight different from the weights described at § 414.1380(c)(1) will be assigned to a performance category, and its weight as described at § 414.1380(c)(1) will be redistributed to another performance category or categories, in accordance with § 414.1380(c)(2)(ii). For an MVP Participant that is an APM Entity, the performance category weights will be redistributed in accordance with § 414.1317(b).

(3) *Facility-based scoring.* If an MVP Participant, that is not an APM Entity or a subgroup, is eligible for facility-based scoring, a facility-based score also will be calculated in accordance with § 414.1380(e).

(4) *Complex patient bonus.* A complex patient bonus will be added to the final score for an MVP Participant in accordance with § 414.1380(c)(3).

(i) For subgroups, the affiliated group's complex patient bonus will be added to the final score.

(ii) [Reserved]

[86 FR 65671, Nov. 19, 2021, as amended at 87 FR 70227, Nov. 18, 2022; 88 FR 79535, Nov. 16, 2023; 89 FR 98562, Dec. 9, 2024]

§ 414.1367 APM performance pathway.

(a) *General.* Beginning with the 2023 MIPS payment year, the APM Performance Pathway is a MIPS scoring methodology available to MIPS eligible clinicians identified on the Participation List or Affiliated Practitioner List of an APM Entity participating in a MIPS APM.

(b) *Criteria for MIPS APMs.* MIPS APMs are those in which:

(1) APM Entities participate in the APM under an agreement with CMS or through a law or regulation; and

(2) The APM bases payment on quality measures and cost/utilization.

(c) *MIPS performance category scoring in the APM Performance Pathway*—(1) *Quality.* Except as provided in paragraphs (c)(1)(i) and (ii) of this section, the quality performance category score is calculated for a MIPS eligible clinician, group, or APM Entity group in accordance with § 414.1380(b)(1) based on the quality measure set applicable to the MIPS eligible clinician, group, or APM Entity group under paragraph (c)(1)(iii) of this section and established by CMS through rulemaking for a MIPS payment year.

(i) Each submitted measure that does not have a benchmark or meet the case minimum requirement is excluded from the MIPS eligible clinician, group, or APM Entity group's total measure achievement points and total available measure achievement points.

(ii) Any measure that is identified as topped out is not subject to the scoring cap described at § 414.1380(b)(1)(iv).

(iii)(A) For performance periods beginning prior to CY 2025 and MIPS payment years beginning prior to 2027, a MIPS eligible clinician, group, or APM Entity group must report the APM Performance Pathway quality measure set.

(B) Beginning with the CY 2025 performance period/2027 MIPS payment year, a MIPS eligible clinician, group, or APM Entity group may choose to report either the APM Performance Pathway quality measure set or the APP Plus quality measure set.

(2) *Cost.* The cost performance category weight is zero percent for MIPS eligible clinicians who are scored through the APM Performance Pathway.

(3) *Improvement activities.* The improvement activities performance category score is calculated for a MIPS eligible clinician, group, or APM Entity group in accordance with §414.1380(b)(3) based on the activities required by the MIPS APM that are included in the MIPS final inventory of improvement activities described in §414.1355(a) (excluding any such activities that the MIPS eligible clinician, group, or APM Entity group does not perform). MIPS eligible clinicians, groups, or APM Entities may report additional improvement activities in accordance with §414.1360.

(4) *Promoting interoperability.* The promoting interoperability performance category will be scored for the MIPS eligible clinician, group, or APM Entity as described in §414.1375.

(d) *APM Performance Pathway performance category weights*—(1) *Performance category weights.* Subject to paragraph (d)(2) of this section, the performance category weights used to calculate the final score for a MIPS eligible clinician, group, or APM Entity reporting through the APM performance Pathway are:

(i) Quality: 50 percent.

(ii) Cost: 0 percent.

(iii) Improvement Activities: 20 percent.

(iv) Promoting Interoperability: 30 percent.

(2) *Reweighting MIPS performance categories.* If CMS determines, in accordance with §414.1380(c)(2), that a different scoring weight should be assigned to the quality or promoting interoperability performance category, CMS will redistribute the performance category weights as follows:

(i) If CMS reweights the quality performance category to 0 percent: Promoting Interoperability performance category is reweighted to 75 percent, and Improvement Activities performance category is reweighted to 25 percent.

(ii) If CMS reweights the Promoting Interoperability performance category to 0 percent: Quality performance category is reweighted to 75 percent, and Improvement Activities performance category is reweighted to 25 percent.

(e) *Final score.* The final score is calculated for a MIPS eligible clinician, group, or APM Entity in accordance with §414.1380(c).

[85 FR 85031, Dec. 28, 2020, as amended at 89 FR 98562, Dec. 9, 2024]

§414.1370 APM scoring standard under MIPS.

(a) *General.* For the 2019 through 2022 MIPS payment years, the APM scoring standard is the MIPS scoring methodology applicable for MIPS eligible clinicians identified on the Participation List for the performance period of an APM Entity participating in a MIPS APM.

(b) *Criteria for MIPS APMs.* MIPS APMs are those in which:

(1) APM Entities participate in the APM under an agreement with CMS or through a law or regulation;

(2) The APM is designed such that APM Entities participating in the APM include at least one MIPS eligible clinician on a Participation List;

(3) The APM bases payment on quality measures and cost/utilization; and

(4) The APM is not either of the following:

(i) *New APMs.* An APM for which the first performance year begins after the first day of the MIPS performance period for the year.

(ii) *APM in final year of operation for which the APM scoring standard is impracticable.* An APM in the final year of operation for which CMS determines, within 60 days after the beginning of the MIPS performance period for the year, that it is impracticable for APM Entity groups to report to MIPS using the APM scoring standard.

(c) *APM scoring standard performance period.* The MIPS performance period under §414.1320 applies for the APM scoring standard.

(d) *APM participant identifier.* The APM participant identifier for an eligible clinician is the combination of four identifiers:

(1) APM identifier (established for the APM by CMS);

(2) APM Entity identifier (established for the APM Entity by CMS);

(3) Medicare-enrolled billing TIN; and

(4) Eligible clinician NPI.

(e) *APM Entity group determination.* For the APM scoring standard, the APM Entity group is determined in the manner prescribed in §414.1425(b)(1).

(1) *Full TIN APM.* In addition to the dates set forth in § 414.1425(b)(1), the APM Entity group includes an eligible clinician who is on a Participation List in a Full TIN APM on December 31 of the MIPS performance period.

(2) For purposes of calculating the APM Entity group score under the APM scoring standard, MIPS scores submitted by virtual groups will not be included.

(f) *APM Entity group scoring under the APM scoring standard.* The MIPS final score calculated for the APM Entity is applied to each MIPS eligible clinician in the APM Entity group. The MIPS payment adjustment is applied at the TIN/NPI level for each of the MIPS eligible clinicians in the APM Entity group.

(1) If a Shared Savings Program ACO does not report data on quality measures as required by the Shared Savings Program under § 425.508 of this chapter, each ACO participant TIN will be treated as a unique APM Entity for purposes of the APM scoring standard and the ACO participant TINs may report data for the MIPS quality performance category according to the MIPS submission and reporting requirements.

(2) MIPS eligible clinicians who participate in a group or have elected to participate in a virtual group and who are also on a MIPS APM Participation List will be included in the assessment under MIPS for purposes of producing a group or virtual group score and under the APM scoring standard for purposes of producing an APM Entity score. The MIPS payment adjustment for these eligible clinicians is based solely on their APM Entity score; if the APM Entity group is exempt from MIPS all eligible clinicians within that APM Entity group are also exempt from MIPS.

(g) *MIPS performance category scoring under the APM scoring standard*—(1) *Quality.* Beginning in the 2020 Performance year—

(i) *MIPS APMs that require APM Entities to submit quality data through a MIPS submission mechanism.* The MIPS quality performance category score for a performance period will be calculated for the APM Entity using the data submitted for the APM Entity through a MIPS submission mechanism in accordance with § 414.1335.

(ii) *MIPS APMs that do not require APM Entities to submit quality data through a MIPS submission mechanism.* The APM Entity will be assigned an APM Quality Reporting Credit worth 50 percent of the total quality performance category score. The APM Quality Reporting Credit will be added to the MIPS quality performance category score to generate an APM Entity quality performance category score, which in no case shall exceed 100. The MIPS quality performance category score for a performance period will be calculated for the APM Entity using the data submitted for the APM Entity through a MIPS submission mechanism in accordance with § 414.1335.

(iii) *Determination of score for each MIPS eligible clinician in an APM entity.* Regardless of whether a MIPS APM requires APM Entities to submit quality data through a MIPS submission mechanism, if data are not submitted for an APM Entity through a MIPS submission mechanism in accordance with § 414.1335, the score for each MIPS eligible clinician in such APM Entity is the higher of either:

(A) A TIN level score based on the measure data for the quality performance category reported by a TIN for the MIPS eligible clinician in accordance with § 414.1335; or

(B) An individual level score based on the measure data for the quality performance category reported by the MIPS eligible clinician in accordance with § 414.1335.

(iv) *Quality improvement score.* For an APM Entity for which CMS calculated a total quality performance category score for one or more participants in the APM Entity for the preceding MIPS performance period, CMS calculates a quality improvement score for the APM Entity group as specified in § 414.1380(b)(1)(xvi).

(2) *Cost.* The cost performance category weight is zero percent for APM Entities in MIPS APMs.

(3) *Improvement activities.* (i) CMS assigns an improvement activities score for each MIPS APM for a MIPS performance period based on the requirements of the MIPS APM. The assigned improvement activities score applies to

each APM Entity group for the MIPS performance period. In the event that the assigned score does not represent the maximum improvement activities score, an APM Entity may report additional activities.

(ii) [Reserved]

(4) *Promoting Interoperability.* (i) For the 2019 and 2020 MIPS payment years, each Shared Savings Program ACO participant TIN must report data on the Promoting Interoperability performance category separately from the ACO, as specified in §414.1375(b)(2). The ACO participant TIN scores are weighted according to the number of MIPS eligible clinicians in each TIN as a proportion of the total number of MIPS eligible clinicians in the APM Entity group, and then aggregated to determine an APM Entity score for the ACI performance category.

(ii) For the 2019 and 2020 MIPS payment years, for APM Entities in MIPS APMs other than the Shared Savings Program, CMS uses one score for each MIPS eligible clinician in the APM Entity group to derive a single average APM Entity score for the Promoting Interoperability performance category. Beginning with the 2021 MIPS payment year, for APM Entities in MIPS APMs including the Shared Savings Program, CMS uses one score for each MIPS eligible clinician in the APM Entity group to derive a single average APM Entity score for the Promoting Interoperability performance category. The score for each MIPS eligible clinician is the higher of either:

(A) A group score based on the measure data for the Promoting Interoperability performance category reported by a TIN for the MIPS eligible clinician according to MIPS submission and reporting requirements for groups; or

(B) An individual score based on the measure data for the Promoting Interoperability performance category reported by the MIPS eligible clinician according to MIPS submission and reporting requirements for individuals.

(iii) In the event that a MIPS eligible clinician participating in a MIPS APM receives an exception from the Promoting Interoperability performance category reporting requirements, such eligible clinician will be assigned a null score when CMS calculates the APM Entity's Promoting Interoperability performance category score under the APM scoring standard.

(A) If all MIPS eligible clinicians in an APM Entity have been excepted from reporting the Promoting Interoperability performance category, the performance category weight will be reweighted to zero for the APM Entity for that MIPS performance period.

(B) [Reserved]

(h) *APM scoring standard performance category weights.* The performance category weights used to calculate the MIPS final score for an APM Entity group for the APM scoring standard performance period are:

(1) *Quality.* (i) For MIPS APMs that require use of the CMS Web Interface: 50 percent.

(ii) For Other MIPS APMs, 0 percent for 2017, 50 percent beginning in 2018.

(2) *Cost.* 0 percent.

(3) *Improvement activities.* (i) For MIPS APMs that require use of the CMS Web Interface: 20 percent.

(ii) For Other MIPS APMs, 25 percent for 2017, 20 percent beginning in 2018.

(4) *Promoting Interoperability.* (i) For MIPS APMs that require use of the CMS Web Interface: 30 percent.

(ii) For Other MIPS APMs, 25 percent for 2017, 30 percent beginning in 2018.

(5) *Reweighting the MIPS Performance categories for the APM scoring standard.* If CMS determines there are not sufficient measures or activities applicable and available to MIPS eligible clinicians, CMS will assign weights as follows:

(i) If CMS reweights the quality performance category to 0 percent:

(A) In 2017, the improvement activities performance category is reweighted to 25 percent and the Promoting Interoperability performance category is reweighted to 75 percent; and

(B) Beginning in 2018, the Promoting Interoperability performance category is reweighted to 75 percent and the improvement activities performance category is reweighted to 25 percent.

(ii) If CMS reweights the Promoting Interoperability performance category to zero percent:

(A) In 2017, the quality performance category is reweighted to 75 percent

and the improvement activities performance category will remain at 25 percent.

(B) Beginning in 2018, the quality performance category is reweighted to 80 percent and the improvement activities performance category will remain at 20 percent.

(i) *Total APM Entity Score.* CMS scores each performance category and then multiplies each performance category score by the applicable performance category weight. CMS then calculates the sum of each weighted performance category score and then applies all applicable adjustments. APM Entities will receive MIPS bonuses applied to the final score as set forth in § 414.1380(b).

[81 FR 77537, Nov. 4, 2016, as amended at 82 FR 53953, Nov. 16, 2017; 83 FR 23610, May 22, 2018; 83 FR 60080, Nov. 23, 2018; 84 FR 63196, Nov. 15, 2019; 85 FR 85031, Dec. 28, 2020]

§ 414.1375 Promoting Interoperability (PI) performance category.

(a) *Final score.* Unless a different scoring weight is assigned by CMS under sections 1848(o)(2)(D), 1848(q)(5)(E)(ii), or 1848(q)(5)(F) of the Act, performance in the Promoting Interoperability performance category comprises 25 percent of a MIPS eligible clinician's final score for each MIPS payment year.

(b) *Reporting for the Promoting Interoperability performance category.* To earn a performance category score for the Promoting Interoperability performance category for inclusion in the final score, a MIPS eligible clinician must be a meaningful EHR user for MIPS and:

(1) *CEHRT.* Use CEHRT as defined at § 414.1305 for the performance period;

(2) *Report MIPS—Promoting Interoperability objectives and measures.* Report on the objectives and associated measures as specified by CMS for the Promoting Interoperability performance category for the performance period as follows:

(i) For the 2019 and 2020 MIPS payment years: For each base score measure, as applicable, report the numerator (of at least one) and denominator, or yes/no statement, or claim an exclusion for each measure that includes an option for an exclusion; and

(ii) Beginning with the 2021 MIPS payment year:

(A) Report that the MIPS eligible clinician completed the actions included in the Security Risk Analysis measure during the year in which the performance period occurs;

(B) For each required measure, as applicable, report the numerator (of at least one) and denominator, or yes/no statement, or an exclusion for each measure that includes an option for an exclusion; and

(C) Beginning with the 2024 MIPS payment year through the 2025 MIPS payment year, submit an attestation, with either an affirmative or negative response, with respect to whether the MIPS eligible clinician completed the annual self-assessment under the SAFER Guides measure during the year in which the performance period occurs.

(D) Beginning with the 2026 MIPS payment year, submit an affirmative attestation regarding the MIPS eligible clinician's completion of the annual self-assessment under the SAFER Guides measure during the year in which the performance period occurs.

(3) *Engaging in activities related to supporting providers with the performance of CEHRT; support for health information exchange and the prevention of information blocking; actions to limit or restrict the compatibility or interoperability of CEHRT*—(i) *Supporting providers with the performance of CEHRT (SPPC).* To engage in activities related to supporting providers with the performance of CEHRT, the MIPS eligible clinician—

(A) Must attest that he or she:

(*1*) Acknowledges the requirement to cooperate in good faith with ONC direct review of his or her health information technology certified under the ONC Health IT Certification Program if a request to assist in ONC direct review is received; and

(*2*) If requested, cooperated in good faith with ONC direct review of his or her health information technology certified under the ONC Health IT Certification Program as authorized by 45 CFR part 170, subpart E, to the extent that such technology meets (or can be used to meet) the definition of CEHRT, including by permitting timely access

to such technology and demonstrating its capabilities as implemented and used by the MIPS eligible clinician in the field.

(B) Optionally, may also attest that he or she:

(*1*) Acknowledges the option to cooperate in good faith with ONC–ACB surveillance of his or her health information technology certified under the ONC Health IT Certification Program if a request to assist in ONC–ACB surveillance is received; and

(*2*) If requested, cooperated in good faith with ONC–ACB surveillance of his or her health information technology certified under the ONC Health IT Certification Program as authorized by 45 CFR part 170, subpart E, to the extent that such technology meets (or can be used to meet) the definition of CEHRT, including by permitting timely access to such technology and demonstrating its capabilities as implemented and used by the MIPS eligible clinician in the field.

(ii) *Support for health information exchange and the prevention of information blocking*. For the 2019, 2020, 2021, 2022, and 2023 MIPS payment years, the MIPS eligible clinician must attest to CMS that he or she—

(A) Did not knowingly and willfully take action (such as to disable functionality) to limit or restrict the compatibility or interoperability of certified EHR technology.

(B) Implemented technologies, standards, policies, practices, and agreements reasonably calculated to ensure, to the greatest extent practicable and permitted by law, that the certified EHR technology was, at all relevant times—

(*1*) Connected in accordance with applicable law;

(*2*) Compliant with all standards applicable to the exchange of information, including the standards, implementation specifications, and certification criteria adopted at 45 CFR part 170;

(*3*) Implemented in a manner that allowed for timely access by patients to their electronic health information; and

(*4*) Implemented in a manner that allowed for the timely, secure, and trusted bi-directional exchange of structured electronic health information with other health care providers (as defined by 42 U.S.C. 300jj(3)), including unaffiliated providers, and with disparate certified EHR technology and health IT vendors.

(C) Responded in good faith and in a timely manner to requests to retrieve or exchange electronic health information, including from patients, health care providers (as defined by 42 U.S.C. 300jj(3)), and other persons, regardless of the requestor's affiliation or technology vendor.

(iii) *Actions to limit or restrict the compatibility or interoperability of CEHRT*. Beginning with the 2024 MIPS payment year, the MIPS eligible clinician must attest to CMS that he or she—

(A) Did not knowingly and willfully take action (such as to disable functionality) to limit or restrict the compatibility or interoperability of certified EHR technology.

(B) [Reserved]

[81 FR 77537, Nov. 4, 2016, as amended at 82 FR 53955, Nov. 16, 2017; 83 FR 60080, Nov. 23, 2018; 86 FR 65673, Nov. 19, 2021; 88 FR 79535, Nov. 16, 2023; 89 FR 54717, July 1, 2024]

§414.1380 Scoring.

(a) *General*. MIPS eligible clinicians are scored under MIPS based on their performance on measures and activities in four performance categories. MIPS eligible clinicians are scored against performance standards for each performance category and receive a final score, composed of their performance category scores, and calculated according to the final score methodology.

(1) *Performance standards*. (i) For the quality performance category, measures are scored between zero and 10 measure achievement points. Performance is measured against benchmarks. Prior to the CY 2023 performance period/2025 MIPS payment year, measure bonus points are available for submitting high-priority measures and submitting measures using end-to-end electronic reporting. Measure bonus points are available for small practices that submit data on at least 1 quality measure. Beginning with the 2020 MIPS payment year, improvement scoring is available in the quality performance category.

(ii) For the cost performance category, measures are scored between 1 and 10 points. Performance is measured against a benchmark. Beginning with the 2025 MIPS payment year, improvement scoring is available in the cost performance category.

(iii) For the improvement activities performance category, each improvement activity is assigned a certain number of points. The points for all submitted activities are summed and scored against a total potential performance category score of 40 points.

(iv) For the Promoting Interoperability performance category, each measure is scored against a maximum number of points. The points for all submitted measures are summed and scored against a total potential performance category score of 100 points.

(2) [Reserved]

(b) *Performance categories.* MIPS eligible clinicians are scored under MIPS in four performance categories.

(1) *Quality performance category*—(i) *Measure achievement points.* For the CY 2017 through 2022 performance periods/2019 through 2024 MIPS payment years, MIPS eligible clinicians receive between 3 and 10 measure achievement points (including partial points) for each measure required under § 414.1335 on which data is submitted in accordance with § 414.1325 that has a benchmark at paragraph (b)(1)(ii) of this section, meets the case minimum requirement at paragraph (b)(1)(iii) of this section, and meets the data completeness requirement at § 414.1340 and for each administrative claims-based measure that has a benchmark at paragraph (b)(1)(ii) of this section and meets the case minimum requirement at paragraph (b)(1)(iii) of this section. Except as provided under paragraph (b)(1)(i)(C) of this section, beginning with the CY 2023 performance period/2025 MIPS payment year, MIPS eligible clinicians receive between 1 and 10 measure achievement points (including partial points) for each such measure. The number of measure achievement points received for each such measure is determined based on the applicable benchmark decile category and the percentile distribution. MIPS eligible clinicians receive zero measure achievement points for each measure required under § 414.1335 on which no data is submitted in accordance with § 414.1325. MIPS eligible clinicians that submit data in accordance with § 414.1325 on a greater number of measures than required under § 414.1335 are scored only on the required measures with the greatest number of measure achievement points. Beginning with the CY 2019 performance period/2021 MIPS payment year, MIPS eligible clinicians that submit data in accordance with § 414.1325 on a single measure via multiple collection types are scored only on the data submission with the greatest number of measure achievement points.

(A) *Lack of benchmark or case minimum.*

(*1*) Except as provided in paragraphs (b)(1)(i)(A)(*2*) and (*3*) of this section, for the CY 2017 through 2022 performance periods/2019 through 2024 MIPS payment years, MIPS eligible clinicians receive 3 measure achievement points for each submitted measure that meets the data completeness requirement, but does not have a benchmark or meet the case minimum requirement. Beginning with the CY 2023 performance period/2025 MIPS payment year, MIPS eligible clinicians other than small practices receive 0 measure achievement points for each such measure, and small practices receive 3 measure achievement points for each such measure.

(*2*) The following measures are excluded from a MIPS eligible clinician's total measure achievement points and total available measure achievement points:

(*i*) Each submitted CMS Web Interface-based measure that meets the data completeness requirement, but does not have a benchmark or meet the case minimum requirement, or is redesignated as pay-for-reporting for all Shared Savings Program accountable care organizations by the Shared Savings Program; and

(*ii*) Each administrative claims-based measure that does not have a benchmark or meet the case minimum requirement.

(*3*) Beginning with the CY 2022 performance period/2024 MIPS payment year, MIPS eligible clinicians receive 7 measure achievement points for each

submitted measure in its first year in MIPS and 5 measure achievement points for each submitted measure in its second year in MIPS that meets the data completeness requirement, but does not have a benchmark or meet the case minimum requirement.

(B) *Lack of complete data.* (*1*) Except as provided in paragraph (b)(1)(i)(B)(*2*) of this section, for each submitted measure that does not meet the data completeness requirement:

(*i*) For the 2019 MIPS payment year, MIPS eligible clinicians receive 3 measure achievement points;

(*ii*) For the 2020 and 2021 MIPS payment years, MIPS eligible clinicians other than small practices receive 1 measure achievement point, and small practices receive 3 measure achievement points; and

(*iii*) Beginning with the 2022 MIPS payment year, MIPS eligible clinicians other than small practices receive zero measure achievement points, and small practices receive 3 measure achievement points.

(*2*) MIPS eligible clinicians receive zero measure achievement points for each submitted CMS Web Interface-based measure that does not meet the data completeness requirement.

(C) *New measures.* Beginning with the CY 2022 performance period/2024 MIPS payment year, for each measure required under §414.1335 on which data is submitted in accordance with §414.1325 that has a benchmark at paragraph (b)(1)(ii) of this section, meets the case minimum requirement at paragraph (b)(1)(iii) of this section, and meets the data completeness requirement at §414.1340, a MIPS eligible clinician receives between 7 and 10 measure achievement points (including partial points) for each such measure in its first year in MIPS and between 5 and 10 measure achievement points for each such measure in its second year in MIPS.

(ii) *Benchmarks.* Except as provided in paragraphs (b)(1)(ii)(B) through (F) of this section, benchmarks will be based on performance by collection type, from all available sources, including MIPS eligible clinicians and APMs, to the extent feasible, during the applicable baseline or performance period.

(A) Each benchmark must have a minimum of 20 individual clinicians or groups who reported the measure meeting the case minimum requirement at paragraph (b)(1)(iii) of this section and the data completeness requirement at §414.1340 and having a performance rate that is greater than zero.

(B) CMS Web Interface collection type uses benchmarks from the corresponding reporting year of the Shared Savings Program.

(C) Beginning with the 2022 MIPS payment year, for each measure that has a benchmark that CMS determines may have the potential to result in inappropriate treatment, CMS will set benchmarks using a flat percentage for all collection types where the top decile is higher than 90 percent under the methodology at paragraph (b)(1)(ii) of this section.

(D) Beginning with the CY 2023 performance period/2025 MIPS payment year, CMS will calculate a benchmark for an administrative claims quality measure using the performance on the measures during the current performance period.

(E) Beginning with the CY 2025 performance period/2027 MIPS payment year, CMS will publish a list in the FEDERAL REGISTER of topped out measures determined to be impacted by limited measure choice on a yearly basis. Measures included in the list are scored from 1 to 10 measure achievement points according to defined topped out measure benchmarks calculated from performance data in the baseline period in which a performance rate of 97 percent corresponds to 10 percent of the performance threshold for the corresponding performance year.

(F) Beginning in the CY 2025 performance period/2027 MIPS payment year, measures of the Medicare CQM collection type use flat benchmarks for their first two performance periods in MIPS.

(iii) *Minimum case requirements.* Except as otherwise specified in the MIPS final list of quality measures described in §414.1330(a)(1), the minimum case requirement is 20 cases.

(iv) *Topped out measures.* CMS will identify topped out measures in the benchmarks published for each Quality Payment Program year.

(A) For the 2020 MIPS payment year, each topped out measure specified by CMS through rulemaking receives no more than 7 measure achievement points, provided that the benchmark for the applicable collection type is identified as topped out in the benchmarks published for the 2018 MIPS performance period.

(B) Beginning with the 2021 MIPS payment year, except as provided for in paragraph (b)(1)(iv)(C) of this section, each measure (except for measures in the CMS Web Interface) for which the benchmark for the applicable collection type is identified as topped out for 2 or more consecutive years receives no more than 7 measure achievement points in the second consecutive year it is identified as topped out, and beyond.

(C) Beginning with the CY 2025 performance period/2027 MIPS payment year, measures impacted by limited measure choice as specified in paragraph (b)(1)(ii)(E) of this section are not subject to the 7 measure achievement point cap specified in paragraph (b)(1)(iv)(B) of this section.

(v) *Measure bonus points.* MIPS eligible clinicians receive measure bonus points for the following measures, except as otherwise required under § 414.1335, regardless of whether the measure is included in the MIPS eligible clinician's total measure achievement points.

(A) *High priority measures.* Subject to paragraph (b)(1)(v)(A)(*1*) of this section, for the CY 2017 through 2021 MIPS performance periods/2019 through 2023 MIPS payment years, MIPS eligible clinicians receive 2 measure bonus points for each outcome and patient experience measure and 1 measure bonus point for each other high priority measure. Beginning in the 2021 MIPS payment year, MIPS eligible clinicians do not receive such measure bonus points for CMS Web Interface measures. Beginning in the 2022 performance period/2024 MIPS payment year, MIPS eligible clinicians will no longer receive these measure bonus points.

(B) *End-to-end electronic reporting.* Subject to paragraph (b)(1)(v)(B)(*1*) of this section, for the CY 2017 through 2021 MIPS performance periods/2019 through 2023 MIPS payment years, MIPS eligible clinicians receive 1 measure bonus point for each measure (except claims-based measures) submitted with end-to-end electronic reporting for a quality measure under certain criteria determined by the Secretary.

(*1*) *Limitations.* (*i*) For the 2019 through 2023 MIPS payment years, the total measure bonus points for measures submitted with end-to-end electronic reporting cannot exceed 10 percent of the total available measure achievement points.

(*ii*) Beginning with the 2021 MIPS payment year, MIPS eligible clinicians that collect data in accordance with § 414.1325 on a single measure via multiple collection types receive measure bonus points only once.

(*iii*) Beginning in the 2024 MIPS payment year, MIPS eligible clinicians will no longer receive measure bonus for submitting using end-to-end electronic reporting.

(C) *Small practices.* Beginning with the 2021 MIPS payment year, MIPS eligible clinicians in small practices receive 6 measure bonus points if they submit data to MIPS on at least 1 quality measure.

(vi) *Improvement scoring.* Improvement scoring is available to MIPS eligible clinicians that demonstrate improvement in performance in the current MIPS performance period compared to performance in the performance period immediately prior to the current MIPS performance period based on measure achievement points.

(A) Improvement scoring is available when the data sufficiency standard is met, which means when data are available and a MIPS eligible clinician has a quality performance category achievement percent score for the previous performance period and the current performance period.

(*1*) Data must be comparable to meet the requirement of data sufficiency which means that the quality performance category achievement percent score is available for the current performance period and the previous performance period and quality performance category achievement percent scores can be compared.

(*2*) Quality performance category achievement percent scores are comparable when submissions are received from the same identifier for two consecutive performance periods.

(*3*) If the identifier is not the same for 2 consecutive performance periods, then for individual submissions, the comparable quality performance category achievement percent score is the highest available quality performance category achievement percent score associated with the final score from the prior performance period that will be used for payment for the individual. For group, virtual group, and APM Entity submissions, the comparable quality performance category achievement percent score is the average of the quality performance category achievement percent score associated with the final score from the prior performance period that will be used for payment for each of the individuals in the group.

(*4*) Improvement scoring is not available for clinicians who were scored under facility-based measurement in the performance period immediately prior to the current MIPS performance period.

(B) The improvement percent score may not total more than 10 percentage points.

(C) The improvement percent score is assessed at the performance category level for the quality performance category and included in the calculation of the quality performance category score as described in paragraph (b)(1)(vii) of this section.

(*1*) The improvement percent score is awarded based on the rate of increase in the quality performance category achievement percent score of MIPS eligible clinicians from the previous performance period to the current performance period.

(*2*) An improvement percent score is calculated by dividing the increase in the quality performance category achievement percent score from the prior performance period to the current performance period by the prior performance period quality performance category achievement percent score multiplied by 10 percent.

(*3*) An improvement percent score cannot be lower than zero percentage points.

(*4*) Beginning with the CY 2018 performance period/2020 MIPS payment year, we will assume a quality performance category achievement percent score of 30 percent if a MIPS eligible clinician earned a quality performance category score less than or equal to 30 percent in the previous year.

(*5*) The improvement percent score is zero if the MIPS eligible clinician did not fully participate in the quality performance category for the current performance period.

(D) For the purpose of improvement scoring methodology, the term ''quality performance category achievement percent score'' means the total measure achievement points divided by the total available measure achievement points, without consideration of measure bonus points or improvement percent score.

(E) For the purpose of improvement scoring methodology, the term ''improvement percent score'' means the score that represents improvement for the purposes of calculating the quality performance category score as described in paragraph (b)(1)(vii) of this section.

(F) For the purpose of improvement scoring methodology, the term ''fully participate'' means the MIPS eligible clinician met all requirements in §§414.1335 and 414.1340.

(vii) *Quality performance category score.* A MIPS eligible clinician's quality performance category score is the sum of all the measure achievement points assigned for the measures required for the quality performance category criteria plus the measure bonus points in paragraph (b)(1)(v) of this section and Complex Organization Adjustment in paragraph (b)(1)(vii)(C) of this section. The sum is divided by the sum of total available measure achievement points. The improvement percent score in paragraph (b)(1)(vi) of this section is added to that result. The quality performance category score cannot exceed 100 percentage points.

(A) For each measure that is submitted, if applicable, and impacted by significant changes or errors prior to the applicable data submission deadline at §414.1325(e), performance is based on data for 9 consecutive months

of the applicable CY performance period. If such data are not available or CMS determines that they may result in patient harm or misleading results, the measure is excluded from a MIPS eligible clinician's total measure achievement points and total available measure achievement points. For purposes of this paragraph (b)(1)(vii)(A), ''significant changes or errors'' means changes to or errors in a measure that are outside the control of the clinician and its agents and that CMS determines may result in patient harm or misleading results. Significant changes or errors include, but are not limited to, changes to codes (such as ICD–10, CPT, or HCPCS codes) or the active status of codes, the inadvertent omission of codes or inclusion of inactive or inaccurate codes, or changes to clinical guidelines or measure specifications. CMS will publish on the CMS website a list of all measures scored under this paragraph (b)(1)(vii)(A) as soon as technically feasible, but by no later than the data submission deadline at § 414.1325(e)(1).

(B) Beginning with the 2021 MIPS payment year, for groups that submit 5 or fewer measures and register for the CAHPS for MIPS survey but do not meet the minimum beneficiary sampling requirements, the total available measure achievement points are reduced by 10 points.

(C) Beginning in the CY 2025 performance period/2027 MIPS payment year, a Virtual Group and an APM Entity receives one measure achievement point for each eCQM submitted that meets the case minimum requirement at paragraph (b)(1)(iii) of this section and the data completeness requirement at § 414.1340. Each measure may not exceed 10 measure achievement points. The total adjustment to the Virtual Group or APM Entity's quality performance category score under this paragraph (b)(1)(vii)(C) may not exceed 10 percent of the total available measure achievement points.

(2) *Cost performance category*. For each cost measure attributed to a MIPS eligible clinician, the clinician receives one to ten achievement points based on the clinician's performance on the measure during the performance period compared to the measure's benchmark. Achievement points are awarded based on which benchmark range the MIPS eligible clinician's performance on the measure is in. CMS assigns partial points based on where the MIPS eligible clinician's performance falls between the top and bottom of the benchmark ranges.

(i) Cost measure benchmarks are determined by CMS based on cost measure performance during the performance period. At least 20 MIPS eligible clinicians or groups must meet the minimum case volume specified under § 414.1350(c) for a cost measure in order for a benchmark to be determined for the measure. If a benchmark is not determined for a cost measure, the measure will not be scored.

(A) For the 2019 through 2025 MIPS payment years, CMS determines cost measure benchmark ranges based on linear percentile distributions.

(B) Beginning with the 2026 MIPS payment year, for each cost measure, CMS determines 10 benchmark ranges based on the median cost of all MIPS eligible clinicians attributed the measure, plus or minus standard deviations. CMS awards achievement points based on which benchmark range a MIPS eligible clinician's average cost for a cost measure corresponds. Additionally, CMS awards achievement points equivalent to 10 percent of the performance threshold for a MIPS eligible clinician whose average cost attributed under a cost measure is equal to the median cost for all MIPS eligible clinicians attributed the measure.

(ii) A MIPS eligible clinician must meet the minimum case volume specified under § 414.1350(c) to be scored on a cost measure.

(iii) The cost performance category score is the sum of the following, not to exceed 100 percent:

(A) The total number of achievement points earned by the MIPS eligible clinician divided by the total number of available achievement points; and

(B) The cost improvement score, as determined under paragraph (b)(2)(iv) of this section.

(iv) The cost improvement score is determined for a MIPS eligible clinician that demonstrates improvement in performance in the current MIPS performance period compared to their

performance in the immediately preceding MIPS performance period.

(A) The cost improvement score is determined at the category level for the cost performance category.

(B) The cost improvement score is calculated only when data sufficient to measure improvement are available. Sufficient data are available when a MIPS eligible clinician or group participates in MIPS using the same identifier in 2 consecutive performance periods and is scored on the cost performance category for 2 consecutive performance periods. If the cost improvement score cannot be calculated because sufficient data are not available, then the cost improvement score is zero.

(C) The cost improvement score is determined at the category-level by subtracting the cost performance category score from the previous performance period from the cost performance category score from the current performance period, then by dividing the difference by the cost performance category score from the previous performance period, and multiplying the result with the maximum available cost improvement score.

(D) The cost improvement score cannot be lower than zero percentage points.

(E) The maximum cost improvement score for the 2020, 2021, 2022, 2023, and 2024 MIPS payment year is zero percentage points. The maximum cost improvement score beginning with the 2025 MIPS payment year is 1 percentage point.

(v) A cost performance category score is not calculated if a MIPS eligible clinician or group is not attributed any cost measures for the performance period because the clinician or group has not met the minimum case volume specified by CMS for any of the cost measures or a benchmark has not been created for any of the cost measures that would otherwise be attributed to the clinician or group.

(A) Beginning with the 2024 MIPS payment year, if data used to calculate a score for a cost measure are impacted by significant changes during the performance period, such that calculating the cost measure score would lead to misleading or inaccurate results, then the affected cost measure is excluded from the MIPS eligible clinician's or group's cost performance category score. For purposes of this paragraph (b)(2)(v)(A), ''significant changes'' are changes external to the care provided, and that CMS determines may lead to misleading or inaccurate results. Significant changes include, but are not limited to, rapid or unprecedented changes to service utilization, and will be empirically assessed by CMS to determine the extent to which the changes impact the calculation of a cost measure score that reflects clinician performance.

(B) Beginning with the 2026 MIPS payment year, if data used to calculate a score for a cost measure are impacted by significant changes or errors affecting the performance period, such that calculating the cost measure score would lead to misleading or inaccurate results, then the affected cost measure is excluded from the MIPS eligible clinician's or group's cost performance category score. For purposes of this paragraph (b)(2)(v)(B), ''significant changes or errors'' are changes or errors external to the care provided, and that CMS determines may lead to misleading or inaccurate results that negatively impact the measure's ability to reliably assess performance. Significant changes or errors include, but are not limited to, rapid or unprecedented changes to service utilization, the inadvertent omission of codes or inclusion of codes, or changes to clinical guidelines or measure specifications. CMS will empirically assess the affected cost measure to determine the extent to which the changes or errors impact the calculation of a cost measure score such that calculating the cost measure score would lead to misleading or inaccurate results that negatively impact the measure's ability to reliably assess performance.

(3) *Improvement activities performance category.* Subject to paragraphs (b)(3)(i) and (ii) of this section, the improvement activities performance category score equals the total points for all submitted improvement activities divided by 40 points, multiplied by 100 percent. In the CY 2023 through 2024 performance periods/2025 through 2026 MIPS payment years, MIPS eligible

clinicians (except for non-patient facing MIPS eligible clinicians, small practices, and practices located in rural areas and geographic HPSAs) receive 10 points for each medium-weighted improvement activity and 20 points for each high-weighted improvement activity required under § 414.1360 on which data is submitted in accordance with § 414.1325. Non-patient facing MIPS eligible clinicians, small practices, and practices located in rural areas and geographic HPSAs receive 20 points for each medium-weighted improvement activity and 40 points for each high-weighted improvement activity required under § 414.1360 on which data is submitted in accordance with § 414.1325. Beginning in the CY 2025 performance period/2027 MIPS payment year, MIPS eligible clinicians (except for non-patient facing MIPS eligible clinicians, small practices, and practices located in rural areas and geographic HPSAs) receive 20 points for each improvement activity required under § 414.1360 on which data is submitted in accordance with § 414.1325. Non-patient facing MIPS eligible clinicians, small practices, and practices located in rural areas and geographic HPSAs receive 40 points for each improvement activity required under § 414.1360 on which data is submitted in accordance with § 414.1325.

(i) For MIPS eligible clinicians participating in APMs, the improvement activities performance category score is at least 50 percent. MIPS eligible clinicians participating in APMs must attest to having completed an improvement activity or submit data for the quality and Promoting Interoperability performance categories in order to receive such credit.

(ii) For MIPS eligible clinicians in a practice that is certified or recognized as a patient-centered medical home or comparable specialty practice, as determined by the Secretary, the improvement activities performance category score is 100 percent. For the 2019 MIPS payment year, at least one practice site within a group's TIN must be certified or recognized as a patient-centered medical home or comparable specialty practice. For the 2020 MIPS payment year and future years, at least 50 percent of the practice sites within a group's TIN must be recognized as a patient-centered medical home or comparable specialty practice. MIPS eligible clinicians that wish to claim this status for purposes of receiving full credit in the improvement activities performance category must attest to their status as a patient-centered medical home or comparable specialty practice in order to receive this credit. A practice is certified or recognized as a patient-centered medical home if it meets any of the following criteria:

(A) The practice has received accreditation from an accreditation organization that is nationally recognized.

(B) The practice is participating in a Medicaid Medical Home Model or Medical Home Model.

(C) The practice is a comparable specialty practice that has received recognition through a specialty recognition program offered through a nationally recognized accreditation organization; or

(D) The practice has received accreditation from other certifying bodies that have certified a large number of medical organizations and meet national guidelines, as determined by the Secretary. The Secretary must determine that these certifying bodies must have 500 or more certified member practices, and require practices to include the following:

(*1*) Have a personal physician/clinician in a team-based practice.

(*2*) Have a whole-person orientation.

(*3*) Provide coordination or integrated care.

(*4*) Focus on quality and safety.

(*5*) Provide enhanced access.

(4) *Promoting Interoperability performance category.* (i) For the 2019 and 2020 MIPS payment years, a MIPS eligible clinician's Promoting Interoperability performance category score equals the sum of the base score, performance score, and any applicable bonus scores, not to exceed 100 percentage points. A MIPS eligible clinician cannot earn a performance score or bonus score unless they have earned a base score.

(A) A MIPS eligible clinician earns a base score by reporting for each base

score measure, as applicable: The numerator (of at least one) and denominator, or a yes/no statement, or an exclusion.

(B) A MIPS eligible clinician earns a performance score by reporting on the performance score measures specified by CMS. A MIPS eligible clinician may earn up to 10 or 20 percentage points as specified by CMS for each performance score measure reported.

(C) A MIPS eligible clinician may earn the following bonus scores:

(*1*) A bonus score of 5 percentage points for reporting to one or more additional public health agencies or clinical data registries.

(*2*) A bonus score of 10 percentage points for attesting to completing one or more improvement activities specified by CMS using CEHRT.

(*3*) For the 2020 MIPS payment year, a bonus score of 10 percentage points for submitting data for the measures for the base score and the performance score generated solely from CEHRT as defined in §414.1305 for 2019 and subsequent years.

(ii) Beginning with the 2019 performance period/2021 MIPS payment year, a MIPS eligible clinician's Promoting Interoperability performance category score equals the sum of the scores for each of the required measures and any applicable bonus scores, not to exceed 100 points.

(A) A MIPS eligible clinician earns a score for each measure by reporting, as applicable: the numerator (of at least one) and denominator, or a yes/no statement. If an exclusion is reported for a measure, the points available for that measure are redistributed to another measure(s).

(B) For the 2019 performance period/2021 MIPS payment year through the 2022 performance period/2024 MIPS payment year, each required measure is worth 10, 20, or 40 points, as specified by CMS. For the 2023 performance period/2025 MIPS payment year and subsequent years, each required measure is worth 10, 15, 25 or 30 points, as specified by CMS.

(C) For the 2019 performance period/2021 MIPS payment year through the 2022 performance period/2024 MIPS payment year, each optional measure is worth five or ten bonus points, as specified by CMS. For the 2023 performance period/2025 MIPS payment year and subsequent years, each optional measure is worth five bonus points, as specified by CMS.

(c) *Final score calculation*. Each MIPS eligible clinician receives a final score of 0 to 100 points for a performance period for a MIPS payment year calculated as follows. If a MIPS eligible clinician is scored on fewer than 2 performance categories, he or she receives a final score equal to the performance threshold.

TABLE 1 TO PARAGRAPH (c) INTRODUCTORY TEXT

For the 2019 MIPS payment year:

Final score = [(quality performance category score × quality performance category weight) + (cost performance category score × cost performance category weight) + (improvement activities performance category score × improvement activities performance category weight) + (Promoting Interoperability performance category score × Promoting Interoperability performance category weight)], not to exceed 100 points.

For the 2020 MIPS payment year:

Final score = [(quality performance category score × quality performance category weight) + (cost performance category score × cost performance category weight) + (improvement activities performance category score × improvement activities performance category weight) + (Promoting Interoperability performance category score × Promoting Interoperability performance category weight)] × 100 + [the complex patient bonus + the small practice bonus], not to exceed 100 points.

Beginning with the 2021 MIPS payment year:

TABLE 1 TO PARAGRAPH (c) INTRODUCTORY TEXT—Continued

Final score = [(quality performance category score × quality performance category weight) + (cost performance category score × cost performance category weight) + (improvement activities performance category score × improvement activities performance category weight) + (Promoting Interoperability performance category score × Promoting Interoperability performance category weight)] × 100 + the complex patient bonus, not to exceed 100 points.

(1) *Performance category weights.* The weights of the performance categories in the final score are as follows, unless a different scoring weight is assigned under paragraph (c)(2) of this section:

(i) Quality performance category weight is defined under § 414.1330(b).

(ii) Cost performance category weight is defined under § 414.1350(d).

(iii) Improvement activities performance category weight is defined under § 414.1355(b).

(iv) Promoting Interoperability performance category weight is defined under § 414.1375(a).

(2) *Reweighting the performance categories.* (i) In accordance with paragraph (c)(2)(ii) of this section, a scoring weight different from the weights specified in paragraph (c)(1) of this section will be assigned to a performance category, and its weight as specified in paragraph (c)(1) of this section will be redistributed to another performance category or categories, in the following circumstances:

(A) CMS determines based on the following circumstances that there are not sufficient measures and activities applicable and available under section 1848(q)(5)(F) of the Act.

(*1*) For the quality performance category, CMS cannot calculate a score for the MIPS eligible clinician because there is not at least one quality measure applicable and available to the clinician.

(*2*) For the cost performance category, CMS cannot reliably calculate a score for the cost measures that adequately captures and reflects the performance of the MIPS eligible clinician.

(*3*) Beginning with the 2021 MIPS payment year, for the quality, cost, improvement activities, and Promoting Interoperability performance categories, the MIPS eligible clinician joins an existing practice during the final 3 months of the performance period year that is not participating in MIPS as a group or joins a practice that is newly formed during the final 3 months of the performance period year.

(*4*) *For the Promoting Interoperability performance category:*

(*i*) For the 2021 through 2025 MIPS payment years, the MIPS eligible clinician is a physical therapist, occupational therapist, clinical psychologist, qualified audiologist, qualified speech-language pathologist, or a registered dietitian or nutrition professional. In the event that a MIPS eligible clinician submits data for the Promoting Interoperability performance category, the scoring weight specified in paragraph (c)(1) of this section will be applied and its weight will not be redistributed.

(*ii*) For the 2019 through 2024 MIPS payment years, the MIPS eligible clinician is a nurse practitioner, physician assistant, clinical nurse specialist, or certified registered nurse anesthetist. In the event that a MIPS eligible clinician submits data for the Promoting Interoperability performance category, the scoring weight specified in paragraph (c)(1) of this section will be applied and its weight will not be redistributed.

(*iii*) For the 2024 through 2026 MIPS payment years, the MIPS eligible clinician is a clinical social worker. In the event that a MIPS eligible clinician submits data for the Promoting Interoperability performance category, the scoring weight specified in paragraph (c)(1) of this section will be applied and its weight will not be distributed.

(*5*) [Reserved]

(*6*) Beginning with the 2020 MIPS payment year, for the quality, cost, and improvement activities performance categories, the MIPS eligible clinician demonstrates through an application submitted to CMS that they

were subject to extreme and uncontrollable circumstances that prevented the clinician from collecting information that the clinician would submit for a performance category or submitting information that would be used to score a performance category for an extended period of time. Beginning with the 2021 MIPS payment year, in the event that a MIPS eligible clinician submits data for the quality, cost, or improvement activities performance categories, the scoring weight specified in paragraph (c)(1) of this section will be applied and its weight will not be redistributed, unless an exception applies. Exception: for the 2021 MIPS payment year only, if a MIPS eligible clinician demonstrates through an application submitted to CMS that they have been adversely affected by the Public Health Emergency for the COVID–19 pandemic and also submits data for the quality, cost, or improvement activities performance categories, the preceding sentence will not apply.

(*7*) For the 2019 MIPS payment year, for the quality and improvement activities performance categories, the MIPS eligible clinician was located in an area affected by extreme and uncontrollable circumstances as identified by CMS. In the event that a MIPS eligible clinician submits data for a performance category, the scoring weight specified in paragraph (c)(1) of this section will be applied and its weight will not be redistributed.

(*8*) Beginning with the 2020 MIPS payment year, for the quality, cost, and improvement activities performance categories, the MIPS eligible clinician was located in an area affected by extreme and uncontrollable circumstances as identified by CMS. In the event that a MIPS eligible clinician submits data for the quality or improvement activities performance categories, the scoring weight specified in paragraph (c)(1) of this section will be applied and its weight will not be redistributed.

(*9*) Beginning with the 2020 MIPS payment year, for the quality, cost, and improvement activities performance categories, CMS determines, based on information known to the agency prior to the beginning of the relevant MIPS payment year, that data for a MIPS eligible clinician are inaccurate, unusable or otherwise compromised due to circumstances outside of the control of the clinician and its agents.

(*10*) Beginning with the 2026 MIPS payment year, for the quality and improvement activities performance categories, CMS determines, based on documentation provided to the agency on or before November 1st of the year preceding the relevant MIPS payment year, that data for a MIPS eligible clinician are inaccessible or unable to be submitted due to circumstances outside of the control of the clinician because the MIPS eligible clinician delegated submission of the data to their third party intermediary, evidenced by a written agreement between the MIPS eligible clinician and third party intermediary, and the third party intermediary did not submit the data for the performance category(ies) on behalf of the MIPS eligible clinician in accordance with applicable deadlines. To determine whether to apply reweighting to the affected performance category(ies), CMS will consider: whether the MIPS eligible clinician knew or had reason to know of the issue with its third party intermediary's submission of the clinician's data for the performance category(ies); whether the MIPS eligible clinician took reasonable efforts to correct the issue; and whether the issue between the MIPS eligible clinician and their third party intermediary caused no data to be submitted for the performance category(ies) in accordance with applicable deadlines.

(B) Under section 1848(q)(5)(E)(ii) of the Act, CMS estimates that the proportion of MIPS eligible clinicians who are physicians as defined in section 1861(r) of the Act and earn a Promoting Interoperability performance category score of at least 75 percent is 75 percent or greater. The estimation is based on data from the performance period that occurs four years before the MIPS payment year and does not include physicians for whom the Promoting Interoperability performance category is weighted at zero percent.

(C) Under section 1848(o)(2)(D) of the Act, a significant hardship exception or other type of exception is granted to a

MIPS eligible clinician based on the following circumstances for the Promoting Interoperability performance category. Except as provided in paragraphs (c)(2)(i)(C)(*10*) and (*11*) of this section, in the event that a MIPS eligible clinician submits data for the Promoting Interoperability performance category, the scoring weight specified in paragraph (c)(1) of this section will be applied and its weight will not be redistributed.

(*1*) The MIPS eligible clinician demonstrates through an application submitted to CMS that they lacked sufficient internet access during the performance period, and insurmountable barriers prevented the clinician from obtaining sufficient internet access.

(*2*) The MIPS eligible clinician demonstrates through an application submitted to CMS that they were subject to extreme and uncontrollable circumstances that caused their CEHRT to be unavailable.

(*3*) The MIPS eligible clinician was located in an area affected by extreme and uncontrollable circumstances as identified by CMS.

(*4*) The MIPS eligible clinician demonstrates through an application submitted to CMS that 50 percent or more of their outpatient encounters occurred in practice locations where they had no control over the availability of CEHRT.

(*5*) The MIPS eligible clinician is a non-patient facing MIPS eligible clinician as defined in § 414.1305.

(*6*) The MIPS eligible clinician is a hospital-based MIPS eligible clinician as defined in § 414.1305.

(*7*) The MIPS eligible clinician is an ASC-based MIPS eligible clinician as defined in § 414.1305.

(*8*) Beginning with the 2020 MIPS payment year, the MIPS eligible clinician demonstrates through an application submitted to CMS that their CEHRT was decertified either during the performance period for the MIPS payment year or during the calendar year preceding the performance period for the MIPS payment year, and the MIPS eligible clinician made a good faith effort to adopt and implement another CEHRT in advance of the performance period. In no case may a MIPS eligible clinician be granted this exception for more than 5 years.

(*9*) For the 2020 MIPS payment year through the 2023 MIPS payment year the MIPS eligible clinician demonstrates through an application submitted to CMS that they are in a small practice as defined in § 414.1305, and overwhelming barriers prevent them from complying with the requirements for the Promoting Interoperability performance category. Beginning with the 2024 MIPS payment year the MIPS eligible clinician is in a small practice as defined in § 414.1305.

(*10*) Beginning with the 2020 MIPS payment year, CMS determines, based on information known to the agency prior to the beginning of the relevant MIPS payment year, that data for a MIPS eligible clinician are inaccurate, unusable or otherwise compromised due to circumstances outside of the control of the clinician and its agents.

(*11*) For the 2021 MIPS payment year only, the MIPS eligible clinician demonstrates through an application submitted to CMS that they have been adversely affected by the Public Health Emergency for the COVID–19 pandemic.

(*12*) Beginning with the 2026 MIPS payment year, CMS determines, based on documentation provided to the agency on or before November 1st of the year preceding the relevant MIPS payment year, that data for a MIPS eligible clinician are inaccessible or unable to be submitted due to circumstances outside of the control of the clinician because the MIPS eligible clinician delegated submission of the data to their third party intermediary, evidenced by a written agreement between the MIPS eligible clinician and third party intermediary, and the third party intermediary did not submit the data for the performance category on behalf of the MIPS eligible clinician in accordance with applicable deadlines. To determine whether to apply reweighting to the Promoting Interoperability performance category, CMS will consider: whether the MIPS eligible clinician knew or had reason to know of the issue with its third party intermediary's submission of the clinician's data for the performance category; whether the MIPS eligible clinician took reasonable efforts to correct

the issue; and whether the issue between the MIPS eligible clinician and their third party intermediary caused no data to be submitted for the performance category in accordance with applicable deadlines.

(ii) A scoring weight different from the weights specified in paragraph (c)(1) of this section will be assigned to a performance category, and its weight as specified in paragraph (c)(1) of this section will be redistributed to another performance category or categories, as follows:

(A) For the 2019 MIPS payment year:

TABLE 2 TO PARAGRAPH (c)(2)(ii)(A)

Performance category (%)	Weighting for the 2019 MIPS payment year (%)	Reweight scenario if no promoting interoperability performance category score (%)	Reweight scenario if no quality performance category score (%)	Reweight scenario if no improvement activities performance category score (%)
Quality	60	85	0	75
Cost	0	0	0	0
Improvement Activities	15	15	50	0
Promoting Interoperability	25	0	50	25

(B) For the 2020 MIPS payment year:

Reweighting scenario	Quality (%)	Cost (%)	Improvement activities (%)	Promoting interoperability (%)
No Reweighting Needed:				
—Scores for all four performance categories	50	10	15	25
Reweight One Performance Category:				
—No Cost	60	0	15	25
—No Promoting Interoperability	75	10	15	0
—No Quality	0	10	45	45
—No Improvement Activities	65	10	0	25
Reweight Two Performance Categories:				
—No Cost and no Promoting Interoperability	85	0	15	0
—No Cost and no Quality	0	0	50	50
—No Cost and no Improvement Activities	75	0	0	25
—No Promoting Interoperability and no Quality	0	10	90	0
—No Promoting Interoperability and no Improvement Activities	90	10	0	0
—No Quality and no Improvement Activities	0	10	0	90

(C) For the 2021 MIPS payment year:

Reweighting scenario	Quality (%)	Cost (%)	Improvement activities (%)	Promoting interoperability (%)
No Reweighting Needed:				
—Scores for all four performance categories	45	15	15	25
Reweight One Performance Category:				
—No Cost	60	0	15	25
—No Promoting Interoperability	70	15	15	0
—No Quality	0	15	40	45
—No Improvement Activities	60	15	0	25
Reweight Two Performance Categories:				
—No Cost and no Promoting Interoperability	85	0	15	0
—No Cost and no Quality	0	0	50	50
—No Cost and no Improvement Activities	75	0	0	25
—No Promoting Interoperability and no Quality	0	15	85	0
—No Promoting Interoperability and no Improvement Activities	85	15	0	0
—No Quality and no Improvement Activities	0	15	0	85

(D) For the 2022 MIPS payment year:

Reweighting scenario	Quality (%)	Cost (%)	Improvement activities (%)	Promoting interoperability (%)
No Reweighting Needed:				
Scores for all four performance categories	45	15	15	25
Reweight One Performance Category:				
No Cost	55	0	15	30
No Promoting Interoperability	70	15	15	0
No Quality	0	15	15	70
No Improvement Activities	60	15	0	25
Reweight Two Performance Categories:				
No Cost and no Promoting Interoperability	85	0	15	0
No Cost and no Quality	0	0	15	85
No Cost and no Improvement Activities	70	0	0	30
No Promoting Interoperability and no Quality	0	50	50	0
No Promoting Interoperability and no Improvement Activities	85	15	0	0
No Quality and no Improvement Activities	0	15	0	85

(E) For the 2023 MIPS payment year:

TABLE 6 TO PARAGRAPH (c)(2)(ii)(E)

Reweighting scenario	Quality (%)	Cost (%)	Improvement activities (%)	Promoting Interoperability (%)
No Reweighting Needed:				
Scores for all four performance categories	40	20	15	25
No Cost	55	0	15	30
No Promoting Interoperability	65	20	15	0
No Quality	0	20	15	65
No Improvement Activities	55	20	0	25
No Cost and no Promoting Interoperability	85	0	15	0
No Cost and no Quality	0	0	15	85
No Cost and no Improvement Activities	70	0	0	30
No Promoting Interoperability and no Quality	0	50	50	0
No Promoting Interoperability and no Improvement Activities	80	20	0	0
No Quality and no Improvement Activities	0	20	0	80

(F) Except as provided in paragraph (c)(2)(ii)(G) of this section, beginning with the 2024 MIPS payment year:

TABLE 7 TO PARAGRAPH (c)(2)(ii)(F)

Reweighting scenario	Quality (%)	Cost (%)	Improvement activities (%)	Promoting interoperability (%)
No Reweighting Needed:				
Scores for all four performance categories	30	30	15	25
No Cost	55	0	15	30
No Promoting Interoperability	55	30	15	0
No Quality	0	30	15	55
No Improvement Activities	45	30	0	25
No Cost and no Promoting Interoperability	85	0	15	0
No Cost and no Quality	0	0	15	85
No Cost and no Improvement Activities	70	0	0	30
No Promoting Interoperability and no Quality	0	50	50	0
No Promoting Interoperability and no Improvement Activities	70	30	0	0
No Quality and no Improvement Activities	0	30	0	70

(G) For small practices beginning with the 2024 MIPS payment year:

TABLE 8 TO PARAGRAPH (c)(2)(ii)(G)

Reweighting scenario	Quality (%)	Cost (%)	Improvement activities (%)	Promoting interoperability (%)
No Reweighting Needed:				
Scores for all four performance categories	30	30	15	25
No Cost	55	0	15	30
No Promoting Interoperability	40	30	30	0
No Quality	0	30	15	55
No Improvement Activities	45	30	0	25
No Cost and no Promoting Interoperability	50	0	50	0
No Cost and no Quality	0	0	15	85
No Cost and no Improvement Activities	70	0	0	30
No Promoting Interoperability and no Quality	0	50	50	0
No Promoting Interoperability and no Improvement Activities	70	30	0	0
No Quality and no Improvement Activities	0	30	0	70

(iii) For the Promoting Interoperability performance category to be reweighted in accordance with paragraph (c)(2)(ii) of this section for a MIPS eligible clinician who elects to participate in MIPS as part of a group or virtual group, all of the MIPS eligible clinicians in the group or virtual group must qualify for reweighting based on the circumstances described in paragraph (c)(2)(i) of this section, or the group or virtual group must meet the definition of a hospital-based MIPS eligible clinician or a non-patient facing MIPS eligible clinician as defined in §414.1305.

(iv) If CMS has granted an application for a hardship exception or any other type of exception to a MIPS eligible clinician under paragraph (c)(2)(i)(A)(*6*) or (c)(2)(i)(C)(*2*) of this section, or has identified a MIPS eligible clinician in a CMS-designated region as being affected by an automatic extreme and uncontrollable circumstances event under paragraph (c)(2)(i)(A)(*8*) or (c)(2)(i)(C)(*3*) of this section, CMS will not apply the improvement activities score described in paragraph (b)(3)(i) of this section to the MIPS eligible clinician's score.

(3) *Complex patient bonus.* For the CY 2020, 2021, 2022, and 2023 MIPS payment years and associated performance periods, provided that a MIPS eligible clinician, group, virtual group or APM Entity submits data for at least one MIPS performance category for the applicable performance period for the MIPS payment year, a complex patient bonus will be added to the final score for the MIPS payment year, as stated in paragraphs (c)(3)(i) through (iv) of this section. For the CY 2022 MIPS performance period/CY 2024 MIPS payment year, provided that a MIPS eligible clinician, group, subgroup, virtual group or APM Entity submits data for at least one MIPS performance category for the applicable performance period for the MIPS payment year, a complex patient bonus will be added to the final score for the MIPS payment year, if applicable, as described in paragraphs (c)(3)(v) through (viii) of this section. Beginning with the CY 2023 MIPS performance period/CY 2025 MIPS payment year, provided that a MIPS eligible clinician, group, subgroup, virtual group or APM Entity submits data for at least one MIPS performance category for the applicable performance period for the MIPS payment year, or is a facility-based MIPS eligible clinician, a complex patient bonus will be added to the final score for the MIPS payment year, if applicable, as described in paragraphs (c)(3)(v) through (viii) of this section.

(i) For the CY 2020, 2021, 2022, and 2023 MIPS payment years and associated performance periods, for MIPS eligible clinicians and groups, the complex patient bonus is calculated as follows: [The average HCC risk score assigned to beneficiaries (pursuant to the HCC risk adjustment model established by CMS pursuant to section 1853(a)(1) of

the Act) seen by the MIPS eligible clinician or seen by clinicians in a group] + [the dual eligible ratio × 5].

(ii) For the CY 2020, 2021, 2022, and 2023 MIPS payment years and associated performance periods, for APM Entities and virtual groups, the complex patient bonus is calculated as follows: [The beneficiary weighted average HCC risk score for all MIPS eligible clinicians, and if technically feasible, TINs for models and virtual groups which rely on complete TIN participation within the APM Entity or virtual group, respectively] + [the average dual eligible ratio for all MIPS eligible clinicians, and if technically feasible, TINs for models and virtual groups which rely on complete TIN participation, within the APM Entity or virtual group, respectively, × 5].

(iii) For the 2020, 2021, 2022, and 2023 MIPS payment years and associated performance periods, the complex patient bonus cannot exceed 5.0 except as provided in paragraph (c)(3)(iv) of this section.

(iv) For the 2022 and 2023 MIPS payment years and associated performance periods, the complex patient bonus is calculated pursuant to paragraphs (c)(3)(i) and (ii) of this section, and the resulting numerical value is then multiplied by 2.0. The complex patient bonus cannot exceed 10.0.

(v) Beginning with the CY 2022 MIPS performance period/CY 2024 MIPS payment year, the complex patient bonus is limited to MIPS eligible clinicians, groups, APM Entities and virtual groups; with a risk indicator at or above the risk indicator calculated median. To determine the median for the respective risk indicator (HCC and dual proportion), risk indicators associated with the final score assigned to a clinician from the most recent prior performance period, for all those who have submitted data for at least one MIPS performance category or are facility-based, are used.

(vi) Beginning with the CY 2022 MIPS performance period/CY 2024 MIPS payment year, for MIPS eligible clinicians and groups, the complex patient bonus components are calculated as follows for the specific risk indicators: Medical complex patient bonus component = 1.5 + 4 * associated HCC standardized score calculated with the average HCC risk score assigned to beneficiaries (pursuant to the HCC risk adjustment model established by CMS pursuant to section 1853(a)(1) of the Act) seen by the MIPS eligible clinician or seen by clinicians in a group or subgroup; social complex patient bonus component = 1.5 + 4 * associated dual proportion standardized score. The components are added together to calculate one overall complex patient bonus. A standardized score for each risk indicator is determined based on the mean and standard deviation of the raw risk indicator score and provides a standardized measurement of how far each risk score is from the mean: (raw risk indicator score − risk indicator mean)/risk indicator standard deviation.

(vii) Beginning with the CY 2022 MIPS performance period/CY 2024 MIPS payment year, for APM Entities and virtual groups, the complex patient bonus components are calculated as follows for the specific risk indicators: Medical complex patient bonus component = 1.5 + 4 * the beneficiary weighted average HCC risk standardized score for all MIPS eligible clinicians, and if technically feasible, TINs for models and virtual groups which rely on complete TIN participation within the APM Entity or virtual group, respectively; social complex patient bonus component = 1.5 + 4 * the average dual proportion standardized score for all MIPS eligible clinicians, and if technically feasible, TINs for models and virtual groups which rely on complete TIN participation, within the APM Entity or virtual group, respectively. The components are added together to calculate one overall complex patient bonus. A standardized score for each risk indicator is determined based on the mean and standard deviation of the raw risk indicator score and provides a standardized measurement of how far each risk score is from the mean: (raw risk indicator score − risk indicator mean)/risk indicator standard deviation.

(viii) Beginning with the CY 2022 MIPS performance period/CY 2024 MIPS payment year, the complex patient bonus cannot exceed 10.0 and cannot be below 0.0.

(4) *Small practice bonus.* A small practice bonus of 5 points will be added to the final score for the 2020 MIPS payment year for MIPS eligible clinicians, groups, virtual groups, and APM Entities that meet the definition of a small practice as defined at §414.1305 and participate in MIPS by submitting data on at least one performance category in the 2018 MIPS performance period.

(d) *Scoring for APM Entities.* MIPS eligible clinicians in APM Entities that are subject to the APM scoring standard are scored using the methodology under §414.1370.

(e) *Scoring for facility-based measurement.* For the payment in 2021 MIPS payment year and subsequent years and subject to paragraph (e)(6)(vi) of this section, a MIPS eligible clinician or group will be scored under the quality and cost performance categories using the methodology described in this paragraph (e).

(1) *General.* The facility-based measurement scoring standard is the MIPS scoring methodology applicable for MIPS eligible clinicians identified as meeting the requirements in paragraph (e)(2) of this section.

(i) The measures used for facility-based measurement are the measure set finalized for the fiscal year value-based purchasing program for which payment begins during the applicable MIPS performance period.

(ii) Beginning with the 2021 MIPS payment year, the scoring methodology applicable for MIPS eligible clinicians scored with facility-based measurement is the Total Performance Score methodology adopted for the Hospital VBP Program, for the fiscal year for which payment begins during the applicable MIPS performance period.

(2) *Eligibility for facility-based measurement.* A MIPS eligible clinician is eligible for facility-based measurement for a MIPS payment year if CMS determines the MIPS eligible clinician to be facility-based as an individual clinician or as part of a group, or beginning with the 2023 performance period/2025 MIPS payment year, a virtual group, as follows:

(i) *Facility-based individual determination.* A MIPS eligible clinician is facility-based if the clinician meets all of the following criteria:

(A) Furnishes 75 percent or more of his or her covered professional services in sites of service identified by the place of service codes used in the HIPAA standard transaction as an inpatient hospital, on-campus outpatient hospital, or emergency room setting based on claims for a 12-month segment beginning on October 1 of the calendar year 2 years prior to the applicable performance period and ending on September 30 of the calendar year preceding the performance period with a 30-day claims run out.

(B) Furnishes at least 1 covered professional service in sites of service identified by the place of service codes used in the HIPAA standard transaction as an inpatient hospital, or emergency room setting.

(C) Can be assigned, under the methodology specified in paragraph (e)(5) of this section, to a facility with a value-based purchasing score for the applicable period.

(ii) *Facility-based MIPS eligible group determination.* A facility-based MIPS eligible group is a group in which 75 percent or more of its eligible clinician NPIs billing under the group's TIN meet the requirements under paragraph (e)(2)(i) of this section.

(3) [Reserved]

(4) *Data submission for facility-based measurement.* There are no data submission requirements for a MIPS eligible individual clinician to be scored under facility-based measurement. A MIPS eligible group must submit data in the improvement activities or Promoting Interoperability performance categories in order to be scored as a facility-based MIPS eligible group.

(5) *Determination of applicable facility score.*

(i) A facility-based MIPS eligible clinician is scored with facility-based measurement using the score derived from the value-based purchasing score for the facility at which the clinician provided services to the most Medicare beneficiaries during the period the claims are drawn from in paragraph (e)(2) of this section. If there is an equal number of Medicare beneficiaries treated at more than one facility, the

value-based purchasing score for the highest scoring facility is used.

(ii) A facility-based MIPS eligible group is scored with facility-based measurement using the score derived from the value-based purchasing score for the facility at which the plurality of clinicians identified as facility-based would have had their score determined under paragraph (e)(5)(i) of this section.

(6) *MIPS performance category scoring under the facility-based measurement scoring standard*—(i) *Measures.* The quality and cost measures are those adopted under the value-based purchasing program of the facility for the year described in paragraph (e)(1)(i) of this section.

(ii) *Benchmarks.* The benchmarks are those adopted under the value-based purchasing program of the facility program for the year described in paragraph (e)(1) of this section.

(iii) *Performance period.* The performance period for facility-based measurement is the performance period for the measures adopted under the value-based purchasing program of the facility program for the year described in paragraph (e)(1) of this section.

(iv) *Quality.* The quality performance category score is established by determining the percentile performance of the facility in the value-based purchasing program for the specified year as described in paragraph (e)(1) of this section and awarding a score associated with that same percentile performance in the MIPS quality performance category score for those MIPS-eligible clinicians who are not eligible to be scored using facility-based measurement for the MIPS payment year. A MIPS eligible clinician or group receiving a facility-based performance score will not earn improvement points based on prior performance in the MIPS quality performance category.

(v) *Cost.* The cost performance category score is established by determining the percentile performance of the facility in the value-based purchasing program for the specified year as described in paragraph (e)(1) of this section and awarding a score associated with that same percentile performance in the MIPS cost performance category score for those MIPS eligible clinicians who are not eligible to be scored using facility-based measurement for the MIPS payment year. A MIPS eligible clinician or MIPS eligible group receiving a facility-based performance score will not earn improvement points based on prior performance in the MIPS cost performance category.

(A) Other cost measures. MIPS eligible clinicians who are scored under facility-based measurement are not scored on cost measures described in paragraph (b)(2) of this section.

(B) [Reserved]

(vi) *Use of score from facility-based measurement.* The MIPS quality and cost performance category scores will be based on the facility-based measurement scoring methodology described in paragraph (e)(6) of this section unless:

(A) For the CY 2019 MIPS performance period/2021 MIPS payment year, through the CY 2021 MIPS performance period/2023 MIPS payment year, a MIPS eligible clinician or group receives a higher combined MIPS quality and cost performance category score through another MIPS submission.

(B) Beginning with the CY 2022 MIPS performance period/2024 MIPS payment year, a MIPS eligible clinician or group receives a higher MIPS final score through another MIPS submission.

[83 FR 60081, Nov. 23, 2018, as amended at 84 FR 63196, Nov. 15, 2019; 85 FR 19287, Apr. 6, 2020; 85 FR 85031, Dec. 28, 2020; 86 FR 65673, Nov. 19, 2021; 86 FR 73159, Dec. 27, 2021; 87 FR 7747, Feb. 10, 2022; 87 FR 70228, Nov. 18, 2022; 88 FR 15921, Mar. 15, 2023; 88 FR 79535, Nov. 16, 2023; 89 FR 98562, Dec. 9, 2024]

§ 414.1385 Targeted review and review limitations.

(a) *Targeted review.* A MIPS eligible clinician, virtual group, subgroup, or group; may request a targeted review of the calculation of the MIPS payment adjustment factor under section 1848(q)(6)(A) of the Act and, as applicable, the calculation of the additional MIPS payment adjustment factor under section 1848(q)(6)(C) of the Act (collectively referred to as the MIPS payment adjustment factors) applicable to such MIPS eligible clinician or group for a year. The process for targeted review is as follows:

(1) A MIPS eligible clinician, virtual group, subgroup, or group; (including their designated support staff), or a third party intermediary as defined at §414.1305, may submit a request for a targeted review.

(2) All requests for targeted review must be submitted during the targeted review request submission period, which begins on the day CMS makes available the MIPS final score, and ends 30 days after publication of the MIPS payment adjustment factors for the MIPS payment year. The targeted review request submission period may be extended as specified by CMS.

(3) A request for a targeted review may be denied if the request is duplicative of another request for a targeted review; the request is not submitted during the targeted review request submission period; or the request is outside of the scope of the targeted review, which is limited to the calculation of the MIPS payment adjustment factors applicable to the MIPS eligible clinician, virtual group, subgroup, or group; for a year. If the targeted review request is denied, there will be no change to the MIPS final score or associated MIPS payment adjustment factors for the MIPS eligible clinician, virtual group, subgroup, or group. If the targeted review request is approved, the MIPS final score and associated MIPS payment adjustment factors may be revised, if applicable, for the MIPS eligible clinician, virtual group, subgroup, or group.

(4) CMS will respond to each request for a targeted review timely submitted and determine whether a targeted review is warranted.

(5) A request for a targeted review may include additional information in support of the request at the time it is submitted. If CMS requests additional information from the MIPS eligible clinician, virtual group, subgroup. or group that is the subject of a request for a targeted review, the information must be provided and received by CMS within 15 days of CMS' request. Non-responsiveness to CMS' request for additional information may result in a final decision based on the information available, although another non-duplicative request for targeted review may be submitted before the end of the targeted review request submission period.

(6) If a request for a targeted review is approved, CMS may recalculate, to the extent feasible and applicable, the scores of a MIPS eligible clinician, virtual group, subgroup, or group with regard to measures, activities, performance categories, and the final score, as well as the MIPS payment adjustment factors.

(7) Decisions based on the targeted review are final, and there is no further review or appeal. CMS will notify the individual or entity that submitted the request for a targeted review of the final decision.

(8) Documentation submitted for a targeted review must be retained by the submitter for 6 years from the end of the MIPS performance period.

(b) *Limitations on review.* Except as specified in paragraph (a)(4) of this section, there is no administrative or judicial review under section 1869 or 1879 of the Act, or otherwise of—

(1) The methodology used to determine the amount of the MIPS payment adjustment factor and the amount of the additional MIPS payment adjustment factor and the determination of such amounts;

(2) The establishment of the performance standards and the performance period;

(3) The identification of measures and activities specified for a MIPS performance category and information made public or posted on the Physician Compare Internet Web site of the CMS; and

(4) The methodology developed that is used to calculate performance scores and the calculation of such scores, including the weighting of measures and activities under such methodology.

[81 FR 77537, Nov. 4, 2016, as amended at 84 FR 63197, Nov. 15, 2019; 88 FR 79536, Nov. 16, 2023]

§414.1390 Data validation and auditing.

(a) *General.* CMS will selectively audit MIPS eligible clinicians and groups on a yearly basis. If a MIPS eligible clinician or group is selected for audit, the MIPS eligible clinician or

group will be required to do the following in accordance with applicable law and timelines CMS establishes:

(1) Comply with data sharing requests, providing all data as requested by CMS or our designated entity. All data must be shared with CMS or our designated entity within 45 days of the data sharing request, or an alternate timeframe that is agreed to by CMS and the MIPS eligible clinician or group. Data will be submitted via email, facsimile, or an electronic method via a secure Web site maintained by CMS.

(2) Provide substantive, primary source documents as requested. These documents may include: Copies of claims, medical records for applicable patients, or other resources used in the data calculations for MIPS measures, objectives, and activities. Primary source documentation also may include verification of records for Medicare and non-Medicare beneficiaries where applicable.

(b) *Certification*. All MIPS eligible clinicians and groups that submit data and information to CMS for purposes of MIPS must certify to the best of their knowledge that the data submitted to CMS is true, accurate, and complete. Such certification must accompany the submission and be made at the time of submission.

(c) *Reopening*. CMS may reopen and revise a MIPS payment adjustment in accordance with the rules set forth at §§ 405.980 through 405.986 of this chapter.

(d) *Record retention*. All MIPS eligible clinicians and groups that submit data and information to CMS for purposes of MIPS must retain such data and information for 6 years from the end of the MIPS performance period.

[81 FR 77537, Nov. 4, 2016, as amended at 82 FR 53959, Nov. 16, 2017]

§ 414.1395 Public reporting.

(a) *General*. (1) CMS posts on Physician Compare, in an easily understandable format, the following:

(i) Information regarding the performance of MIPS eligible clinicians, including, but not limited to, final scores and performance category scores for each MIPS eligible clinician; and

(ii) The names of eligible clinicians in Advanced APMs and, to the extent feasible, the names and performance of such Advanced APMs.

(2) CMS periodically posts on Physician Compare aggregate information on the MIPS, including the range of final scores for all MIPS eligible clinicians and the range of the performance of all MIPS eligible clinicians with respect to each performance category.

(3) The information made available under this section will indicate, where appropriate, that publicized information may not be representative of an eligible clinician's entire patient population, the variety of services furnished by the eligible clinician, or the health conditions of individuals treated.

(b) *Maintain existing public reporting standards*. With the exception of data that must be mandatorily reported on Physician Compare, for each program year, CMS relies on established public reporting standards to guide the information available for inclusion on Physician Compare. The public reporting standards require data included on Physician Compare to be statistically valid, reliable, and accurate; comparable across collection types; and meet the reliability threshold. And, to be included on the public facing profile pages, the data must also resonate with website users, as determined by CMS.

(c) *New measures and activities*. (1) CMS does not publicly report any data on new quality or cost measure for the first 2 years in which it is in the program, after which CMS evaluates the measure to determine whether it is suitable for public reporting under paragraph (b) of this section.

(2) CMS does not publicly report any MVP data on new improvement activity or Promoting Interoperability measure, objective, or activity included in an MVP for the first year in which it is included in the MVP.

(d) *30-day preview period*. For each program year, CMS provides a 30-day preview period for any clinician or group with Quality Payment Program data before the data are publicly reported on Physician Compare.

[82 FR 53959, Nov. 16, 2017, as amended at 83 FR 60087, Nov. 23, 2018; 84 FR 63198, Nov. 15, 2019; 86 FR 65677, Nov. 19, 2021]

§414.1400 Third party intermediaries.

(a) *General.* (1) MIPS data may be submitted on behalf of a MIPS eligible clinician, group, virtual group, subgroup, or APM Entity by any of the following third party intermediaries:

(i) QCDR;

(ii) Qualified registry;

(iii) Before the CY 2025 performance period/2027 payment year, Health IT vendor;

(iv) CMS-approved survey vendor.

(2) Third party intermediary approval criteria—

(i) To be approved as a third party intermediary, an organization must meet the following requirements:

(A) The organization's principal place of business and the location in which it stores data must be in the U.S.

(B) The organization must have the ability to indicate the source of any data it will submit to CMS if the data will be derived from CEHRT, a QCDR, qualified registry, or health IT vendor.

(C) The organization must certify that it intends to provide services throughout the entire performance period and applicable data submission period.

(ii) The determination of whether to approve an entity as a third party intermediary for a MIPS payment year may take into account:

(A) Whether the organization failed to comply with the requirements of this section for any prior MIPS payment year for which it was approved as third party intermediary, including past compliance; and

(B) Whether the entity provided inaccurate information regarding the requirements of this subpart to any eligible clinician.

(iii) Beginning with the 2023 MIPS payment year, third party intermediaries must attend and complete training and support sessions in the form and manner, and at the times, specified by CMS.

(3) For third-party intermediary program requirements:

(i) All data submitted to CMS by a third party intermediary on behalf of a MIPS eligible clinician, group, virtual group, subgroup, or APM Entity must be certified by the third party intermediary as true, accurate, and complete to the best of its knowledge. Such certification must be made in a form and manner and at such time as specified by CMS.

(ii) All data submitted to CMS by a third party intermediary must be submitted in the form and manner specified by CMS.

(A) The submission of data on measures by a third party intermediary to CMS must include data on all of the MIPS eligible clinician's patients, regardless of payer, unless otherwise specified by the collection type.

(B) [Reserved]

(iii) If the clinician chooses to opt-in to participate in MIPS in accordance with §414.130, the third party intermediary must be able to transmit that decision to CMS.

(iv) Prior to discontinuing services to any MIPS eligible clinician, group, virtual group, subgroup, or APM Entity during a performance period, a third party intermediary must support the transition of such MIPS eligible clinician, group, virtual group, subgroup, or APM Entity to an alternate third party intermediary, submitter type, or, for any measure on which data has been collected, collection type according to a CMS approved transition plan by a date specified by CMS. The transition plan must address the following issues, unless different or additional information is specified by CMS:

(A) The issues that contributed to the withdrawal mid-performance period or discontinuation of services mid-performance period.

(B) Impacted entities:

(*1*) The number of clinicians, groups, virtual groups, subgroups or APM entities (inclusive of MIPS eligible, opt-in and voluntary participants) that would need to find another way to report.

(*2*) As applicable, identify any QCDRs that were granted licenses to QCDR measures which would no longer be available for reporting due to the transition.

(C) The steps the third party intermediary will take to ensure that the clinicians, groups, virtual groups, subgroups, or APM Entities identified in paragraph (a)(3)(iv)(B)(1) of this section are notified of the transition in a timely manner, and successfully transitioned to an alternate third party intermediary, submitter type, or,

for any measure or activity on which data has been collected, collection type, as applicable.

(D) A detailed timeline that outlines timing for communications, the start of the transition, and completion of the transition of these clinicians, groups, virtual groups, subgroups, or APM Entities.

(E) The third party intermediary must communicate to CMS that the transition was completed by the date included in the detailed timeline.

(v) As a condition of its qualification and approval to participate in MIPS as a third party intermediary, a third party intermediary must:

(A) Make available to CMS the contact information of each MIPS eligible clinician, group, virtual group, subgroup, or APM Entity on behalf of whom it submits data. The contact information must include, at a minimum, the MIPS eligible clinician, group, virtual group, subgroup, or APM Entity phone number, address, and, if available, email.

(B) Retain all data submitted to CMS for purposes of MIPS for 6 years from the end of the MIPS performance period.

(C) Upon request, provide CMS with any records or data retained in connection with its operation as a third party intermediary for up to 6 years from the end of the MIPS performance period.

(vi) Beginning with the 2023 MIPS payment year, third party intermediaries must attend and complete training and support sessions in the form and manner, and at the times, specified by CMS.

(b) *Additional requirements for QCDRs and qualified registries*—(1) *General.* (i) Beginning with the CY 2021 performance period/2023 MIPS payment year, QCDRs and qualified registries must be able to submit data for all of the following MIPS performance categories:

(A) Quality, except:

(*1*)The CAHPS for MIPS survey; and

(*2*) For qualified registries, QCDR measures;

(B) Improvement activities; and

(C) Promoting Interoperability, if the eligible clinician, group, virtual group, or subgroup is using CEHRT, unless the third party intermediary's MIPS eligible clinicians, groups, virtual groups, or subgroups fall under the reweighting policies at §414.1380(c)(2)(i)(A)(4)(i) through (iii) or (c)(2)(i)(C)(1) through (7) or (c)(2)(i)(C)(9).

(ii) Beginning with the CY 2023 performance period/2025 MIPS payment year, QCDRs and qualified registries must support MVPs that are applicable to the MVP participant on whose behalf they submit MIPS data. QCDRs and qualified registries may also support the APP. A QCDR or qualified registry must support all measures and activities included in the MVP with the following exceptions:

(A) If an MVP is intended for reporting by multiple specialties, a QCDR or a qualified registry are required to report those measures pertinent to the specialty of its MIPS eligible clinicians.

(B) If an MVP includes a QCDR measure, it is not required to be reported by a QCDR other than the measure owner.

(iii) Beginning with the CY 2023 performance period/2025 MIPS payment year, A QCDR or qualified registry must support subgroup reporting.

(2) *Self-nomination.* For the CY 2019 performance period/2021 MIPS payment year and future years, an existing QCDR or qualified registry that is in good standing may use the Simplified Self-Nomination process form during the self-nomination period, from July 1 and September 1 of the CY preceding the applicable performance period.

(3) *Conditions for approval.* (i) Beginning with the CY 2020 performance period/2022 MIPS payment year, the QCDR or qualified registry must have at least 25 participants by January 1 of the year prior to the applicable performance period.

(ii) If an entity seeking to qualify as a QCDR or qualified registry uses an external organization for purposes of data collection, calculation, or transmission, it must have a signed, written agreement with the external organization that specifically details the responsibilities of the entity and the external organization. The written agreement must be effective as of September 1 of the year preceding the applicable performance period.

(iii) Beginning with the CY 2021 performance period/2023 MIPS payment year, the QCDR or qualified registry

must provide performance feedback to their clinicians and groups at least 4 times a year, and provide specific feedback to their clinicians and groups on how they compare to other clinicians who have submitted data on a given measure within the QCDR or qualified registry. Exceptions to this requirement may occur if the QCDR or qualified registry submits notification to CMS within the performance period promptly within the month of realization of the impending deficiency and provides sufficient rationale as to why they do not believe they would be able to meet this requirement (for example, if the QCDR does not receive the data from their clinician until the end of the performance period).

(iv) Beginning with the CY 2023 performance period/2025 MIPS payment year, the QCDR or qualified registry must submit a data validation plan annually, at the time of self-nomination for CMS' approval and may not change the plan once approved without the prior approval of the agency.

(v) Beginning with the CY 2021 performance period/2023 MIPS payment year, the QCDR or qualified registry must conduct annual data validation audits in accordance with this paragraph (b)(3)(v).

(A) The QCDR or qualified registry must conduct data validation for the payment year prior to submitting any data for that payment year to CMS for purposes of the MIPS program.

(B) The QCDR or qualified registry must conduct data validation on data for each performance category for which it will submit data, including if applicable the Quality, Improvement Activities, and Promoting Interoperability performance categories.

(C) The QCDR or qualified registry must conduct data validation on data for each submitter type for which it will submit data, including MIPS eligible clinicians, groups, virtual groups, subgroups, APM entities, voluntary participants, and opt-in participants, if applicable.

(D) The QCDR or qualified registry must use clinical documentation (provided by the clinicians they are submitting data for) to validate that the action or outcome measured actually occurred or was performed.

(E) The QCDR or qualified registry must conduct each data validation audit using a sampling methodology that meets the following requirements:

(*1*) Uses a sample size of at least 3 percent of a combination of the individual MIPS eligible clinicians, groups, virtual groups, subgroups and APM entities for which the QCDR or qualified registry will submit data to CMS, except that the sample size may be no fewer than a combination of 10 individual clinicians, groups, virtual groups, subgroups and APM entities, no more than a combination of 50 individual clinicians, groups, virtual groups, subgroups and APM entities.

(*2*) Uses a sample that includes at least 25 percent of the patients of each individual clinician, group, virtual group, subgroup or APM entity in the sample, except that the sample for each individual clinician, group, virtual group, subgroup or APM entity must include a minimum of 5 patients and need not include more than 50 patients.

(F) Each QCDR or qualified registry data validation audit must include the following:

(*1*) Verification of the eligibility status of each eligible clinician, group, virtual group, subgroup, opt-in participant, and voluntary participant.

(*2*) Verification of the accuracy of TINs and NPIs.

(*3*) Calculation of reporting and performance rates.

(*4*) Verification that only the MIPS quality measures and QCDR measures, as applicable, that are relevant to the performance period will be used for MIPS submission.

(G) In a form and manner and by a deadline specified by CMS, the QCDR or qualified registry must report the results of each data validation audit, including the overall data deficiencies or data error rate, the types of deficiencies or data errors discovered, the percentage of clinicians impacted by any deficiency or error, and, how and when each deficiency or data error type was corrected.

(*1*) QCDRs and qualified registries must conduct validation on the data they intend to submit for the MIPS performance period and provide the results of the executed data validation

plan by May 31st of the year following the performance period.

(*2*) [Reserved]

(vi) Beginning with the CY 2021 performance period/2023 MIPS payment year, the QCDR or qualified registry must conduct targeted audits in accordance with this paragraph (b)(3)(vi).

(A) If a data validation audit under paragraph (b)(3)(v) of this section identifies one or more deficiency or data error, the QCDR or qualified registry must conduct a targeted audit into the impact and root cause of each such deficiency or data error for that MIPS payment year.

(B) The QCDR or qualified registry must conduct any required targeted audits for the MIPS payment year and correct any deficiencies or data errors identified through such audit prior to the submission of data for that MIPS payment year.

(C) The QCDR or qualified registry must conduct the targeted audit using the sampling methodology that meets the requirements described in paragraph (b)(3)(iv)(E) of this section. The sample for the targeted audit must not include data from the sample used for the data validation audit in which the deficiency or data error was identified.

(D) In a form and manner and by a deadline specified by CMS, the QCDR or qualified registry must report the results of each targeted audit, including the overall deficiency or data error rate, the types of deficiencies or data errors discovered, the percentage of clinicians impacted by each deficiency or data error, and how and when each deficiency or data error type was corrected.

(vii) For the CY 2023 performance period/2025 MIPS payment year, a QCDR or qualified registry that was approved but did not submit any MIPS data for any of the 2019 through 2023 MIPS payment years must submit a participation plan for CMS' approval. The participation plan must include the QCDR and/or qualified registry's detailed plans about how the QCDR or qualified registry intends to encourage clinicians to submit MIPS data to CMS through the QCDR or qualified registry.

(viii) Beginning with the CY 2024 performance period/2026 MIPS payment year, a QCDR or qualified registry that was approved but did not submit any MIPS data for either of the 2 years preceding the applicable self-nomination period must submit a participation plan for CMS' approval. This participation plan must include the QCDR's and/or qualified registry's detailed plans about how the QCDR or qualified registry intends to encourage clinicians to submit MIPS data to CMS through the QCDR or qualified registry.

(ix) During the self-nomination period, a QCDR or a qualified registry must submit to CMS quality measure numbers, Promoting Interoperability identifiers, improvement activity identifiers and MVP titles.

(x) A QCDR or a qualified registry must be able to submit to CMS data for at least six quality measures including at least one outcome measure.

(A) If no outcome measure is available, a QCDR or qualified registry must be able to submit to CMS results for at least one other high priority measure.

(B) [Reserved]

(xi) A QCDR or a qualified registry must submit to CMS risk-adjusted measure results when submitting data for measures that include risk adjustment in the measure specification.

(xii) A QCDRs or qualified registry must enter into appropriate Business Associate Agreements with MIPS eligible clinicians to collect and process their data.

(xiii) A QCDR or a qualified registry must maintain records of their authorization to submit data to CMS for the purpose of MIPS participation for each NPI whom the QCDR or qualified registry will submit data to CMS for. The records must:

(A) Be annually obtained by the QCDR or qualified registry at the time the clinician or group enters into an agreement with the QCDR or qualified registry for the submission of MIPS data to the QCDR or qualified registry.

(B) Be signed by an eligible clinician, if reporting individually, or by an authorized representative of the reporting group, subgroup, Virtual Group, or APM Entity.

(C) Records of the authorization must be maintained for 6 years after the performance period ends.

(xiv) A QCDR or a qualified registry must attest that the information listed on the qualified posting is accurate.

(xv) A QCDR or a qualified registry must provide to CMS, upon request, the data submitted by the QCDR or qualified registry *for purposes of MIPS*.

(xvi) A QCDR or qualified registry must attest to the following:

(A) A QCDR or a qualified registry must attest that it has required each MIPS eligible clinician on whose behalf it reports to provide the QCDR or qualified registry with all documentation necessary to verify the accuracy of the data on quality measures that the eligible clinician submitted to the QCDR or qualified registry.

(B) A QCDR or qualified registry must also attest that it has required each MIPS eligible clinician to permit the QCDR or qualified registry to provide the information described in paragraph (b)(3)(xviii)(A) of this section to CMS upon request.

(xvii) A QCDR or a qualified registry must accept and maintain clinician data by January 1 of the applicable performance period.

(4) *QCDR measures for the quality performance category*—(i) *QCDR measure self-nomination requirements.* For the CY 2018 performance period/2020 MIPS payment year and future years, at the time of self-nomination an entity seeking to become a QCDR must submit the following information for any measure it intends to submit for the payment year.

(A) For MIPS quality measures, the entity must submit specifications including the MIPS measure IDs and specialty-specific measure sets, as applicable.

(B) For a QCDR measure, the entity must submit for CMS approval measure specifications including: Name/title of measure, descriptions of the denominator, numerator, and when applicable, denominator exceptions, denominator exclusions, risk adjustment variables, and risk adjustment algorithms. In addition, no later than 15 calendar days following CMS posting of all approved specifications for a QCDR measure, the entity must publicly post the CMS-approved measure specifications for the QCDR measure (including the CMS-assigned QCDR measure ID) and provide CMS with a link to where this information is posted. The approved QCDR measure specifications must remain published through the performance period and data submission period.

(C) For a QCDR measure, the QCDR must provide, if available, data from years prior before the start of the performance period.

(ii) *QCDR measure submission requirements.* A QCDR must include the CMS-assigned QCDR measure ID when submitting data on any QCDR measure to CMS.

(iii) *QCDR measure approval criteria.* (A) QCDR measure requirements for approval are:

(*1*) QCDR measures that are beyond the measure concept phase of development.

(*2*) QCDR measures that address significant variation in performance.

(*3*) Beginning with the CY 2022 performance period/2024 MIPS payment year, CMS may approve a QCDR measure only if the QCDR measure meets face validity. Beginning with the CY 2024 performance period/2026 MIPS payment year, a QCDR measure approved for a previous performance year must be fully developed and tested, with complete testing results at the clinician level, prior to self-nomination.

(*4*) Beginning with the CY 2022 performance period/2023 MIPS payment year, QCDRs are required to collect data on a QCDR measure, appropriate to the measure type, prior to submitting the QCDR measure for CMS consideration during the self-nomination period.

(*5*) Beginning with the CY 2020 performance period/2022 MIPS payment year, CMS may provisionally approve the individual QCDR measures for 1 year with the condition that QCDRs address certain areas of duplication with other approved QCDR measures or MIPS quality measures in order to be considered for the program in subsequent years. If such areas of duplication are not addressed, CMS may reject the duplicative QCDR measure.

(B) QCDR measure considerations for approval include, but are not limited to:

(*1*) Measures that are outcome-based rather than clinical process measures.

(*2*) Measures that address patient safety and adverse events.

(*3*) Measures that identify appropriate use of diagnosis and therapeutics.

(*4*) Measures that address the domain of care coordination.

(*5*) Measures that address the domain for patient and caregiver experience.

(*6*) Measures that address efficiency, cost, and resource use.

(*7*) Beginning with the CY 2021 performance period/2023 MIPS payment year -

(*i*) That QCDRs link their QCDR measures as feasible to at least one cost measure, improvement activity, or an MVP at the time of self-nomination.

(*ii*) In cases where a QCDR measure does not have a clear link to a cost measure, improvement activity, or an MVP, CMS would consider exceptions if the potential QCDR measure otherwise meets the QCDR measure requirements and considerations.

(*8*) Beginning with the CY 2020 performance period/2022 MIPS payment year CMS may consider the extent to which a QCDR measure is available to MIPS eligible clinicians reporting through QCDRs other than the QCDR measure owner for purposes of MIPS. If CMS determines that a QCDR measure is not available to MIPS eligible clinicians, groups, and virtual groups reporting through other QCDRs, CMS may not approve the measure.

(*9*) Greater consideration is given to measures for which QCDRs:

(*i*) Conducted an environmental scan of existing QCDR measures; MIPS quality measures; quality measures retired from the legacy Physician Quality Reporting System (PQRS) program; and

(*ii*) Utilized the CMS Quality Measure Development Plan Annual Report and the Blueprint in the CMS Measures Management System to identify measurement gaps prior to measure development.

(*10*) Beginning with the CY 2020 performance period/2022 MIPS payment year, CMS places greater preference on QCDR measures that meet case minimum and reporting volumes required for benchmarking after being in the program for 2 consecutive CY performance periods. Those that do not, may not continue to be approved.

(*i*) Beginning with the CY 2020 performance period/2022 MIPS payment year, in instances where a QCDR believes the low-reported QCDR measure that did not meet benchmarking thresholds is still important and relevant to a specialist's practice, that the QCDR may develop and submit a QCDR measure participation plan for our consideration. This QCDR measure participation plan must include the QCDR's detailed plans and changes to encourage eligible clinicians and groups to submit data on the low-reported QCDR measure for purposes of the MIPS program.

(*ii*) [Reserved]

(C) Beginning with the CY 2021 performance period/2023 MIPS payment year, QCDR measures may be approved for 2 years, at CMS discretion by attaining approval status by meeting QCDR measure considerations and requirements. Upon annual review, CMS may revoke a QCDR measure's second year approval, if the QCDR measure is found to be: Topped out; duplicative of a more robust measure; reflects an outdated clinical guideline; or if the QCDR self-nominating the QCDR measure is no longer in good standing.

(iv) *QCDR measure rejection criteria.* Beginning with the CY 2020 performance period/2022 MIPS payment year, QCDR measure rejection considerations include, but are not limited to:

(A) QCDR measures that are duplicative or identical to other QCDR measures or MIPS quality measures that are currently in the program.

(B) QCDR measures that are duplicative or identical to MIPS quality measures that have been removed from MIPS through rulemaking.

(C) QCDR measures that are duplicative or identical to quality measures used under the legacy Physician Quality Reporting System (PQRS) program, which have been retired.

(D) QCDR measures that meet the topped out definition as described at § 414.1305.

(E) QCDR measures that are process-based, with consideration to whether the removal of the process measure impacts the number of measures available for a specific specialty.

(F) Whether the QCDR measure has potential unintended consequences to a patient's care.

(G) Considerations and evaluation of the measure's performance data, to determine whether performance variance exists.

(H) QCDR measures that split a single clinical practice or action into several QCDR measures.

(I) QCDR measures that are ''checkbox'' with no actionable quality action.

(J) QCDR measures that do not meet the case minimum and reporting volumes required for benchmarking after being in the program for 2 consecutive years.

(K) QCDR measures with clinician attribution issues, where the quality action is not under the direct control of the reporting clinician.

(L) QCDR measures that focus on rare events or ''never events'' in the measurement period.

(M) QCDR does not have permission to use a QCDR measure owned by another QCDR for the applicable performance period.

(N) If a QCDR measure owner is not approved or is not in good standing, any associated QCDR measures will not be approved.

(O) QCDR measures submitted after self-nomination.

(P) More than 30 QCDR measures are submitted by a single QCDR.

(c) *Additional requirements for Health IT vendors.* (1) Beginning with the CY 2021 performance period/2023 MIPS payment year, health IT vendors must be able to submit data for the MIPS performance categories as follows:

(i) Health IT vendors that support MVPs must be able to submit data for all of the MIPS performance categories:

(A) Quality, except:

(*1*) The CAHPS for MIPS survey; and

(*2*) QCDR measures;

(B) Improvement activities; and

(C) Promoting Interoperability, if the eligible clinician, group, virtual group, or subgroup is using CEHRT, unless:

(*1*) The third party intermediary's MIPS eligible clinicians, groups, virtual groups, or subgroups fall under the reweighting policies at § 414.1380(c)(2)(i)(A)(*4*)(*i*) through (*iii*) or (c)(2)(i)(C)(*1*) through (*7*) or (c)(2)(i)(C)(*9*).

(*2*) [Reserved]

(ii) Health IT vendors that do not support MVPs must be able to submit data for at least one of the MIPS performance categories described in paragraphs (c)(1)(i) of this section.

(iii) Beginning with the CY 2023 performance period/2025 MIPS payment year, Health IT vendors must support MVPs that are applicable to the MVP participant on whose behalf they submit MIPS data. Health IT vendors may also support the APP.

(2) [Reserved]

(d) *Additional requirements for CMS-approved survey vendors.* (1) CMS-approved survey vendors may submit data on the CAHPS for MIPS survey for the MIPS quality performance category.

(2) Entities seeking to be a CMS-approved survey vendor for any MIPS performance period must submit a survey vendor application to CMS in a form and manner specified by CMS for each MIPS performance period for which it wishes to transmit such data. The application and any supplemental information requested by CMS must be submitted by deadlines specified by CMS. For an entity to be a CMS-approved survey vendor, it must meet the following criteria:

(3) The entity must have sufficient experience, capability, and capacity to accurately report CAHPS data, including:

(i) At least 3 years of experience administering mixed-mode surveys (that is, surveys that employ multiple modes to collect date), including mail survey administration followed by survey administration via Computer Assisted Telephone Interview (CATI);

(ii) At least 3 years of experience administering surveys to a Medicare population;

(iii) At least 3 years of experience administering CAHPS surveys within the past 5 years;

(iv) Experience administering surveys in English and at least one other language for which a translation of the CAHPS for MIPS survey is available;

(v) Use equipment, software, computer programs, systems, and facilities that can verify addresses and phone

numbers of sampled beneficiaries, monitor interviewers, collect data via CATI, electronically administer the survey and schedule call-backs to beneficiaries at varying times of the day and week, track fielded surveys, assign final disposition codes to reflect the outcome of data collection of each sampled case, and track cases from mail surveys through telephone follow-up activities; and

(vi) Employment of a program manager, information systems specialist, call center supervisor and mail center supervisor to administer the survey.

(4) The entity has certified that it has the ability to maintain and transmit quality data in a manner that preserves the security and integrity of the data.

(5) The entity has successfully completed, and has required its subcontractors to successfully complete, vendor training(s) administered by CMS or its contractors.

(6) The entity has submitted a quality assurance plan and other materials relevant to survey administration, as determined by CMS, including cover letters, questionnaires and telephone scripts.

(7) The entity has agreed to participate and cooperate, and has required its subcontractors to participate and cooperate, in all oversight activities related to survey administration conducted by CMS or its contractors.

(8) The entity has sent an interim survey data file to CMS that establishes the entity's ability to accurately report CAHPS data.

(e) *Remedial action and termination of third party intermediaries.* (1) If CMS determines that a third party intermediary has ceased to meet one or more of the applicable criteria for approval, failed to comply with the program requirements of this section, has submitted a false certification under paragraph (a)(3) of this section, or has submitted data that are inaccurate, unusable, or otherwise compromised, CMS may take one or more of the following remedial actions after providing written notice to the third party intermediary:

(i) Require the third party intermediary to submit a corrective action plan (CAP) by a date specified by CMS. The CAP must address the following issues, unless different or additional information is specified by CMS:

(A) The issues that contributed to the non-compliance.

(B) The impact to individual clinicians, groups, virtual groups, subgroups, or APM Entities, regardless of whether they are participating in the program because they are MIPS eligible, voluntarily participating, or opting in to participating in the MIPS program, and any QCDRs that were granted licenses to the measures of a QCDR upon which a CAP has been imposed.

(C) The corrective actions to be implemented by the third party intermediary to ensure that the non-compliance has been resolved and will not recur in the future.

(D) The detailed timeline for achieving compliance with the applicable requirements.

(E) The communication plan for communicating the impact to the parties identified in paragraph (e)(1)(i)(B) of this section.

(F) Once the issue has been resolved, the detailed final resolution and an update, if any, to the monitoring plan provided pursuant to § 414.1400(e)(1)(i)(C).

(ii) Publicly disclose as follows:

(A) For the purposes of the CY 2025 performance period/2027 MIPS payment year and prior reporting periods and payment years, publicly disclose the entity's data error rate on the CMS website until the data error rate falls below 3 percent.

(B) Beginning with the CY 2025 performance period/2027 MIPS payment year, publicly disclose on the CMS website that CMS took remedial action against or terminated the third party intermediary.

(2) CMS may immediately or with advance notice terminate a third party intermediary for one or more of the following reasons:

(i) CMS has grounds to impose remedial action;

(ii) CMS has not received a CAP within the specified time-period or the CAP is not accepted by CMS; or

(iii) The third party intermediary fails to correct the deficiencies or data errors by the date specified by CMS.

(iv) The third party intermediary has not maintained current contact information for correspondence.

(v) The third party intermediary is on remedial action for 2 consecutive years.

(3) A data submission that contains data inaccuracies affecting the third party intermediary's clinicians may lead to remedial action/termination of the third party intermediary for future program year(s) based on CMS discretion.

(4) For purposes of this paragraph (e), CMS may determine that submitted data are inaccurate, unusable, or otherwise compromised, if the submitted data includes, without limitation, TIN/NPI mismatches, formatting issues, calculation errors, or data audit discrepancies.

(5) Beginning with the CY 2024 performance period/2026 MIPS payment year, a QCDR or qualified registry that submits a participation plan as required under paragraph (b)(3)(viii) of this section, but does not submit MIPS data for the applicable performance period for which they self-nominated under paragraph (b)(3)(viii) of this section, will be terminated.

(f) *Auditing of entities submitting MIPS data.* Third party intermediaries may be randomly selected for compliance evaluation or may be selected at the suggestion of CMS if there is an area of concern regarding the third party intermediary. For example, areas of concern could include, but are not limited to: high data errors, support call absences, delinquent deliverables, remedial action status, clinician concerns regarding the third party intermediary, a continuing pattern of Quality Payment Program Service Center inquiries or support call questions, and/or CMS concerns regarding the third party intermediary.

[86 FR 65677, Nov. 19, 2021, as amended at 87 FR 70229, Nov. 18, 2022; 88 FR 79536, Nov. 16, 2023]

§ 414.1405 Payment.

(a) *General.* Each MIPS eligible clinician receives a MIPS payment adjustment factor, and if applicable an additional MIPS payment adjustment factor for exceptional performance, for a MIPS payment year determined by comparing their final score to the performance threshold and additional performance threshold for the year.

(b) *Performance threshold.* A performance threshold will be specified for each MIPS payment year.

(1) MIPS eligible clinicians with a final score at or above the performance threshold receive a zero or positive MIPS payment adjustment factor on a linear sliding scale such that an adjustment factor of 0 percent is assigned for a final score at the performance threshold and an adjustment factor of the applicable percent is assigned for a final score of 100.

(2) MIPS eligible clinicians with a final score below the performance threshold receive a negative MIPS payment adjustment factor on a linear sliding scale such that an adjustment factor of 0 percent is assigned for a final score at the performance threshold and an adjustment factor of the negative of the applicable percent is assigned for a final score of 0; further, MIPS eligible clinicians with final scores that are equal to or greater than zero, but not greater than one-fourth of the performance threshold, receive a negative MIPS payment adjustment factor that is equal to the negative of the applicable percent.

(3) A scaling factor not to exceed 3.0 may be applied to positive MIPS payment adjustment factors to ensure budget neutrality such that the estimated increase in aggregate allowed charges resulting from the application of the positive MIPS payment adjustment factors for the MIPS payment year equals the estimated decrease in aggregate allowed charges resulting from the application of negative MIPS payment adjustment factors for the MIPS payment year.

(4) The performance threshold for the 2019 MIPS payment year is 3 points.

(5) The performance threshold for the 2020 MIPS payment year is 15 points.

(6) The performance threshold for the 2021 MIPS payment year is 30 points.

(7) The performance threshold for the 2022 MIPS payment year is 45 points.

(8) The performance threshold for the 2023 MIPS payment year is 60 points.

(9) Pursuant to the methodology established at paragraph (g) of this section:

(i) The performance threshold for the 2024 MIPS payment year is 75 points. The prior period used to determine the performance threshold is the 2019 MIPS payment year.

(ii) The performance threshold for the 2025 MIPS payment year is 75 points. The prior period used to determine the performance threshold is the 2019 MIPS payment year.

(iii) The performance threshold for the 2026 MIPS payment year is 75 points. The prior period to determine the performance threshold is the 2019 MIPS payment year.

(10) Pursuant to the methodology established at paragraph (g)(2) of this section:

(i) The performance threshold for the 2027 MIPS payment year is 75 points. The prior period used to determine the performance threshold is the 2019 MIPS payment year.

(ii) [Reserved]

(c) *Applicable percent.* For MIPS payment year 2019, 4 percent. For MIPS payment year 2020, 5 percent. For MIPS payment year 2021, 7 percent. For MIPS payment year 2022 and each subsequent MIPS payment year, 9 percent.

(d) *Additional performance threshold.* An additional performance threshold will be specified for each of the MIPS payment years 2019 through 2024.

(1) In addition to the MIPS payment adjustment factor, MIPS eligible clinicians with a final score at or above the additional performance threshold receive an additional MIPS payment adjustment factor for exceptional performance on a linear sliding scale such that an additional adjustment factor of 0.5 percent is assigned for a final score at the additional performance threshold and an additional adjustment factor of 10 percent is assigned for a final score of 100, subject to the application of a scaling factor as determined by CMS, such that the estimated aggregate increase in payments resulting from the application of the additional MIPS payment adjustment factors for the MIPS payment year shall not exceed $500,000,000 for each of the MIPS payment years 2019 through 2024.

(2) [Reserved]

(3) The additional performance threshold for the 2019 MIPS payment year is 70 points.

(4) The additional performance threshold for the 2020 MIPS payment year is 70 points.

(5) The additional performance threshold for the 2021 MIPS payment year is 75 points.

(6) The additional performance threshold for the 2022 and 2023 MIPS payment years is 85 points.

(7) The additional performance threshold for the 2024 MIPS payment year is 89 points.

(e) *Application of adjustments to payments.* Except as specified in paragraph (f) of this section, in the case of covered professional services (as defined in section 1848(k)(3)(A) of the Act) furnished by a MIPS eligible clinician during a MIPS payment year beginning with 2019, the amount otherwise paid under Part B with respect to such covered professional services and MIPS eligible clinician for such year, is multiplied by 1, plus the sum of the MIPS payment adjustment factor divided by 100, and as applicable, the additional MIPS payment adjustment factor divided by 100.

(f) *Exception to application of MIPS payment adjustment factors to model-specific payments under section 1115A APMs.* Beginning with the 2019 MIPS payment year, the payment adjustment factors specified under paragraph (e) of this section are not applicable to payments that meet all of the following conditions:

(1) Are made only to participants in a model tested under section 1115A of the Act;

(2) Would otherwise be subject to the requirement to apply the MIPS payment adjustment factors if the payment is made with respect to a MIPS eligible clinician participating in a section 1115A model; and

(3) Either have a specified payment amount or are paid according to a methodology for calculating a model-specific payment that is applied in a consistent manner to all model participants, such that application of the MIPS payment adjustment factors would potentially interfere with CMS's ability to effectively evaluate the impact of the APM.

(g) *Performance threshold methodology.* (1) For each of the 2024, 2025, and 2026 MIPS payment years, the performance

threshold is the mean of the final scores for all MIPS eligible clinicians from a prior period as specified under paragraph (b)(9) of this section.

(2) For each of the 2027, 2028, and 2029 MIPS payment years, the performance threshold is the mean of the final scores for all MIPS eligible clinicians from a prior period as specified under paragraph (b)(10) of this section.

[81 FR 77537, Nov. 4, 2016, as amended at 82 FR 53960, Nov. 16, 2017; 83 FR 60089, Nov. 23, 2018; 84 FR 63200, Nov. 15, 2019; 86 FR 65681, Nov. 19, 2021; 87 FR 70229, Nov. 18, 2022; 88 FR 79538, Nov. 16, 2023; 89 FR 9784, Feb. 12, 2024; 89 FR 98564, Dec. 9, 2024]

§414.1410 Advanced APM determination.

(a) *General.* An APM is an Advanced APM for a payment year if CMS determines that it meets the criteria in §414.1415 during the QP Performance Period.

(b) *Advanced APM determination process.* CMS determines Advanced APMs in the following manner:

(1) *Advanced APM determination.* (i) No later than January 1, 2017, CMS will post on its Web site a list of all Advanced APMs for the first QP Performance Period.

(ii) CMS updates the Advanced APM list on its Web site at intervals no less than annually.

(iii) CMS will include notice of whether a new APM is an Advanced APM in the first public notice of the new APM.

(2) [Reserved]

[81 FR 77537, Nov. 4, 2016, as amended at 82 FR 53960, Nov. 16, 2017]

§414.1415 Advanced APM criteria.

(a) *Use of certified electronic health record technology (CEHRT)*—(1) *Required use of CEHRT.* To be an Advanced APM, an APM must:

(i) For QP Performance Periods ending with 2018, require at least 50 percent, or for QP Performance Periods beginning with 2019 and ending with 2024, 75 percent, of eligible clinicians in each participating APM Entity group, or for APMs in which hospitals are the APM Entities, each hospital, to use CEHRT to document and communicate clinical care to their patients or health care providers;

(ii) For QP Performance Periods prior to 2019, for the Shared Savings Program, apply a penalty or reward to an APM Entity based on the degree of the use of CEHRT of the eligible clinicians in the APM Entity; and

(iii) For QP Performance Periods beginning with 2025, require use of CEHRT as defined at paragraph (3) under CEHRT at §414.1305.

(2) [Reserved].

(b) *Payment based on quality measures.* (1) To be an Advanced APM, an APM must include quality measure performance as a factor when determining payment to participants for covered professional services under the terms of the APM.

(2) At least one of the quality measures used in the payment arrangement as specified in paragraph (b)(1) of this section must:

(i) For QP Performance Periods before January 1, 2020, have an evidence-based focus, be reliable and valid, and meet at least one of the following criteria:

(A) Used in the MIPS quality performance category, as described in §414.1330;

(B) Endorsed by a consensus-based entity;

(C) Developed under section 1848(s) of the Act;

(D) Submitted in response to the MIPS Call for Quality Measures under section 1848(q)(2)(D)(ii) of the Act; or

(E) Any other quality measures that CMS determines to have an evidence-based focus and to be reliable and valid; and

(ii) For QP Performance Periods beginning on or after January1, 2020, be:

(A) Finalized on the MIPS final list of measures, as described in §414.1330;

(B) Endorsed by a consensus-based entity; or

(C) Determined by CMS to be evidenced-based, reliable, and valid.

(3) The quality measures upon which an Advanced APM bases the payment in paragraph (b)(1) of this section must include at least one measure that is an outcome measure unless CMS determines that there are no available or applicable outcome measures included in the MIPS final quality measures list for the Advanced APM's first QP Performance Period. Beginning January 1,

2020, the included outcome measure must satisfy the criteria in paragraph (b)(2) of this section.

(4) A single quality measure that meets the criteria under both paragraphs (b)(2) and (3) of this section may be used to satisfy the requirements of paragraph (b)(1) of this section.

(c) *Financial risk.* To be an Advanced APM, except as described in paragraph (c)(6) of this section, an APM must either meet the financial risk standard under paragraph (c)(1) or (2) of this section and the nominal amount standard under paragraph (c)(3) or (4) of this section or be an expanded Medical Home Model under section 1115A(c) of the Act.

(1) *Generally applicable financial risk standard.* Except for paragraph (c)(2) of this section, to be an Advanced APM, an APM must, based on whether an APM Entity's actual expenditures for which the APM Entity is responsible under the APM exceed expected expenditures during a specified QP Performance Period, do one or more of the following:

(i) Withhold payment for services to the APM Entity or the APM Entity's eligible clinicians;

(ii) Reduce payment rates to the APM Entity or the APM Entity's eligible clinicians; or

(iii) Require the APM Entity to owe payment(s) to CMS.

(2) *Medical Home Model financial risk standard.* The APM Entity participates in a Medical Home Model that, based on the APM Entity's failure to meet or exceed one or more specified performance standards, which may include expected expenditures, does one or more of the following:

(i) Withholds payment for services to the APM Entity or the APM Entity's eligible clinicians;

(ii) Reduces payment rates to the APM Entity or the APM Entity's eligible clinicians;

(iii) Requires the APM Entity to owe payment(s) to CMS; or

(iv) Causes the APM Entity to lose the right to all or part of an otherwise guaranteed payment or payments.

(3) *Generally applicable nominal amount standard.* (i) Except as provided in paragraph (c)(4) of this section, the total amount an APM Entity potentially owes CMS or foregoes under an APM must be at least equal to either:

(A) For QP Performance Periods beginning in 2023, 8 percent of the average estimated total Medicare Parts A and B revenue of all providers and suppliers in participating APM Entities; or

(B) 3 percent of the expected expenditures for which an APM Entity is responsible under the APM.

(ii) [Reserved]

(4) *Medical Home Model nominal amount standard.* (i) For a Medical Home Model to meet the Medical Home Model nominal amount standard, the total annual amount that an APM Entity potentially owes CMS or foregoes must be at least the following amounts:

(A) For QP Performance Period 2017, 2.5 percent of the average estimated total Medicare Parts A and B revenue of all providers and suppliers in participating APM Entities.

(B) For QP Performance Period 2018, 2.5 percent of the average estimated total Medicare Parts A and B revenue of all providers and suppliers in participating APM Entities.

(C) For QP Performance Period 2019, 3 percent of the average estimated total Medicare Parts A and B revenue of all providers and suppliers in participating APM Entities.

(D) For QP Performance Period 2020, 4 percent of the average estimated total Medicare Parts A and B revenue of all providers and suppliers in participating APM Entities.

(E) For QP Performance Periods 2021 and later, 5 percent of the average estimated total Medicare Parts A and B revenue of all providers and suppliers in participating APM Entities.

(ii) [Reserved]

(5) For the purposes of this section, expected expenditures means the beneficiary expenditures for which an APM Entity is responsible under an APM. For episode payment models, expected expenditures means the episode target price. For purposes of assessing financial risk for Advanced APM determinations, the expected expenditures under the terms of the APM should not exceed the Medicare Part A and Part B expenditures for a participant in the

absence of the APM. If the expected expenditures under the APM exceed the Medicare Part A and Part B expenditures that an APM Entity would be expected to incur in the absence of the APM, such excess expenditures are not considered when CMS assesses financial risk under the APM for purposes of Advanced APM determinations.

(6) *Capitation.* A full capitation arrangement meets this Advanced APM criterion. For purposes of this part, a full capitation arrangement means a payment arrangement in which a per capita or otherwise predetermined payment is made under the APM for all items and services furnished to a population of beneficiaries during a fixed period of time, and no settlement is performed to reconcile or share losses incurred or savings earned by the APM Entity. Arrangements between CMS and Medicare Advantage Organizations under the Medicare Advantage program (part 422 of this title) are not considered capitation arrangements for purposes of this paragraph (c)(6).

(7) *Medical Home Model 50 eligible clinician limit.* Beginning in the 2023 QP Performance Period, notwithstanding paragraphs (c)(2) and (4) of this section, if an APM Entity participating in a Medical Home Model is comprised of more than 50 eligible clinicians, as determined by that APM Entity's Participation List on any of the three QP determination dates (March 31, June 30, and August 31 of the QP Performance Period), the requirements of paragraphs (c)(1) and (3) of this section apply.

[81 FR 77537, Nov. 4, 2016, as amended at 82 FR 53960, Nov. 16, 2017; 83 FR 60090, Nov. 23, 2018; 84 FR 540, Jan. 31, 2019; 84 FR 63200, Nov. 15, 2019; 87 FR 70229, Nov. 18, 2022; 88 FR 79538, Nov. 16, 2023]

§414.1420 Other payer advanced APM criteria.

(a) *Other Payer Advanced APM criteria.* A payment arrangement with a payer other than Medicare is an Other Payer Advanced APM for a QP Performance Period if CMS determines that the arrangement meets the following criteria during the QP Performance Period:

(1) Use of CEHRT, as described in paragraph (b) of this section;

(2) Quality measures comparable to measures under the MIPS quality performance category apply, as described in paragraph (c) of this section; and

(3) Either:

(i) Requires APM Entities to bear more than nominal financial risk if actual aggregate expenditures exceed expected aggregate expenditures as described in paragraph (d) of this section; or

(ii) Is a Medicaid Medical Home Model that meets criteria comparable to Medical Home Models expanded under section 1115A(c) of the Act as described in paragraph (d) of this section.

(b) *Use of CEHRT.* To be an Other Payer Advanced APM:

(1) CEHRT must be used, for QP Performance Periods ending with 2019, by at least 50 percent; and for QP Performance Periods for 2020 through 2024, by at least 75 percent, of participants in each participating APM Entity group, or each hospital if hospitals are the APM Entities, in the other payer arrangement to document and communicate clinical care; and

(2) For QP Performance Periods beginning on or after January 1, 2024, use of CEHRT (as defined in §414.1305, paragraph (3) in the definition of ''Certified Electronic Health Record Technology (CEHRT)''), must be a requirement of participation in the APM.

(c) *Use of quality measures.* (1) To be an Other Payer Advanced APM, a payment arrangement must apply quality measures comparable to measures under the MIPS quality performance category, as described in paragraph (c)(2) of this section.

(2) At least one of the quality measures used in the payment arrangement as specified in paragraph (c)(1) of this section must:

(i) For QP Performance Period before January 1, 2020, have an evidence-based focus, be reliable and valid, and meet at least one of the following criteria:

(A) Used in the MIPS quality performance category, as described in §414.1330;

(B) Endorsed by a consensus-based entity;

(C) Developed under section 1848(s) of the Act;

(D) Submitted in response to the MIPS Call for Quality Measures under section 1848(q)(2)(D)(ii) of the Act; or

(E) Any other quality measures that CMS determines to have an evidence-based focus and to be reliable and valid; and

(ii) For QP Performance Periods beginning on or after January 1, 2020, be:

(A) Finalized on the MIPS final list of measures, as described in § 414.1330;

(B) Endorsed by a consensus-based entity; or

(C) Determined by CMS to be evidenced-based, reliable, and valid.

(3) To meet the quality measure use criterion under paragraph (c)(1) of this section, a payment arrangement must:

(i) For QP Performance Periods before January 1, 2020, use an outcome measure if there is an applicable outcome measure on the MIPS quality measure list. This criterion also applies for payment arrangements determined to be Other Payer Advanced APMs on or before January 1, 2020, but only for the Other Payer Advanced APM determination made with respect to the arrangement for the CY 2020 QP Performance Period (regardless of whether that determination is a single- or multi-year determination).

(ii) For QP Performance Periods on or after January 1, 2020, use at least one measure that is an outcome measure and meets the criteria in paragraph (c)(2)(ii) of this section if there is such an applicable outcome measure on the MIPS quality measure list.

(4) A single quality measure that meets the criteria under both paragraphs (c)(2) and (3) of this section may be used to satisfy the requirements of paragraph (c)(1) of this section.

(d) *Financial risk.* To be an Other Payer Advanced APM, except as described in paragraph (d)(7) of this section, a payment arrangement must meet either the financial risk standard under paragraph (d)(1) or (2) of this section and the nominal amount standard under paragraph (d)(3) or (4) of this section, or be a Medicaid Medical Home Model with criteria comparable to an expanded Medical Home Model under section 1115A(c) of the Act.

(1) *Generally applicable financial risk standard.* Except for APM Entities to which paragraph (d)(2) of this section applies, to be an Other Payer Advanced APM, an APM Entity must, based on whether an APM Entity's actual expenditures for which the APM Entity is responsible under the payment arrangement exceed expected expenditures during a specified period of performance do one or more of the following:

(i) Withhold payment for services to the APM Entity or the APM Entity's eligible clinicians;

(ii) Reduce payment rates to the APM Entity or the APM Entity's eligible clinicians; or

(iii) Require direct payment by the APM Entity to the payer.

(2) *Medicaid Medical Home Model and Aligned Other Payer Medical Home Model financial risk standard.* The APM Entity participates in a Medicaid Medical Home Model or an Aligned Other Payer Medical Home Model that, based on the APM Entity's failure to meet or exceed one or more specified performance standards, does one or more of the following:

(i) Withhold payment for services to the APM Entity or the APM Entity's eligible clinicians;

(ii) Require direct payment by the APM Entity to the payer;

(iii) Reduce payment rates to the APM Entity or the APM Entity's eligible clinicians; or

(iv) Require the APM Entity to lose the right to all or part of an otherwise guaranteed payment or payments.

(3) *Generally applicable nominal amount standard.* Except for payment arrangements described in paragraph (d)(2) of this section, the total amount an APM Entity potentially owes a payer or foregoes under a payment arrangement must be at least:

(i) For QP Performance Periods beginning in 2023, 8 percent of the total combined revenues from the payer to providers and other entities under the payment arrangement if financial risk is expressly defined in terms of revenue; or, 3 percent of the expected expenditures for which an APM Entity is responsible under the payment arrangement.

(ii) Except for risk arrangements described under paragraph (d)(2) of this section, the risk arrangement must

have a marginal risk rate of at least 30 percent.

(4) *Medicaid Medical Home Model and Aligned Other Payer Medical Home Model nominal amount standard.* For a Medicaid Medical Home Model or an Aligned Other Payer Medical Home Model to meet the Medicaid Medical Home Model nominal amount standard, the total annual amount that an APM Entity potentially owes a payer or forgoes must be at least the following amounts:

(i) For QP Performance Period 2019, 3 percent of the average estimated total revenue of the participating providers or other entities under the payer.

(ii) For QP Performance Period 2020, 4 percent of the average estimated total revenue of the participating providers or other entities under the payer.

(iii) For QP Performance Periods 2021 and later, 5 percent of the average estimated total revenue of the participating providers or other entities under the payer.

(5) *Marginal risk rate.* For purposes of this section, the marginal risk rate is defined as the percentage of actual expenditures that exceed expected expenditures for which an APM Entity is responsible under an other payer payment arrangement.

(i) In the event that the marginal risk rate varies depending on the amount by which actual expenditures exceed expected expenditures, the average marginal risk rate across all possible levels of actual expenditures would be used for comparison to the marginal risk rate specified in paragraph (d)(3)(ii) of this section, with exceptions for large losses as described in paragraph (d)(5)(ii) of this section and small losses as described in paragraph (d)(5)(iii) of this section.

(ii) *Allowance for large losses.* The determination in paragraph (d)(3)(ii) of this section may disregard the marginal risk rates that apply in cases when actual expenditures exceed expected expenditures by an amount sufficient to require the APM Entity to make financial risk payments under the other payer payment arrangement greater than or equal to the total risk requirement under paragraph (d)(3)(i) of this section.

(iii) *Allowance for minimum loss rate.* The determination in paragraph (d)(3)(ii) of this section may disregard the marginal risk rates that apply in cases when actual expenditures exceed expected expenditures by less than 4 percent of expected expenditures.

(6) *Expected expenditures.* For the purposes of this section, expected expenditures is defined as the Other Payer APM benchmark. For episode payment models, expected expenditures means the episode target price. For purposes of assessing financial risk for Other Payer Advanced APM determinations, the expected expenditures under the payment arrangement should not exceed the expenditures for a participant in the absence of the payment arrangement. If expected expenditures under the payment arrangement exceed the expenditures that the participant would be expected to incur in the absence of the payment arrangement, such excess expenditures are not considered when assessing financial risk under the payment arrangement for Other Payer Advanced APM determinations.

(7) *Capitation.* A full capitation arrangement meets this Other Payer Advanced APM criterion. For purposes of paragraph (d)(3) of this section, a full capitation arrangement means a payment arrangement in which a per capita or otherwise predetermined payment is made under the payment arrangement for all items and services furnished to a population of beneficiaries during a fixed period of time, and no settlement is performed for the purposes of reconciling or sharing losses incurred or savings earned by the participant. Arrangements made directly between CMS and Medicare Advantage Organizations under the Medicare Advantage program (part 422 of this title) are not considered capitation arrangements for purposes of this paragraph.

(8) *Aligned Other Payer Medical Home Model and Medicaid Medical Home Model 50 eligible clinician limit.* Beginning with the 2023 QP Performance Period, notwithstanding paragraphs (d)(2) and (4) of this section, if an APM Entity participating in an Aligned Other Payer Medical Home Model or Medicaid Medical Home Model is comprised of 50 or

more eligible clinicians is comprised of more than 50 eligible clinicians, as determined by the information submitted for any of the three QP determination dates (March 31, June 30, and August 31 of the QP Performance Period) as specified in § 414.1440(e), the requirements of paragraphs (d)(1) and (3) of this section apply.

[81 FR 77537, Nov. 4, 2016, as amended at 82 FR 53961, Nov. 16, 2017; 83 FR 23610, May 22, 2018; 83 FR 60090, Nov. 23, 2018; 84 FR 63200, Nov. 15, 2019; 87 FR 70230, Nov. 18, 2022; 88 FR 79539, Nov. 16, 2023]

§ 414.1425 Qualifying APM participant determination: In general.

(a) *List used for QP determination.* (1) For Advanced APMs in which all APM Entities may include eligible clinicians on a Participation List, the Participation List is used to identify the APM Entity group for purposes of QP determinations, regardless of whether the APM Entity may also include eligible clinicians on an Affiliated Practitioner List.

(2) For Advanced APMs in which APM Entities do not include eligible clinicians on a Participation List but do include eligible clinicians on an Affiliated Practitioner List, the Affiliated Practitioner List is used to identify the eligible clinicians for purposes of QP determinations.

(3) For Advanced APMs in which some APM Entities may include eligible clinicians on a Participation List and other APM Entities may only include eligible clinicians on an Affiliated Practitioner List depending on the type of APM Entity, paragraph (a)(1) of this section applies to APM Entities that may include eligible clinicians on a Participation List, and paragraph (a)(2) of this section applies to APM Entities that may only include eligible clinicians on an Affiliated Practitioner List.

(b) *Group or individual determination under the Medicare Option. (1) APM Entity group determination.* Except for paragraphs (b)(2) and (3) of this section and as set forth in § 414.1440, for purposes of the QP determinations for a year, eligible clinicians are grouped and assessed through their collective participation in an APM Entity group that is in an Advanced APM. To be included in the APM Entity group for purposes of the QP determination, an eligible clinician's APM participant identifier must be present on a Participation List of an APM Entity group on one of the dates: March 31, June 30, or August 31 of the QP Performance Period. An eligible clinician included on a Participation List on any one of these dates is included in the APM Entity group even if that eligible clinician is not included on that Participation List at one of the prior or later listed dates. CMS performs QP determinations for the eligible clinicians in an APM entity group three times during the QP Performance Period using claims data for services furnished from January 1 through each of the respective QP determination dates: March 31, June 30, and August 31. An eligible clinician can only be determined to be a QP if the eligible clinician appears on the Participation List on a date (March 31, June 30, or August 31) CMS uses to determine the APM Entity group and to make QP determinations collectively for the APM Entity group based on participation in the Advanced APM.

(2) *Affiliated practitioner individual determination under the Medicare Option.* For Advanced APMs to which paragraph (a)(2) of this section applies, QP determinations are made individually for each eligible clinician. To be assessed as an Affiliated Practitioner, an eligible clinician must be identified on an Affiliated Practitioner List on one of the dates: March 31, June 30, or August 31 of the QP Performance Period. An eligible clinician included on an Affiliated Practitioner List on any one of these dates is assessed as an Affiliated Practitioner even if that eligible clinician is not included on the Affiliated Practitioner List at one of the prior or later listed dates. For such eligible clinicians, CMS performs QP determinations during the QP Performance Period using claims data for services furnished from January 1 through each of the respective QP determination dates that the eligible clinician is on the Affiliated Practitioner List: March 31, June 30, and August 31.

(c) *QP determination.* (1) CMS makes QP determinations as set forth in §§ 414.1435 and 414.1440.

(2) An eligible clinician cannot be both a QP and a Partial QP for a year. A determination that an eligible clinician is a QP means that the eligible clinician is not a Partial QP.

(3) An eligible clinician is a QP for a year under the Medicare Option if the eligible clinician is in an APM Entity group that achieves a Threshold Score that meets or exceeds the corresponding QP payment amount threshold or QP patient count threshold for that QP Performance Period as described in §414.1430(a)(1) and (3). An eligible clinician is a QP for the year under the All-Payer Combination Option if the eligible clinician individually, or as part of an APM Entity group, achieves a Threshold Score that meets or exceeds the corresponding QP payment amount threshold or QP patient count threshold for that QP Performance Period as described in §414.1430(b)(1) and (3).

(4) Notwithstanding paragraph (c)(3) of this section, an eligible clinician is a QP for a year if:

(i) The eligible clinician is included in more than one APM Entity group and none of the APM Entity groups in which the eligible clinician is included meets the QP payment amount threshold or the QP patient count threshold, or the eligible clinician is an Affiliated Practitioner; and

(ii) CMS determines that the eligible clinician individually achieves a Threshold Score that meets or exceeds the QP payment amount threshold or the QP patient count threshold.

(5) Beginning in the 2020 QP Performance Period, an eligible clinician in an APM Entity is not a QP for a year if:

(i) The APM Entity voluntarily or involuntarily terminates from an Advanced APM before the end of the QP Performance Period; or

(ii) The APM Entity voluntarily or involuntarily terminates from an Advanced APM at a date on which the APM Entity would not bear financial risk for that QP performance period under the terms of the Advanced APM, even if such termination date occurs within such QP Performance Period.

(6) Beginning in the 2020 QP Performance Period, an eligible clinician is not a QP for a year if:

(i) One or more of the APM Entities in which the eligible clinician participates voluntarily or involuntarily terminates from the Advanced APM before the end of the QP Performance Period, and the eligible clinician does not achieve a Threshold Score that meets or exceeds the QP payment amount threshold or QP patient count threshold based on participation in the remaining non-terminating APM Entities; or

(ii) One or more of the APM Entities in which the eligible clinician participates voluntarily or involuntarily terminates from the Advanced APM at a date on which the APM Entity would not bear financial risk under the terms of the Advanced APM, and the eligible clinician does not achieve a Threshold Score that meets or exceeds the QP payment amount threshold or QP patient count threshold based on participation in the remaining non-terminating APM Entities.

(7) Advanced APMs that start or end during the QP Performance Period:

(i) Notwithstanding paragraph (a) of this section and §§414.1435 and 414.1440, CMS makes QP determinations and Partial QP determinations for the APM Entity group or individual eligible clinician under §414.1425(b) for Advanced APMs that start or end during the QP Performance Period and that are actively tested for 60 or more continuous days during the QP Performance Period using claims data for services furnished during those dates on which the Advanced APM is actively tested. For Advanced APMs that start active testing during the QP Performance Period, CMS performs QP and Partial QP determinations during the QP Performance Period using claims data for services furnished from the start of active testing of the Advanced APM through each of the QP determination dates that occur on or after the Advanced APM has been actively tested for 60 or more continuous days: March 31, June 30, and August 31. For Advanced APMs that end active testing during the QP Performance Period, CMS performs QP and Partial QP determinations using claims data for services furnished from January 1 or the start of active testing, whichever occurs later, through the

final day of active testing of the Advanced APM for each of the QP determination dates that occur on or after the Advanced APM has been actively tested for 60 or more continuous days during that QP Performance Period: March 31, June 30, and August 31.

(ii) For QP determinations specified under paragraph (c)(4) of this section and Partial QP determinations under paragraph (d)(2) of this section, QP determinations are made using claims data for the full QP Performance Period even if the eligible clinician participates in one or more Advanced APMs that start or end during the QP Performance Period.

(d) *Partial QP determination.* (1) An eligible clinician is a Partial QP for a year under the Medicare Option if the eligible clinician is in an APM Entity group that achieves Threshold Score that meets or exceeds the corresponding Partial QP payment amount threshold or Partial QP patient count threshold for that QP Performance Period as described in §414.1430(a)(2) and (4). An eligible clinician is a Partial QP for the year under the All-Payer Combination Option if the eligible clinician achieves individually, or as part of an APM Entity group, a Threshold Score that meets or exceeds the corresponding Partial QP payment amount threshold or Partial QP patient count threshold for that QP Performance Period as described in §414.1430(b)(2) and (4).

(2) Notwithstanding paragraph (d)(1) of this section, an eligible clinician is a Partial QP for a year if:

(i) The eligible clinician is included in more than one APM Entity group and none of the APM Entity groups in which the eligible clinician is included meets the corresponding QP or Partial QP threshold, or the eligible clinician is an Affiliated Practitioner; and

(ii) CMS determines that the eligible clinician individually achieves a Threshold Score that meets or exceeds the corresponding Partial QP Threshold.

(3) Beginning in the 2020 QP Performance Period, an eligible clinician is not a Partial QP for a year if:

(i) The APM Entity voluntarily or involuntarily terminates from an Advanced APM before the end of the QP Performance Period; or

(ii) The APM Entity voluntarily or involuntarily terminates from an Advanced APM at a date on which the APM Entity would not bear financial risk for that performance period under the terms of the Advanced APM.

(4) Beginning in the 2020 QP Performance Period, an eligible clinician is not a Partial QP for a year if:

(i) One or more of the APM Entities in which the eligible clinician participates voluntarily or involuntarily terminates from the Advanced APM before the end of the QP Performance Period, and the eligible clinician does not achieve a Threshold Score that meets or exceeds the Partial QP payment amount threshold or Partial QP patient count threshold based on participation in the remaining non-terminating APM Entities; or

(ii) One or more of the APM Entities in which the eligible clinician participates voluntarily or involuntarily terminates from the Advanced APM at a date on which the APM Entity would not bear financial risk under the terms of the Advanced APM, and the eligible clinician does not achieve a Threshold Score that meets or exceeds the Partial QP payment amount threshold or Partial QP patient count threshold based on participation in the remaining non-terminating APM Entities.

(e) *Notification of QP determination.* CMS notifies eligible clinicians determined to be QPs or Partial QPs for a year as soon as practicable following each QP determination date in the QP Performance Period.

(f) *Order of threshold options.* (1) For payment years 2019 and 2020, CMS performs QP determinations for an eligible clinicians only under the Medicare Option described in §414.1435.

(2) For payment years 2021 and later, CMS performs QP determinations for eligible clinicians under the Medicare Option, as described in §414.1435 and, except as specified in paragraphs (d)(2)(i) and (ii) of this section, the All-Payer Combination Option, described in §414.1440.

(i) If CMS determines the eligible clinician to be a QP under the Medicare Option, then CMS does not calculate a

Threshold Score for such eligible clinician under the All-Payer Combination Option.

(ii) If the Threshold Score for an eligible clinician under the Medicare Option is less than the amount specified in §414.1430(b)(2)(ii) and (b)(3)(iii), then CMS does not perform a QP determination for such eligible clinician(s) under the All-Payer Combination Option.

[81 FR 77537, Nov. 4, 2016, as amended at 82 FR 53961, Nov. 16, 2017; 84 FR 63201, Nov. 15, 2019]

§414.1430 Qualifying APM participant determination: QP and partial QP thresholds.

(a) *Medicare Option*—(1) *QP payment amount threshold.* The QP payment amount thresholds are the following values for the indicated payment years:

(i) 2019 and 2020: 25 percent.

(ii) 2021 and 2022: 50 percent.

(iii) 2023 and 2024: 50 percent.

(iv) 2025: 50 percent.

(v) 2026: 50 percent.

(vi) 2027 and later: 75 percent.

(2) *Partial QP payment amount threshold.* The Partial QP payment amount thresholds are the following values for the indicated payment years:

(i) 2019 and 2020: 20 percent.

(ii) 2021 and 2022: 40 percent.

(iii) 2023 and 2024: 40 percent.

(iv) 2025: 40 percent.

(v) 2026: 40 percent.

(vi) 2027 and later: 50 percent.

(3) *QP patient count threshold.* The QP patient count thresholds are the following values for the indicated payment years:

(i) 2019 and 2020: 20 percent

(ii) 2021 and 2022: 35 percent

(iii) 2023 and 2024: 35 percent.

(iv) 2025: 35 percent.

(v) 2026: 35 percent.

(vi) 2027 and later: 50 percent.

(4) *Partial QP patient count threshold.* The Partial QP patient count thresholds are the following values for the indicated payment years:

(i) 2019 and 2020: 10 percent

(ii) 2021 and 2022: 25 percent

(iii) 2023 and 2024: 25 percent.

(iv) 2025: 25 percent.

(v) 2026: 25 percent.

(vi) 2027 and later: 35 percent.

(b) *All-Payer Combination Option*—(1) *QP payment amount threshold.*

(i) The QP payment amount thresholds are the following values for the indicated payment years:

(A) 2021 through 2026: 50 percent.

(B) 2027 and later: 75 percent.

(ii) To meet the QP payment amount threshold under this option, the eligible clinician must also meet a 25 percent QP payment amount threshold under the Medicare Option.

(2) *Partial QP payment amount threshold.* (i) The Partial QP payment amount thresholds are the following values for the indicated payment years:

(A) 2021 through 2026: 40 percent.

(B) 2027 and later: 50 percent.

(ii) To meet the QP payment amount threshold under this option, the eligible clinician must also meet a 20 percent Partial QP payment amount threshold under the Medicare Option.

(3) *QP patient count threshold.* (i) The QP patient count thresholds are the following values for the indicated payment years:

(A) 2021 through 2026: 35 percent.

(B) 2027 and later: 50 percent.

(ii) To meet the QP patient count threshold under this option, the eligible clinician must also meet a 20 percent QP patient count threshold under the Medicare Option.

(4) *Partial QP patient count threshold.* (i) The Partial QP patient count thresholds are the following values for the indicated payment years:

(A) 2021 through 2026: 25 percent.

(B) 2027 and later: 35 percent.

(ii) To meet the Partial QP patient count threshold under this option, the eligible clinician group or eligible clinician must also meet a 10 percent QP patient count threshold under the Medicare Option.

[81 FR 77537, Nov. 4, 2016, as amended at 86 FR 65681, Nov. 19, 2021; 87 FR 70230, Nov. 18, 2022; 88 FR 79539, Nov. 16, 2023; 89 FR 98564, Dec. 9, 2024]

§414.1435 Qualifying APM participant determination: Medicare option.

(a) *Payment amount method.* The Threshold Score for an APM Entity or eligible clinician is calculated as a percent by dividing the value described under paragraph (a)(1) of this section by the value described under paragraph (a)(2) of this section.

(1) *Numerator*. The aggregate of payments for Medicare Part B covered professional services furnished by the APM Entity group to attributed beneficiaries during the QP Performance Period.

(2) *Denominator*. The aggregate of payments for Medicare Part B covered professional services furnished by the APM Entity group to all attribution-eligible beneficiaries during the QP Performance Period.

(3) *Claims and adjustments*. In the calculations under paragraphs (a)(1) and (2) of this section, CMS compiles claims and treats claims adjustments, supplemental service payments, and alternative payment methods in the same manner as described in § 414.1450.

(b) *Patient count method*. The Threshold Score for each eligible clinician in an APM Entity group is calculated as a percent under the patient count method by dividing the value described under paragraph (b)(1) of this section by the value described under paragraph (b)(2) of this section.

(1) *Numerator*. The number of attributed beneficiaries to whom the APM Entity group furnishes Medicare Part B covered professional services or services by a Rural Health Clinic (RHC) or Federally-Qualified Health Center (FQHC) during the QP Performance Period.

(2) *Denominator*. The number of attribution-eligible beneficiaries to whom the APM Entity group or eligible clinician furnish Medicare Part B covered professional services or services by a Rural Health Clinic (RHC) or Federally-Qualified Health Center (FQHC) during the QP Performance Period.

(3) *Unique beneficiaries*. For each APM Entity group, a unique Medicare beneficiary is counted no more than one time for the numerator and no more than one time for the denominator.

(4) *Beneficiaries count multiple times*. Based on attribution under the terms of an Advanced APM, a single Medicare beneficiary may be counted in the numerator or denominator for multiple different APM Entity groups.

(c) *Attribution*.

(1) Attributed beneficiaries are determined from each Advanced APM Entity's attributed beneficiary lists generated by each Advanced APM's specific attribution methodology except as set forth in this paragraph (c)(1).(i) Beneficiaries who have been prospectively attributed to an APM Entity for a QP Performance Period will be excluded from the attribution-eligible beneficiary count for any other APM Entity that is participating in an APM where that beneficiary would be ineligible to be added to the APM Entity's attributed beneficiary list.

(ii) [Reserved]

(2) When operationally feasible, this attributed beneficiary list will be the final beneficiary list used for reconciliation purposes in the Advanced APM.

(3) When it is not operationally feasible to use the final attributed beneficiary list, the attributed beneficiary list will be taken from the Advanced APM's most recently available attributed beneficiary list at the end of the QP Performance Period.

(d) *Use of methods*. CMS calculates Threshold Scores for an APM Entity or eligible clinician as provided by § 414.1425(b) under both the payment amount and patient count methods for each QP Performance Period. CMS then assigns to the eligible clinicians included in the APM Entity group or to the eligible clinician the score that results in the greater QP status. QP status is greater than Partial QP status, and Partial QP status is greater than no QP status.

[81 FR 77537, Nov. 4, 2016, as amended at 82 FR 53963, Nov. 16, 2017; 85 FR 85035, Dec. 28, 2020]

§ 414.1440 Qualifying APM participant determination: All-payer combination option.

(a) *Payments excluded from calculations*. (1) These calculations include a combination of both Medicare payments for Part B covered professional services and all other payments for all other payers, except for payments made by:

(i) The Secretary of Defense for the costs of Department of Defense health care programs;

(ii) The Secretary of Veterans Affairs for the cost of Department of Veterans Affairs health care programs; and

(iii) Under Title XIX in a State in which no Medicaid APM or Medicaid

Medical Home Model that is an Other Payer Advanced APM is available.

(2) Payments and associated patient counts under paragraph (a)(1)(iii) of this section are included in the numerator and denominator as specified in paragraphs (b)(2) and (3) and paragraphs (c)(2) and (3) of this section for an eligible clinician if CMS determines that there is at least one Medicaid APM or Medicaid Medical Home Model that is an Other Payer Advanced APM available in the county where the eligible clinician sees the most patients during the QP Performance Period, and that the eligible clinician is not ineligible to participate in the Other Payer Advanced APM based on their specialty.

(b) *Payment amount method*—(1) *In general.* The Threshold Score for either an APM Entity group or eligible clinician will be calculated by dividing the value described under the numerator by the value described under the denominator as specified in paragraphs (b)(2) and (3) of this section.

(2) *Numerator.* The aggregate amount of all payments from all payers, except those excluded under paragraph (a) of this section, attributable to the eligible clinician or to the APM Entity group under the terms of all Advanced APMs and Other Payer Advanced APMs during the QP Performance Period.

(3) *Denominator.* The aggregate amount of all payments from all payers, except those excluded under paragraph (a) of this section, made to the eligible clinician or to the APM Entity group during the QP Performance Period.

(c) *Patient count method*—(1) *In general.* The Threshold Score for either an APM Entity group or eligible clinician is calculated by dividing the value described under the numerator by the value described under the denominator as specified in paragraphs (c)(2) and (3) of this section.

(2) *Numerator.* The number of unique patients to whom an APM Entity group or eligible clinician furnishes services that are included in the measures of aggregate expenditures used under the terms of all Advanced APMs and Other Payer Advanced APMs during the QP Performance Period.

(3) *Denominator.* The number of unique patients to whom the APM Entity group or eligible clinician furnishes services under all non-excluded payers during the QP Performance Period.

(4) *Unique patients.* CMS may count a single patient in the numerator and/or denominator for multiple different payers.

(d) *QP Determinations under the All-Payer Combination Option.* (1) CMS performs QP determinations following the QP Performance Period using payment amount and/or patient count information submitted from January 1 through each of the respective QP determination dates: March 31, June 30, and August 31. CMS will use data for the same time periods for the Medicare and other payer portions of Threshold Score calculations under the All-Payer Combination Option. CMS will use the payment amount or patient count method, applying the more advantageous of the two for both the Medicare and other payer portions of the Threshold score calculation, regardless of the method used for the Medicare Threshold Score calculation.

(2) An APM Entity may request that CMS make QP determinations at the APM Entity level, an eligible clinician may request that CMS make QP determinations at the eligible clinician level, and an eligible clinician or an APM Entity may request that CMS makes QP determinations at the TIN-level in instances where all clinicians who reassigned billing rights to the TIN are participating in a single APM Entity. CMS makes QP determinations at either the APM Entity, eligible clinician, or TIN level. Eligible clinicians assessed at the eligible clinician level under the Medicare Option at §414.1425(b)(2) will be assessed at the eligible clinician level only under the All-Payer Combination Option. Eligible Clinicians may meet the Medicare and the All-Payer Combination Option thresholds using the payment amount method for both thresholds, the patient account method for both thresholds, or the payment amount method for one threshold and the patient account method for the other threshold.

(3) CMS uses data at the same level for the Medicare and other payer portions of Threshold Score calculations under the All-Payer Combination Option. When QP determinations are made at the eligible clinician or, at the TIN level when all clinicians who have reassigned billing rights to the TIN are included in a single APM Entity; and if the Medicare Threshold score for the APM Entity group is higher than when calculated for the eligible clinician or TIN, CMS makes QP determinations using a weighted Medicare Threshold Score that is factored into an All-Payer Combination Option Threshold Score.

(e) *Information used to calculate Threshold Scores under the All-Payer Combination Option.* (1) An APM Entity or eligible clinician may request as set forth in § 414.1445(b)(2) that CMS determine whether a payment arrangement in which they participate meets the Other Payer Advanced APM criteria and may demonstrate participation in an Other Payer Advanced APM determined as a result of a request made in § 414.1445(a)(1) or (b)(1) in a form and manner specified by CMS.

(2) To request a QP determination under the All-Payer Combination Option, for each payment arrangement submitted as set forth in paragraph (e)(1) of this section, the APM Entity or eligible clinician must include:

(i) The amount of revenue for services furnished through the payment arrangement, the total revenue received from all payers except those excluded as provided in paragraph (a)(2) of this section, the number of patients furnished any service through the arrangement, and the total number of patients furnished any services, except those excluded as provided in paragraph (a)(2) of this section; and

(ii) In the case of an APM Entity or eligible clinician requesting a QP determination under either a Medicaid Medical Home Model or Aligned Other Payer Medical Home Model pursuant to the criteria in § 414.1420, information specified by CMS for purposes of compliance with the 50 eligible clinician limit specified at § 414.1420(d)(8).

(3) An APM Entity or eligible clinician must submit the information specified in paragraph (e)(2) of this section in a form and manner specified by CMS. An APM Entity or eligible clinician may submit the information specified in paragraph (e)(2) of this section for the following periods of time in the relevant QP Performance Period: January 1 through March 31, January 1 through June 30, and January 1 through August 31.

(4) To request a QP determination under the All-Payer Combination Option, an APM Entity or eligible clinician must submit this information to CMS no later than the QP Determination Submission Deadline, which is December 1 of the calendar year that is 2 years prior to the payment year.

(f) *Requirement to submit sufficient information*—(1) *Sufficient Information.* CMS makes a QP determination with respect to the eligible clinician under the All-Payer Combination Option only if the APM Entity or eligible clinician submits the information required under paragraph (e) of this section sufficient for CMS to assess the eligible clinician under either the payment amount or patient count as described in paragraphs (b) and (c) of this section.

(2) *Certification.* The APM Entity or eligible clinician who submits information to request a QP determination under the All-Payer Combination Option must certify that the information submitted to CMS is true, accurate, and complete. Such certification must accompany the submission and be made at the time of submission. In the case of information submitted by an APM Entity, the certification must be made by an individual with the authority to bind the APM Entity.

(g) *Notification of QP determination.* CMS notifies eligible clinicians determined to be QPs or Partial QPs for a year as soon as practicable after QP calculations are conducted.

[81 FR 77537, Nov. 4, 2016, as amended at 82 FR 53963, Nov. 16, 2017; 83 FR 60091, Nov. 23, 2018; 87 FR 70230, Nov. 18, 2022]

§ 414.1445 Determination of other payer advanced APMs.

(a) *Determination of Medicaid APMs.* Beginning in 2018, and each year thereafter, at a time determined by CMS, a state, APM Entity, or eligible clinician may request, in a form and manner

specified by CMS, that CMS determine whether a payment arrangement authorized under Title XIX is either a Medicaid APM or a Medicaid Medical Home Model that meets the Other Payer Advanced APM criteria as set forth in §414.1420. A state must submit its request by April 1 of the year prior to the relevant QP Performance Period, and an APM Entity or eligible clinician must submit its request by November 1 of the year prior to the relevant QP Performance Period. CMS will not determine that a payment arrangement is a Medicaid APM or Medicaid Medical Home Model that meets the Other Payer Advanced APM criteria as set forth in §414.1420 for a year after the relevant QP Performance Period.

(b) *Determination of Other Payer Advanced APMs*—(1) *Payer initiated Other Payer Advanced APM determination process.* Beginning in 2018, and each year thereafter, at a time determined by CMS a payer with a Medicare Health Plan payment arrangement may request, in a form and manner specified by CMS, that CMS determine whether a Medicare Health Plan payment arrangement meets the Other Payer Advanced APM criteria set forth in §414.1420. A payer with a Medicare Health Plan payment arrangement must submit its requests by the annual Medicare Advantage bid deadline of the year prior to the relevant QP Performance Period. A Medicare Health Plan is a Medicare Advantage plan, a section 1876 cost plan, a PACE organization operated under section 1894, and any similar plan which provides Medicare benefits under demonstration or waiver authority (other than an APM as defined in section 1833(z)(3)(C) of the Act).

(2) *Eligible clinician initiated Other Payer Advanced APM determination process.* Except as provided by paragraph (a) of this section, at a time specified by CMS, an APM Entity or eligible clinician may request that CMS determine whether a payment arrangement meets the Other Payer Advanced APM criteria as set forth in §414.1420 in a form and manner specified by CMS. An APM Entity or eligible clinician must submit requests by December 1 of the calendar year of the relevant QP Performance Period.

(c) *Information required for Other Payer Advanced APM determinations.* (1) In order to make an Other Payer Advanced APM determination as set forth in paragraphs (a) and (b) of this section, a payer, APM Entity, or eligible clinician must submit the information specified by CMS in a form and manner specified by CMS. If a payer, APM Entity, or eligible clinician fails to submit the information required, CMS will not make a determination as to whether a payment arrangement meets the Other Payer Advanced APM criteria as set forth in §414.1420.

(2) If an eligible clinician submits information showing that a payment arrangement requires that the eligible clinician must use CEHRT as defined in §414.1305 to document and communicate clinical care, CMS will presume that the CEHRT criterion in §414.1420(b) is satisfied for that payment arrangement.

(i) Based on the submission by an eligible clinician or payer of evidence that CMS determines sufficiently demonstrates that CEHRT is used as specified in §414.1420(b) by participants in the payment arrangement, CMS will consider the CEHRT criterion in §414.1420(b) is satisfied for that payment arrangement.

(ii) [Reserved]

(3) If a payment arrangement has no outcome measure, the payer, APM Entity, or eligible clinician requesting a determination of whether a payment arrangement meets the Other Payer Advanced APM criteria must certify that there is no available or applicable outcome measure on the MIPS measure list.

(d) *Certification.* A payer, APM Entity, or eligible clinician that submits information pursuant to paragraph (c) of this section must certify that the information it submitted to CMS is true, accurate, and complete. Such certification must accompany the submission and be made at the time of submission. In the case of information submitted by a payer or an APM Entity, the certification must be made by an individual with the authority to bind the payer or the APM Entity.

(e) *Timing of Other Payer Advanced APM determinations.* CMS makes Other Payer Advanced APM determinations

prior to making QP determinations under § 414.1440.

(f) *Notification of Other Payer Advanced APM determinations.* CMS makes Other Payer Advanced APM determinations and notifies the requesting payer, APM Entity, or eligible clinician of such determinations as soon as practicable following the relevant submission deadline.

[82 FR 53964, Nov. 16, 2017, as amended at 83 FR 60091, Nov. 23, 2018]

§ 414.1450 APM incentive payment.

(a) *In general.* (1) CMS makes a lump sum payment to QPs in the amount described in paragraph (b) of this section in the manner described in paragraphs (d) and (e) of this section.

(i) For payment years 2019 through 2026, CMS makes a lump sum payment to QPs in the amount described in paragraph (b) of this section in the manner described in paragraphs (d) and (e) of this section.

(ii) [Reserved]

(2) CMS provides notice of the amount of the APM Incentive Payment to QPs as soon as practicable following the calculation and validation of the APM Incentive Payment amount, but in any event no later than 1 year after the incentive payment base period.

(b) *APM Incentive Payment amount.*

(1) For payment years 2019 through 2024, the amount of the APM Incentive Payment is equal to 5 percent, with respect to payment year 2025, 3.5 percent, or with respect to payment year 2026, 1.88 percent of the estimated aggregate payments for covered professional services as defined in section 1848(k)(3)(A) of the Act furnished during the calendar year immediately preceding the payment year. CMS uses the paid amounts on claims for covered professional services to calculate the estimated aggregate payments on which CMS will calculate the APM Incentive Payment.

(2) The estimated aggregate payment amount for covered professional services includes all such payments to any and all of the TIN/NPI combinations associated with the NPI of the QP.

(3) In calculating the estimated aggregate payment amount for a QP, CMS uses claims submitted with dates of service from January 1 through December 31 of the incentive payment base period, and processing dates of January 1 of the base period through March 31 of the subsequent payment year.

(4) The payment adjustment amounts, negative or positive, as described in sections 1848(m), (o), (p), and (q) of the Act are not included in calculating the APM Incentive Payment amount.

(5) Incentive payments made to eligible clinicians under sections 1833(m), (x), and (y) of the Act are not included in calculating the APM Incentive Payment amount.

(6) Financial risk payments such as shared savings payments or net reconciliation payments are excluded from the amount of covered professional services in calculating the APM Incentive Payment amount.

(7) Supplemental service payments in the amount of covered professional services are included in calculating the APM Incentive Payment amount according to this paragraph (b). Supplemental service payments are included in the amount of covered professional services when calculating the APM Incentive Payment amount when the supplemental service payment meets the following four criteria:

(i) Is payment for services that constitute physicians services authorized under section 1832(a) and defined under section 1861(s) of the Act.

(ii) Is made for only Part B services under the criterion in paragraph (b)(9)(i) of this section.

(iii) Is directly attributable to services furnished to an individual beneficiary.

(iv) Is directly attributable to an eligible clinician, including an eligible clinician that is a group of individual eligible clinicians.

(8) For payment amounts that are affected by a cash flow mechanism, the payment amounts that would have occurred if the cash flow mechanism were not in place are used in calculating the APM Incentive Payment amount.

(c) *APM Incentive Payment recipient.* CMS will pay the APM Incentive Payment amount for a payment year to a solvent TIN or TINs associated with the QP, identified based on Medicare Part B claims submitted for covered

professional services during the base period or payment year, according to this section. If no TIN or TINs with which the QP has an association can be identified at a step, CMS will move to the next and successive steps listed in paragraphs (c)(1) through (8) of this section until CMS identifies a TIN or TINs with which the QP is associated, and to which CMS will make the APM Incentive Payment. If more than one TIN is identified at a step, the payment will be proportionately divided among the TINs according to the relative total paid amounts for Part B covered professional services paid to each TIN for services provided during the base year.

(1) Any TIN associated with the QP that, during the QP Performance Period, is associated with an APM Entity through which the eligible clinician achieved QP status;

(2) Any TIN associated with the QP that, during the APM Incentive Payment base period, is associated with an APM Entity through which the eligible clinician achieved QP status;

(3) Any TIN associated with the QP that, during the APM Incentive Payment base period, is associated with an APM Entity participating in an Advanced APM through which the eligible clinician had achieved QP status;

(4) Any TIN associated with the QP that, during the APM Incentive Payment base period, participated in an APM Entity in an Advanced APM;

(5) Any TIN associated with the QP that, during the APM Incentive Payment base period, participated with an APM Entity in any track of the APM through which the eligible clinician achieved QP status;

(6) Any TIN associated with the QP that, during the APM Incentive Payment base period, participated with an APM Entity in an APM other than an Advanced APM;

(7) Any TIN associated with the QP that submitted a claim for covered professional services furnished by the QP during the APM Incentive Payment base period, even if such TIN has no relationship to any APM Entity or APM; then

(8) If we have not identified any TIN associated with the QP to which we can make the APM Incentive Payment, we will attempt to contact the QP via a public notice to request their Medicare payment information. The QPs identified in the public notice, or any other eligible clinicians who believe that they are entitled to an APM Incentive Payment must then notify CMS of their claim as directed in the public notice by September 1 of the payment year, or 60 days after CMS announces that initial payments for the year have been made, whichever is later. After that time, any claims by a QP to an APM Incentive Payment will be forfeited for such payment year.

(d) *Timing of the APM Incentive Payment.* APM Incentive Payments made under this section are made as soon as practicable following the calculation and validation of the APM Incentive Payment amount, but in any event no later than 1 year after the incentive payment base period.

(e) *Treatment of APM Incentive Payment amount in APMs.* (1) APM Incentive Payments made under this section are not included in determining actual expenditures under an APM.

(2) APM Incentive Payments made under this section are not included in calculations for the purposes of rebasing benchmarks in an APM.

(f) *Treatment of APM Incentive Payment for other Medicare incentive payments and payment adjustments.* APM Incentive Payments made under this section will not be included in determining the amount of incentive payment made to eligible clinicians under section 1833(m), (x), and (y) of the Act.

[81 FR 77537, Nov. 4, 2016, as amended at 85 FR 85035, Dec. 28, 2020; 86 FR 65681, Nov. 19, 2021; 87 FR 70230, Nov. 18, 2022; 88 FR 79539, Nov. 16, 2023; 89 FR 98564, Dec. 9, 2024]

§414.1455 Limitation on review.

(a) There is no right to administrative or judicial review under sections 1869, 1878, or otherwise, of the Act of the following:

(1) The determination that an eligible clinician is a QP or Partial QP under §414.1425.

(2) The determination of the amount of the APM Incentive Payment under §414.1450, including any estimation as part of such determination.

(b)(1) An eligible clinician or APM Entity may request targeted review of

a QP or Partial QP determination only if they believe in good faith that, due to a CMS clerical error, an eligible clinician was omitted from a Participation List.

(2) If CMS determines that there was such a clerical error, if the QP determination for the eligible clinician would have been made at the APM Entity level under §414.1425(b)(1), CMS will assign to the eligible clinician the most favorable QP status that was determined at the APM Entity level on any snapshot dates for the relevant QP Performance Period on which the eligible clinician participated in the APM Entity.

(3) The process for targeted review is as follows:

(i) An eligible clinician or APM Entity may submit a request for targeted review.

(ii) All requests for targeted review must be submitted during the targeted review request submission period, which is a 60-day period that begins with the publication of MIPS performance feedback as described at §414.1385(a)(2). The targeted review request submission period may be extended as specified by CMS.

(iii) All requests for targeted review must be submitted in accordance with the form and manner specified by CMS.

(iv) A request for targeted review may be denied if the request is duplicative of another request for a targeted review; the request is not submitted during the targeted review request submission period; or the request is outside the scope of targeted review specified in this section. If the targeted review request is denied, CMS will make no changes to the QP status of the eligible clinician for whom targeted review was requested.

(v) CMS will respond to each timely submitted request for targeted review.

(vi) A request for targeted review may include additional information in support of the request at the time it is submitted. CMS may also request additional information from the requestor. If CMS requests additional information relating to the eligible clinician or the APM Entity group that is the subject of a request for targeted review, responsive information must be provided and received by CMS within 30 days of the request. If CMS does not receive a timely response to a request for additional information, CMS may make a final decision on the targeted review request based on the information available.

(vii) If targeted review requests reveal a pattern of CMS error with impacts that extend beyond the scope of eligible clinicians or APM Entities that submitted such targeted review requests, CMS may adjust the QP status of other affected eligible clinicians as provided in paragraph (b)(2) of this section.

(viii) Decisions on a targeted review request are final, and not subject to any further administrative or judicial review in accordance with paragraph (a) of this section.

[85 FR 85035, Dec. 28, 2020]

§414.1460 Monitoring and program integrity.

(a) *Vetting eligible clinicians.* Prior to payment of the APM Incentive Payment, CMS determines if eligible clinicians were in compliance with all Medicare conditions of participation and the terms of the relevant Advanced APMs in which they participated during the QP Performance Period. A determination under this provision is not binding for other purposes.

(b) *Rescinding QP Determinations.* CMS may rescind a QP determination if:

(1) Any of the information CMS relied on in making the QP determination was inaccurate or misleading.

(2) The QP is terminated from an Advanced APM or Other Payer Advanced APM during the QP Performance Period or Incentive Payment Base Period; or

(3) The QP is found to be in violation of the terms of the relevant Advanced APM or any relevant Federal, State, or tribal statute or regulation during the QP Performance Period or Incentive Payment Base Period.

(c) *Information submitted for All-Payer Combination Option.* Information submitted by payers, APM Entities, or eligible clinicians for purposes of the All-Payer Combination Option may be subject to audit by CMS.

(d) *Reducing, denying, and recouping of APM Incentive Payments.* (1) CMS

may reduce or deny an APM Incentive Payment to an eligible clinician.

(i) Who CMS determines is not in compliance with all Medicare conditions of participation and the terms of the relevant Advanced APM in which they participate during the QP Performance Period or Incentive Payment Base Period;

(ii) Who is terminated by an APM or Advanced APM during the QP Performance Period or Incentive Payment Base Period; or

(iii) Whose APM Entity is terminated by an APM or Advanced APM for noncompliance with any Medicare condition of participation or the terms of the relevant Advanced APM in which they participate during the QP Performance Period or Incentive Payment Base Period.

(2) CMS may reopen, revise, and recoup an APM Incentive Payment that was made in error in accordance with procedures similar to those set forth at §§405.980 through §405.986 and §§405.370 through 405.379 of this chapter or as established under the relevant APM.

(e) *Maintenance of records.* (1) A payer that submits information to CMS under §414.1445 for assessment under the All-Payer Combination Option must maintain such books, contracts, records, documents, and other evidence as necessary to enable the audit of an Other Payer Advanced APM determination. Such information and supporting documentation must be maintained for a period of 6 years after submission.

(2) An APM Entity or eligible clinician that submits information to CMS under §414.1445 for assessment under the All-Payer Combination Option or §414.1440 for QP determinations must maintain such books, contracts, records, documents, and other evidence as necessary to enable the audit of an Other Payer Advanced APM determination, QP determinations, and the accuracy of APM Incentive Payments for a period of 6 years from the end of the QP Performance Period or from the date of completion of any audit, evaluation, or inspection, whichever is later.

(3) A payer, APM Entity or eligible clinician that submits information to CMS under §§414.1440 or 414.1445 must provide such information and supporting documentation to CMS upon request.

(f) *OIG authority.* None of the provisions of this part limit or restrict OIG's authority to audit, evaluate, investigate, or inspect the Advanced APM Entity, its eligible clinicians, and other individuals or entities performing functions or services related to its APM activities.

[81 FR 77537, Nov. 4, 2016, as amended at 82 FR 53965, Nov. 16, 2017]

§414.1465 Physician-focused payment models.

(a) *Definition.* A physician-focused payment model (PFPM) is an Alternative Payment Model:

(1) In which Medicare is a payer;

(2) In which eligible clinicians that are eligible professionals as defined in section 1848(k)(3)(B) of the Act are participants and play a core role in implementing the APM's payment methodology; and

(3) Which targets the quality and costs of services that eligible professionals participating in the Alternative Payment Model provide, order, or can significantly influence.

(b) *Criteria.* In carrying out its review of physician-focused payment model proposals, the PTAC must assess whether the physician-focused payment model meets the following criteria for PFPMs sought by the Secretary. The Secretary seeks PFPMs that:

(1) *Incentives: Pay for higher-value care.* (i) Value over volume: provide incentives to practitioners to deliver high-quality health care.

(ii) Flexibility: provide the flexibility needed for practitioners to deliver high-quality health care.

(iii) Quality and Cost: are anticipated to improve health care quality at no additional cost, maintain health care quality while decreasing cost, or both improve health care quality and decrease cost.

(iv) Payment methodology: pay APM Entities with a payment methodology designed to achieve the goals of the PFPM Criteria. Addresses in detail through this methodology how Medicare, and other payers if applicable, pay APM Entities, how the payment

methodology differs from current payment methodologies, and why the PFPM cannot be tested under current payment methodologies.

(v) Scope: aim to broaden or expand the CMS APM portfolio by addressing an issue in payment policy in a new way or including APM Entities whose opportunities to participate in APMs have been limited.

(vi) Ability to be evaluated: have evaluable goals for quality of care, cost, and any other goals of the PFPM.

(2) *Care delivery improvements: Promote better care coordination, protect patient safety, and encourage patient engagement.* (i) Integration and Care Coordination: encourage greater integration and care coordination among practitioners and across settings where multiple practitioners or settings are relevant to delivering care to the population treated under the PFPM.

(ii) Patient Choice: encourage greater attention to the health of the population served while also supporting the unique needs and preferences of individual patients.

(iii) Patient Safety: aim to maintain or improve standards of patient safety.

(3) *Information Enhancements: Improving the availability of information to guide decision-making.* (i) Health Information Technology: encourage use of health information technology to inform care.

(ii) [Reserved]

Subpart P—Home Infusion Therapy Services Payment

SOURCE: 84 FR 60643, Nov. 8, 2019, unless otherwise noted.

CONDITIONS FOR PAYMENT

§ 414.1500 Basis, purpose, and scope.

This subpart implements section 1861(iii) of the Act with respect to the requirements that must be met for Medicare payment to be made for home infusion services furnished to eligible beneficiaries.

§ 414.1505 Requirement for payment.

In order for home infusion therapy services to qualify for payment under the Medicare program the services must be furnished to an eligible beneficiary by, or under arrangements with, a qualified home infusion therapy supplier that meets the following requirements:

(a) The health and safety standards for qualified home infusion therapy suppliers at § 486.520(a) through (c) of this chapter.

(b) All requirements set forth in §§ 414.1510 through 414.1550.

(c) The home infusion therapy supplier must be enrolled in Medicare consistent with the provisions of § 424.68 and part 424, subpart P of this chapter.

[84 FR 60643, Nov. 8, 2019, as amended at 85 FR 70355, Nov. 4, 2020]

§ 414.1510 Beneficiary qualifications for coverage of services.

To qualify for Medicare coverage of home infusion therapy services, a beneficiary must meet each of the following requirements:

(a) *Under the care of an applicable provider.* The beneficiary must be under the care of an applicable provider, as defined in section 1861(iii)(3)(A) of the Act as a physician, nurse practitioner, or physician assistant.

(b) *Under a physician plan of care.* The beneficiary must be under a plan of care that meets the requirements for plans of care specified in § 414.1515.

§ 414.1515 Plan of care requirements.

(a) *Contents.* The plan of care must contain those items listed in § 486.520(b) of this chapter that specify the standards relating to a plan of care that a qualified home infusion therapy supplier must meet in order to participate in the Medicare program.

(b) *Physician's orders.* The physician's orders for services in the plan of care must specify at what frequency the services will be furnished, as well as the discipline that will furnish the ordered professional services. Orders for care may indicate a specific range in frequency of visits to ensure that the most appropriate level of services is furnished.

(c) *Plan of care signature requirements.* The plan of care must be signed and dated by the ordering physician prior to submitting a claim for payment. The ordering physician must sign and date the plan of care upon any changes to the plan of care.

PAYMENT SYSTEM

§414.1550 Basis of payment.

(a) *General rule.* For home infusion therapy services furnished on or after January 1, 2021, Medicare payment is made on the basis of 80 percent of the lesser of the following:

(1) The actual charge for the item or service.

(2) The fee schedule amount for the item or service, as determined in accordance with the provisions of this section.

(b) *Unit of single payment.* A unit of single payment is made for items and services furnished by a qualified home infusion therapy supplier per payment category for each infusion drug administration calendar day, as defined at §486.505 of this chapter.

(c) *Initial establishment of the payment amounts.* In calculating the initial single payment amounts for CY 2021, CMS determined such amounts using the equivalent to 5 hours of infusion services in a physician's office as determined by codes and units of such codes under the annual fee schedule issued under section 1848 of the Act as follows:

(1) *Category 1.* (i) Includes certain intravenous infusion drugs for therapy, prophylaxis, or diagnosis, including antifungals and antivirals; inotropic and pulmonary hypertension drugs; pain management drugs; chelation drugs; and other intravenous drugs as added to the durable medicare equipment local coverage determination (DME LCD) for external infusion pumps.

(ii) Payment equals 1 unit of 96365 plus 4 units of 96366.

(2) *Category 2.* (i) Includes certain subcutaneous infusion drugs for therapy or prophylaxis, including certain subcutaneous immunotherapy infusions.

(ii) Payment equals 1 unit of 96369 plus 4 units of 96370.

(3) *Category 3.* (i) Includes intravenous chemotherapy infusions, including certain chemotherapy drugs and biologicals.

(ii) Payment equals 1 unit of 96413 plus 4 units of 96415.

(4) *Initial visit.* (i) For each of the three categories listed in paragraphs (c)(1) through (3) of this section, the payment amounts are set higher for the first visit by the qualified home infusion therapy supplier to initiate the furnishing of home infusion therapy services in the patient's home and lower for subsequent visits in the patient's home. The difference in payment amounts is a percentage based on the relative payment for a new patient rate over an existing patient rate using the annual physician fee schedule evaluation and management payment amounts for a given year and calculated in a budget neutral manner.

(ii) The first visit payment amount is subject to the following requirements if a patient has previously received home infusion therapy services:

(A) The previous home infusion therapy services claim must include a patient status code to indicate a discharge.

(B) If a patient has a previous claim for HIT services, the first visit home infusion therapy services claim subsequent to the previous claim must show a gap of more than 60 days between the last home infusion therapy services claim and must indicate a discharge in the previous period before a HIT supplier may submit a home infusion therapy services claim for the first visit payment amount.

(d) *Required payment adjustments.* The single payment amount represents payment in full for all costs associated with the furnishing of home infusion therapy services and is subject to the following adjustments:

(1) An adjustment for a geographic wage index and other costs that may vary by region, using an appropriate wage index based on the site of service of the beneficiary.

(2) Beginning in 2022, an annual increase in the single payment amounts from the prior year by the percentage increase in the Consumer Price Index (CPI) for all urban consumers (United States city average) for the 12-month period ending with June of the preceding year.

(3)(i) An annual reduction in the percentage increase described in paragraph (d)(2) of this section by the productivity adjustment described in section 1886(b)(3)(B)(xi)(II) of the Act.

(ii) The application of the paragraph (c)(3)(i) of this section may result in the both of the following:

(A) A percentage being less than zero for a year.

(B) Payment being less than the payment rates for the preceding year.

(e) *Medical review.* All payments under this system may be subject to a medical review adjustment reflecting the following:

(1) Beneficiary eligibility.

(2) Plan of care requirements.

(3) Medical necessity determinations.

Subpart Q—Payment for Lymphedema Compression Treatment Items

SOURCE: 88 FR 77876, Nov. 13, 2023, unless otherwise noted.

§ 414.1600 Purpose and definitions.

(a) *Purpose.* This subpart implements section 1834(z) of the Act and establishes procedures for making benefit category determinations and payment determinations for lymphedema compression treatment items.

(b) *Definitions.* For purposes of this subpart the following definitions apply:

Benefit category determination means a national determination regarding whether an item or service meets the Medicare definition of lymphedema compression treatment item at section 1861(mmm) of the Act and the rules of this subpart and is not otherwise excluded from coverage by statute.

Lymphedema compression treatment item means an item as described in § 410.2.

§ 414.1650 Payment basis for lymphedema compression treatment items.

(a) *General payment rule.* For items furnished on or after January 1, 2024, Medicare pays for lymphedema compression treatment items on the basis of 80 percent of the lesser of—

(1) The actual charge for the item; or

(2) The payment amount for the item, as determined in accordance with paragraph (b) of this section.

(b) *Payment amounts.* The payment amounts for covered lymphedema compression treatment items paid for under this subpart are established based on one of the following:

(1) If payment amounts are available from Medicaid state plans, then 120 percent of the average of the Medicaid payment amounts.

(2) If payment amounts are not available from Medicaid state plans, then 100 percent of the average of average internet retail prices and payment amounts from TRICARE (Department of Defense).

(3) If payment amounts are not available from Medicaid state plans or TRICARE, then 100 percent of average internet retail prices.

(c) *Updates to payment amounts.* The payment amounts for covered lymphedema compression treatment items established in accordance with paragraph (b) of this section are increased on an annual basis beginning on January 1 of the year subsequent to the year in which the payment amounts are initially established based on the percent change in the Consumer Price Index for all Urban Consumers (CPI–U) for the 12-month period ending with June of the previous year.

§ 414.1660 Continuity of pricing when HCPCS codes are divided or combined.

(a) *General rule.* If HCPCS codes for lymphedema compression treatment items are divided or combined, the payment amounts for the old codes are mapped to the new codes to ensure continuity of pricing.

(b) *Mapping of payment amounts.* (1) If there is a single code that describes two or more distinct complete items (for example, two different but related or similar items), and separate codes are subsequently established for each item, then the payment amounts that applied to the single code continue to apply to each of the items described by the new codes.

(2) If the codes for several different items are combined into a single code, then the payment amounts for the new code are established using the average (arithmetic mean), weighted by allowed services, of the payment amounts for the formerly separate codes.

§414.1670 Procedures for making benefit category determinations and payment determinations for new lymphedema compression treatment items.

The procedures for determining whether new items and services addressed in a request for a HCPCS Level II code(s) or by other means meet the definition of items and services paid for in accordance with this subpart are as follows:

(a) At the start of a HCPCS coding cycle, CMS performs an analysis to determine if the item is statutorily excluded from coverage under Medicare under section 1862 of the Act.

(1) If not excluded by statute, then CMS determines whether the item is a lymphedema compression treatment item as defined under section 1861(mmm) of the Act.

(2) If excluded by statute, the analysis is concluded.

(b) If a preliminary determination is made that the item is a lymphedema compression treatment item, CMS makes a preliminary payment determination for the item or service.

(c) CMS posts preliminary benefit category determinations and payment determinations on *CMS.gov* approximately 2 weeks prior to a public meeting.

(d) After consideration of public consultation provided at a public meeting on preliminary benefit category determinations and payment determinations for items, CMS establishes the benefit category determinations and payment determinations for items through program instructions.

§414.1680 Frequency limitations.

(a) *General rule.* With the exception of replacements of items that are lost, stolen, or irreparably damaged, or if needed due to a change in the patient's medical or physical condition, no payment may be made for gradient compression garments or wraps with adjustable straps furnished other than at the frequencies established in paragraphs (b) and (c) of this section.

(b) *Initial furnishing of lymphedema compression treatment items.* The following frequency limitations apply to items initially furnished to the beneficiary if determined to be reasonable and necessary for the treatment of lymphedema:

(1) Three units of daytime gradient compression garments or wraps with adjustable straps per affected extremity or part of the body.

(2) Two garments for nighttime use per affected extremity or part of the body.

(c) *Replacements of lymphedema compression treatment items.* The following frequency limitations apply to replacements of lymphedema compression treatment items if determined to be reasonable and necessary for the treatment of lymphedema:

(1) Payment for the replacement of gradient compression garments or wraps with adjustable straps per each affected extremity or part of the body can be made once every 6 months.

(2) Payment for the replacement of nighttime garments per each affected extremity or part of the body can be made once every 2 years.

(d) *Replacements of lymphedema compression bandaging systems or supplies.* Specific frequency limitations are not established for these items. Determinations regarding the quantity of compression bandaging supplies needed by each beneficiary are made by the DME MAC that processes the claims for the supplies.

§414.1690 Application of competitive bidding information.

The payment amounts for lymphedema compression treatment items under §414.1650(b) may be adjusted using information on the payment determined as part of implementation of the programs under subpart F using the methodologies set forth at §414.210(g).

Subpart R—Home Intravenous Immunoglobulin (IVIG) Items and Services Payment

SOURCE: 88 FR 77877, Nov. 13, 2023, unless otherwise noted.

§414.1700 Basis of payment.

(a) *General rule.* For home intravenous immunoglobulin (IVIG) items or services furnished on or after January 1, 2024, Medicare payment is made

on the basis of 80 percent of the lesser of the following:

(1) The actual charge for the item or service.

(2) The fee schedule amount for the items and services, as determined in accordance with the provisions of this section.

(b) *Per visit amount.* A single payment amount is made for items and services furnished by a DME supplier per visit.

(c) *Initial establishment of the payment amount.* In establishing the initial per visit IVIG items and services payment amount for CY 2024, CMS used the CY 2023 bundled payment rate under the IVIG Demonstration updated by the home health payment percentage update for CY 2024.

(d) *Annual payment adjustment.* The per visit payment amount represents payment in full for all costs associated with the furnishing of home IVIG items and services and is subject to the following adjustment:

(1) Beginning in 2025, an annual increase in the per-visit payment amount from the prior year by the home health update percentage increase for the current calendar year.

(2) [Reserved]

PART 415—SERVICES FURNISHED BY PHYSICIANS IN PROVIDERS, SUPERVISING PHYSICIANS IN TEACHING SETTINGS, AND RESIDENTS IN CERTAIN SETTINGS

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AUTHORITY: 42 U.S.C. 1302 and 1395hh.

SOURCE: 60 FR 63178, Dec. 8, 1995, unless otherwise noted.

Subpart A—General Provisions

§ 415.1 Basis and scope.

(a) *Basis.* This part is based on the provisions of the following sections of the Act: Section 1848 establishes a fee

schedule for payment for physician services. Section 1861(q) specifies what is included in the term ''physician services'' covered under Medicare. Section 1862(a)(14) sets forth the exclusion of nonphysician services furnished to hospital patients under Part B of Medicare. Section 1886(d)(5)(B) provides for a payment adjustment under the prospective payment system for the operating costs of inpatient hospital services furnished to Medicare beneficiaries in cost reporting periods beginning on or after October 1, 1983, to account for the indirect costs of medical education. Section 1886(h) establishes the methodology for Medicare payment of the cost of direct GME activities.

(b) *Scope.* This part sets forth rules for fiscal intermediary payments to providers for physician services, Part B carrier payments for physician services to beneficiaries in providers, physician services in teaching settings, and services of residents.

Subpart B—Fiscal Intermediary Payments to Providers for Physician Services

§ 415.50 Scope.

This subpart sets forth rules for payment by fiscal intermediaries to providers for services furnished by physicians. Payment for covered services is made either under the prospective payment system (PPS) to PPS-participating providers in accordance with part 412 of this chapter or under the reasonable cost method to non-PPS participating providers in accordance with part 413 of this chapter.

§ 415.55 General payment rules.

(a) *Allowable costs.* Except as specified otherwise in §§ 413.102 of this chapter (concerning compensation of owners), 415.60 (concerning allocation of physician compensation costs), and 415.162 (concerning payment for physician services furnished to beneficiaries in teaching hospitals), costs a provider incurs for services of physicians are allowable only if the following conditions are met:

(1) The services do not meet the conditions in § 415.102(a) regarding fee schedule payment for services of physicians to a beneficiary in a provider.

(2) The services include a surgeon's supervision of services of a qualified anesthetist, but do not include physician availability services, except for reasonable availability services furnished for emergency rooms and the services of standby surgical team physicians.

(3) The provider has incurred a cost for salary or other compensation it furnished the physician for the services.

(4) The costs incurred by the provider for the services meet the requirements in § 413.9 of this chapter regarding costs related to patient care.

(5) The costs do not include supervision of interns and residents unless the provider elects reasonable cost payment as specified in § 415.160, or any other costs incurred in connection with an approved GME program that are payable under §§ 413.75 through 413.83 of this chapter.

(b) *Allocation of allowable costs.* The provider must follow the rules in § 415.60 regarding allocation of physician compensation costs to determine its costs of services.

(c) *Limits on allowable costs.* The intermediary must apply the limits on compensation set forth in § 415.70 to determine its payments to a provider for the costs of services.

[60 FR 63178, Dec. 8, 1995, as amended at 70 FR 47490, Aug. 12, 2005]

§ 415.60 Allocation of physician compensation costs.

(a) *Definition.* For purposes of this subpart, *physician compensation costs* means monetary payments, fringe benefits, deferred compensation, and any other items of value (excluding office space or billing and collection services) that a provider or other organization furnishes a physician in return for the physician services. Other organizations are entities related to the provider within the meaning of § 413.17 of this chapter or entities that furnish services for the provider under arrangements within the meaning of the Act.

(b) *General rule.* Except as provided in paragraph (d) of this section, each provider that incurs physician compensation costs must allocate those costs, in proportion to the percentage of total time that is spent in furnishing each category of services, among—

(1) Physician services to the provider (as described in § 415.55);

(2) Physician services to patients (as described in § 415.102); and

(3) Activities of the physician, such as funded research, that are not paid under either Part A or Part B of Medicare.

(c) *Allowable physician compensation costs.* Only costs allocated to payable physician services to the provider (as described in § 415.55) are allowable costs to the provider under this subpart.

(d) *Allocation of all compensation to services to the provider.* Generally, the total physician compensation received by a physician is allocated among all services furnished by the physician, unless—

(1) The provider certifies that the compensation is attributable solely to the physician services furnished to the provider; and

(2) The physician bills all patients for the physician services he or she furnishes to them and personally receives the payment from or on behalf of the patients. If returned directly or indirectly to the provider or an organization related to the provider within the meaning of § 413.17 of this chapter, these payments are not compensation for physician services furnished to the provider.

(e) *Assumed allocation of all compensation to beneficiary services.* If the provider and physician agree to accept the assumed allocation of all the physician services to direct services to beneficiaries as described under § 415.102(a), CMS does not require a written allocation agreement between the physician and the provider.

(f) *Determination and payment of allowable physician compensation costs.* (1) Except as provided under paragraph (e) of this section, the intermediary pays the provider for these costs only if—

(i) The provider submits to the intermediary a written allocation agreement between the provider and the physician that specifies the respective amounts of time the physician spends in furnishing physician services to the provider, physician services to patients, and services that are not payable under either Part A or Part B of Medicare; and

(ii) The compensation is reasonable in terms of the time devoted to these services.

(2) In the absence of a written allocation agreement, the intermediary assumes, for purposes of determining reasonable costs of the provider, that 100 percent of the physician compensation cost is allocated to services to beneficiaries as specified in paragraph (b)(2) of this section.

(g) *Recordkeeping requirements.* Except for services furnished in accordance with the assumed allocation under paragraph (e) of this section, each provider that claims payment for services of physicians under this subpart must meet all of the following requirements:

(1) Maintain the time records or other information it used to allocate physician compensation in a form that permits the information to be validated by the intermediary or the carrier.

(2) Report the information on which the physician compensation allocation is based to the intermediary or the carrier on an annual basis and promptly notify the intermediary or carrier of any revisions to the compensation allocation.

(3) Retain each physician compensation allocation, and the information on which it is based, for at least 4 years after the end of each cost reporting period to which the allocation applies.

§ 415.70 Limits on compensation for physician services in providers.

(a) *Principle and scope.* (1) Except as provided in paragraphs (a)(2) and (a)(3) of this section, CMS establishes reasonable compensation equivalency limits on the amount of compensation paid to physicians by providers. These limits are applied to a provider's costs incurred in compensating physicians for services to the provider, as described in § 415.55(a).

(2) Limits established under this section do not apply to costs of physician compensation attributable to furnishing inpatient hospital services that are paid for under the prospective payment system implemented under part 412 of this chapter or to costs of physician compensation attributable to approved GME programs that are payable

under §§413.75 through 413.83 of this chapter.

(3) Compensation that a physician receives for activities that may not be paid for under either Part A or Part B of Medicare is not considered in applying these limits.

(b) *Methodology for establishing limits.* (1) *For cost reporting periods beginning before January 1, 2015.* CMS establishes a methodology for determining annual reasonable compensation equivalency limits and, to the extent possible, considers average physician incomes by specialty and type of location using the best available data.

(2) *For cost reporting periods beginning on or after January 1, 2015.* CMS establishes a methodology for determining annual reasonable compensation equivalency limits and, to the extent possible, considers average physician incomes by specialty using the best available data.

(c) *Application of limits.* If the level of compensation exceeds the limits established under paragraph (b) of this section, Medicare payment is based on the level established by the limits.

(d) *Adjustment of the limits.* The intermediary may adjust limits established under paragraph (b) of this section to account for costs incurred by the physician or the provider related to malpractice insurance, professional memberships, and continuing medical education.

(1) For the costs of membership in professional societies and continuing medical education, the intermediary may adjust the limit by the lesser of—

(i) The actual cost incurred by the provider or the physician for these activities; or

(ii) Five percent of the appropriate limit.

(2) For the cost of malpractice expenses incurred by either the provider or the physician, the intermediary may adjust the reasonable compensation equivalency limit by the cost of the malpractice insurance expense related to the physician service furnished to patients in providers.

(e) *Exception to limits.* An intermediary may grant a provider an exception to the limits established under paragraph (b) of this section only if the provider can demonstrate to the intermediary that it is unable to recruit or maintain an adequate number of physicians at a compensation level within these limits.

(f) *Notification of changes in methodologies and payment limits.* (1) Before the start of a cost reporting period to which limits established under this section will be applied, CMS publishes a notice in the FEDERAL REGISTER that sets forth the amount of the limits and explains how it calculated the limits.

(2) If CMS proposes to revise the methodology for establishing payment limits under this section, CMS publishes a notice, with opportunity for public comment, in the FEDERAL REGISTER. The notice explains the proposed basis and methodology for setting limits, specifies the limits that would result, and states the date of implementation of the limits.

(3) If CMS updates limits by applying the most recent economic index data without revising the limit methodology, CMS publishes the revised limits in a notice in the FEDERAL REGISTER without prior publication of a proposal or public comment period.

[60 FR 63178, Dec. 8, 1995, as amended at 70 FR 47490, Aug. 12, 2005; 79 FR 50358, Aug. 22, 2014]

Subpart C—Part B Carrier Payments for Physician Services to Beneficiaries in Providers

§415.100 Scope.

This subpart implements section 1887(a)(1)(A) of the Act by providing general conditions that must be met in order for services furnished by physicians to beneficiaries in providers to be paid for on the basis of the physician fee schedule under part 414 of this chapter. Section 415.102 sets forth the conditions for fee schedule payment for physician services to beneficiaries in providers. Section 415.105 sets forth general requirements for determining the amounts of payment for services that meet the conditions of this section. Sections 415.120 and 415.130 set forth additional conditions for payment for physician services in the specialties of radiology and pathology (laboratory services).

§ 415.102 Conditions for fee schedule payment for physician services to beneficiaries in providers.

(a) *General rule.* If the physician furnishes services to beneficiaries in providers, the carrier pays on a fee schedule basis provided the following requirements are met:

(1) The services are personally furnished for an individual beneficiary by a physician.

(2) The services contribute directly to the diagnosis or treatment of an individual beneficiary.

(3) The services ordinarily require performance by a physician.

(4) In the case of radiology or laboratory services, the additional requirements in § 415.120 or § 415.130, respectively, are met.

(b) *Exception.* If a physician furnishes services in a provider that do not meet the requirements in paragraph (a) of this section, but are related to beneficiary care furnished by the provider, the intermediary pays for those services, if otherwise covered. The intermediary follows the rules in §§ 415.55 and 415.60 for payment on the basis of reasonable cost or PPS, as appropriate.

(c) *Effect of billing charges for physician services to a provider.* (1) If a physician furnishes services that may be paid under the reasonable cost rules in § 415.55 or § 415.60, and paid by the intermediary, or would be paid under those rules except for the PPS rules in part 412 of this chapter, and under the payment rules for GME established by §§ 413.75 through 413.83 of this chapter, neither the provider nor the physician may seek payment from the carrier, beneficiary, or another insurer.

(2) If a physician furnishes services to an individual beneficiary that do not meet the applicable conditions in §§ 415.120 (concerning conditions for payment for radiology services) and 415.130 (concerning conditions for payment for physician pathology services), the carrier does not pay on a fee schedule basis.

(3) If the physician, the provider, or another entity bills the carrier or the beneficiary or another insurer for physician services furnished to the provider, as described in § 415.55(a), CMS considers the provider to which the services are furnished to have violated its provider participation agreement, and may terminate that agreement. See part 489 of this chapter for rules governing provider agreements.

(d) *Effect of physician assumption of operating costs.* If a physician or other entity enters into an agreement (such as a lease or concession) with a provider, and the physician (or entity) assumes some or all of the operating costs of the provider department in which the physician furnishes physician services, the following rules apply:

(1) If the conditions set forth in paragraph (a) of this section are met, the carrier pays for the physician services under the physician fee schedule in part 414 of this chapter.

(2) To the extent the provider incurs a cost payable on a reasonable cost basis under part 413 of this chapter, the intermediary pays the provider on a reasonable cost basis for the costs associated with producing these services, including overhead, supplies, equipment costs, and services furnished by nonphysician personnel.

(3) The physician (or other entity) is treated as being related to the provider within the meaning of § 413.17 of this chapter (concerning cost to related organizations).

(4) The physician (or other entity) must make its books and records available to the provider and the intermediary as necessary to verify the nature and extent of the costs of the services furnished by the physician (or other entity).

[60 FR 63178, Dec. 8, 1995, as amended at 70 FR 47490, Aug. 12, 2005]

§ 415.105 Amounts of payment for physician services to beneficiaries in providers.

(a) *General rule.* The carrier determines amounts of payment for physician services to beneficiaries in providers in accordance with the general rules governing the physician fee schedule payment in part 414 of this chapter, except as provided in paragraph (b) of this section.

(b) *Application in certain settings*—(1) *Teaching hospitals.* The carrier applies the rules in subpart D of this part (concerning physician services in teaching settings), in addition to those in this section, in determining whether fee

schedule payment should be made for physician services to individual beneficiaries in a teaching hospital.

(2) *Hospital-based ESRD facilities.* The carrier applies §§414.310 through 414.314 of this chapter, which set forth determination of reasonable charges under the ESRD program, to determine the amount of payment for physician services furnished to individual beneficiaries in a hospital-based ESRD facility approved under part 405 subpart U.

§415.110 Conditions for payment: Medically directed anesthesia services.

(a) *General payment rule.* Medicare pays for the physician's medical direction of anesthesia services for one service or two through four concurrent anesthesia services furnished after December 31, 1998, only if each of the services meets the condition in §415.102(a) and the following additional conditions:

(1) For each patient, the physician—

(i) Performs a pre-anesthetic examination and evaluation;

(ii) Prescribes the anesthesia plan;

(iii) Personally participates in the most demanding aspects of the anesthesia plan including, if applicable, induction and emergence;

(iv) Ensures that any procedures in the anesthesia plan that he or she does not perform are performed by a qualified individual as defined in operating instructions;

(v) Monitors the course of anesthesia administration at frequent intervals;

(vi) Remains physically present and available for immediate diagnosis and treatment of emergencies; and

(vii) Provides indicated post-anesthesia care.

(2) The physician directs no more than four anesthesia services concurrently and does not perform any other services while he or she is directing the single or concurrent services so that one or more of the conditions in paragraph (a)(1) of this section are not violated.

(3) If the physician personally performs the anesthesia service, the payment rules in §414.46(c) of this chapter apply (Physician personally performs the anesthesia procedure).

(b) *Medical documentation.* The physician alone inclusively documents in the patient's medical record that the conditions set forth in paragraph (a)(1) of this section have been satisfied, specifically documenting that he or she performed the pre-anesthetic exam and evaluation, provided the indicated post-anesthesia care, and was present during the most demanding procedures, including induction and emergence where applicable.

[63 FR 58912, Nov. 2, 1998]

§415.120 Conditions for payment: Radiology services.

(a) *Services to beneficiaries.* The carrier pays for radiology services furnished by a physician to a beneficiary on a fee schedule basis only if the services meet the conditions for fee schedule payment in §415.102(a) and are identifiable, direct, and discrete diagnostic or therapeutic services furnished to an individual beneficiary, such as interpretation of x-ray plates, angiograms, myelograms, pyelograms, or ultrasound procedures. The carrier pays for interpretations only if there is a written report prepared for inclusion in the patient's medical record maintained by the hospital.

(b) *Services to providers.* The carrier does not pay on a fee schedule basis for physician services to the provider (for example, administrative or supervisory services) or for provider services needed to produce the x-ray films or other items that are interpreted by the radiologist. However, the intermediary pays the provider for these services in accordance with §415.55 for provider costs; §415.102(d)(2) for costs incurred by a physician, such as under a lease or concession agreement; or part 412 of this chapter for payment under PPS.

§415.130 Conditions for payment: Physician pathology services.

(a) *Definitions.* The following definitions are used in this section.

(1) *Covered hospital* means, with respect to an inpatient or an outpatient, a hospital that had an arrangement with an independent laboratory that was in effect as of July 22, 1999, under which a laboratory furnished the technical component of physician pathology services to fee-for-service Medicare

beneficiaries who were hospital inpatients or outpatients, and submitted claims for payment for this technical component directly to a Medicare carrier.

(2) *Fee-for-service Medicare beneficiaries* means those beneficiaries who are entitled to benefits under Part A or are enrolled under Part B of Title XVIII of the Act or both and are not enrolled in any of the following:

(i) A Medicare + Choice plan under Part C of Title XVIII of the Act.

(ii) A plan offered by an eligible organization under section 1876 of the Act;

(iii) A program of all-inclusive care for the elderly (PACE) under 1894 of the Act; or

(iv) A social health maintenance organization (SHMO) demonstration project established under section 4018(b) of the Omnibus Budget Reconciliation Act of 1987.

(b) *Physician pathology services.* The carrier pays for pathology services furnished by a physician to an individual beneficiary on a fee schedule basis only if the services meet the conditions for payment in §415.102(a) and are one of the following services:

(1) Surgical pathology services.

(2) Specific cytopathology, hematology, and blood banking services that have been identified to require performance by a physician and are listed in program operating instructions.

(3) Clinical consultation services that meet the requirements in paragraph (c) of this section.

(4) Clinical laboratory interpretative services that meet the requirements of paragraphs (c)(1), (c)(3), and (c)(4) of this section and that are specifically listed in program operating instructions.

(c) *Clinical consultation services.* For purposes of this section, clinical consultation services must meet the following requirements:

(1) Be requested by the beneficiary's attending physician.

(2) Relate to a test result that lies outside the clinically significant normal or expected range in view of the condition of the beneficiary.

(3) Result in a written narrative report included in the beneficiary's medical record.

(4) Require the exercise of medical judgment by the consultant physician.

(d) *Physician pathology services furnished by an independent laboratory.* (1) The technical component of physician pathology services furnished by an independent laboratory to a hospital inpatient or outpatient on or before June 30, 2012, may be paid to the laboratory by the contractor under the physician fee schedule if the Medicare beneficiary is a patient of a covered hospital as defined in paragraph (a)(1) of this section.

(2) For services furnished after June 30, 2012, an independent laboratory may not bill the Medicare contractor for the technical component of physician pathology services furnished to a hospital inpatient or outpatient.

(3) For services furnished on or after January 1, 2008, the date of service policy in §414.510 of this chapter applies to the TC of specimens for physician pathology services.

[60 FR 63178, Dec. 8, 1995, as amended at 64 FR 59442, Nov. 2, 1999; 66 FR 55332, Nov. 1, 2001; 71 FR 69788, Dec. 1, 2006; 72 FR 66405, Nov. 27, 2007; 73 FR 69938, Nov. 19, 2008; 75 FR 73626, Nov. 29, 2010; 76 FR 73473, Nov. 28, 2011; 77 FR 69371, Nov. 16, 2012]

§415.140 Conditions for payment: Split (or shared) visits.

(a) *Definitions.* For purposes of this section, the following definitions apply:

Facility setting for purposes of this section means institutional settings in which payment for services and supplies furnished incident to a physician or practitioner's professional services is prohibited under §410.26(b)(1) of this subchapter.

Split (or shared) visit means an evaluation and management (E/M) visit in the facility setting that is performed in part by both a physician and a nonphysician practitioner who are in the same group, in accordance with applicable law and regulations such that the service could be could be billed by either the physician or nonphysician practitioner if furnished independently by only one of them.

Substantive portion means more than half of the total time spent by the physician and nonphysician practitioner performing the split (or shared) visit,

or a substantive part of the medical decision making except as otherwise provided in this paragraph. For critical care visits, substantive portion means more than half of the total time spent by the physician and nonphysician practitioner performing the split (or shared) visit.

(b) *Conditions of payment.* For purposes of this section, the following conditions of payment apply:

(1) *Substantive portion of split (or shared) visit.* In general, payment is made to the physician or nonphysician practitioner who performs the substantive portion of the split (or shared) visit.

(2) *Medical record documentation.* Documentation in the medical record must identify the physician and nonphysician practitioner who performed the visit. The individual who performed the substantive portion of the visit (and therefore bills for the visit) must sign and date the medical record.

(3) *Claim modifier.* The designated modifier must be included on the claim to identify that the service was a split (or shared) visit.

[86 FR 65682, Nov. 19, 2021, as amended at 87 FR 70230, Nov. 18, 2022; 88 FR 79539, Nov. 16, 2023]

Subpart D—Physician Services in Teaching Settings

§415.150 Scope.

This subpart sets forth the rules governing payment for the services of physicians in teaching settings and the criteria for determining whether the payments are made as one of the following:

(a) Services to the hospital under the reasonable cost election in §§415.160 through 415.164.

(b) Provider services through the direct GME payment mechanism in §§413.75 through 413.83 of this chapter.

(c) Physician services to beneficiaries under the physician fee schedule as set forth in part 414 of this chapter.

[60 FR 63178, Dec. 8, 1995, as amended at 70 FR 47490, Aug. 12, 2005]

§415.152 Definitions.

As used in this subpart—

Approved graduate medical education (GME) program means one of the following:

(1) A residency program approved by the Accreditation Council for Graduate Medical Education, by the American Osteopathic Association, by the Commission on Dental Accreditation of the American Dental Association, or by the Council on Podiatric Medical Education of the American Podiatric Medical Association.

(2) A program otherwise recognized as an ''approved medical residency program'' under §413.75(b) of this chapter.

Direct medical and surgical services means services to individual beneficiaries that are either personally furnished by a physician or furnished by a resident under the supervision of a physician in a teaching hospital making the cost election described in §§415.160 through 415.162.

Nonprovider setting means a setting other than a hospital, skilled nursing facility, home health agency, or comprehensive outpatient rehabilitation facility in which residents furnish services. These include, but are not limited to, family practice or multispecialty clinics and physician offices.

Resident means one of the following:

(1) An individual who participates in an approved GME program, including programs in osteopathy, dentistry, and podiatry.

(2) A physician who is not in an approved GME program, but who is authorized to practice only in a hospital, for example, individuals with temporary or restricted licenses, or unlicensed graduates of foreign medical schools. For purposes of this subpart, the term *resident* is synonymous with the terms *intern* and *fellow.*

Teaching hospital means a hospital engaged in an approved GME residency program in medicine, osteopathy, dentistry, or podiatry.

Teaching physician means a physician (other than another resident) who involves residents in the care of his or her patients.

Teaching setting means any provider, hospital-based provider, or nonprovider settings in which Medicare payment for the services of residents is made under the direct GME payment provisions of §§413.75 through 413.83, or on a

reasonable-cost basis under the provisions of § 409.26 or § 409.40(f) for resident services furnished in skilled nursing facilities or home health agencies, respectively.

[60 FR 63178, Dec. 8, 1995, as amended at 61 FR 59554, Nov. 22, 1996; 63 FR 26359, May 12, 1998; 70 FR 47490, Aug. 12, 2005; 74 FR 44001, Aug. 27, 2009; 75 FR 50418, Aug. 16, 2010]

§ 415.160 Election of reasonable cost payment for direct medical and surgical services of physicians in teaching hospitals: General provisions.

(a) *Scope.* A teaching hospital may elect to receive payment on a reasonable cost basis for the direct medical and surgical services of its physicians in lieu of fee schedule payments that might otherwise be made for these services.

(b) *Conditions.* A teaching hospital may elect to receive these payments only if—

(1) The hospital notifies its intermediary in writing of the election and meets the conditions of either paragraph (b)(2) or paragraph (b)(3) of this section;

(2) All physicians who furnish services to Medicare beneficiaries in the hospital agree not to bill charges for these services; or

(3) All physicians who furnish services to Medicare beneficiaries in the hospital are employees of the hospital and, as a condition of employment, are precluded from billing for these services.

(c) *Effect of election.* If a teaching hospital elects to receive reasonable cost payment for physician direct medical and surgical services furnished to beneficiaries—

(1) Those services and the supervision of interns and residents furnishing care to individual beneficiaries are covered as hospital services, and

(2) The intermediary pays the hospital for those services on a reasonable cost basis under the rules in § 415.162. (Payment for other physician compensation costs related to approved GME programs is made as described in § 413.78 of this chapter.)

(d) *Election declined.* If the teaching hospital does not make this election, payment is made—

(1) For physician services furnished to beneficiaries on a fee schedule basis as described in part 414 subject to the rules in this subpart, and

(2) For the supervision of interns and residents as described in §§ 413.75 through 413.83.

[60 FR 63178, Dec. 8, 1995, as amended at 70 FR 47490, Aug. 12, 2005]

§ 415.162 Determining payment for physician services furnished to beneficiaries in teaching hospitals.

(a) *General rule.* Payments for direct medical and surgical services of physicians furnished to beneficiaries and supervision of interns and residents furnishing care to beneficiaries is made by Medicare on the basis of reasonable cost if the hospital exercises the election as provided for in § 415.160. If this election is made, the following occurs:

(1) Physician services furnished to beneficiaries and supervision of interns and residents furnishing care to beneficiaries are paid on a reasonable-cost basis, as provided for in paragraph (b) of this section.

(2) Payment for certain medical school costs may be made as provided for in paragraph (c) of this section.

(3) Payments for services donated by volunteer physicians to beneficiaries are made to a fund designated by the organized medical staff of the teaching hospital or medical school as provided for in paragraph (d) of this section.

(b) *Reasonable cost of physician services and supervision of interns and residents.* (1) Physician services furnished to beneficiaries and supervision of interns and residents furnishing care to beneficiaries in a teaching hospital are payable as provider services on a reasonable-cost basis.

(2) For purposes of this paragraph, *reasonable cost* is defined as the direct salary paid to these physicians, plus applicable fringe benefits.

(3) The costs must be allocated to the services as provided by paragraph (j) of this section and apportioned to program beneficiaries as provided by paragraph (g) of this section.

(4) Other allowable costs incurred by the provider related to the services described in this paragraph are payable subject to the requirements applicable to all other provider services.

(c) *Reasonable costs for the services furnished by a medical school or related organization in a hospital.* An amount is payable to the hospital by CMS under the Medicare program provided that the costs would be payable if incurred directly by the hospital rather than under the arrangement. The amount must not be in excess of the reasonable costs (as defined in paragraphs (c)(1) and (c)(2) of this section) incurred by a teaching hospital for services furnished by a medical school or organization as described in §413.17 of this chapter for certain costs to the medical school (or a related organization) in furnishing services in the hospital.

(1) *Reasonable costs of physician services*—(i) *When the medical school and the hospital are related organizations.* If the medical school (or organization related to the medical school) and the hospital are related by common ownership or control as described in §413.17 of this chapter—

(A) The costs of these services are allowable costs to the hospital under the provisions of §413.17 of this chapter; and

(B) The reimbursable costs to the hospital are determined under the provisions of this section in the same manner as the costs incurred for physicians on the hospital staff and without regard to payments made to the medical school by the hospital.

(ii) *When the medical school and the hospital are not related organizations.* (A) If the medical school and the hospital are not related organizations under the provisions of §413.17 of this chapter and the hospital makes payment to the medical school for the costs of those services furnished to all patients, payment is made by Medicare to the hospital for the reasonable cost incurred by the hospital for its payments to the medical school for services furnished to beneficiaries.

(B) Costs incurred under an arrangement must be allocated to the full range of services furnished to the hospital by the medical school physicians on the same basis as provided for under paragraph (j) of this section, and costs allocated to direct medical and surgical services furnished to hospital patients must be apportioned to beneficiaries as provided for under paragraph (g) of this section.

(C) If the medical school and the hospital are not related organizations under the provisions of §413.17 of this chapter and the hospital makes payment to the medical school only for the costs of those services furnished to beneficiaries, costs of the medical school not to exceed 105 percent of the sum of physician direct salaries, applicable fringe benefits, employer's portion of FICA taxes, Federal and State unemployment taxes, and workmen's compensation paid by the medical school or an organization related to the medical school may be recognized as allowable costs of the medical school.

(D) These allowable medical school costs must be allocated to the full range of services furnished by the physicians of the medical school or organization related as provided by paragraph (j) of this section.

(E) Costs allocated to direct medical and surgical services furnished to hospital patients must be apportioned to beneficiaries as provided by paragraph (g) of this section.

(2) *Reasonable costs of other than direct medical and surgical services.* These costs are determined in accordance with paragraph (c)(1) of this section except that—

(i) If the hospital makes payment to the medical school for other than direct medical and surgical services furnished to beneficiaries and supervision of interns and residents furnishing care to beneficiaries, these payments are subject to the required cost-finding and apportionment methods applicable to the cost of other hospital services (except for direct medical and surgical services furnished to beneficiaries); or

(ii) If the hospital makes payment to the medical school only for these services furnished to beneficiaries, the cost of these services is not subject to cost-finding and apportionment as otherwise provided by this subpart, and the reasonable cost paid by Medicare must be determined on the basis of the health insurance ratio(s) used in the apportionment of all other provider costs (excluding physician direct medical and surgical services furnished to beneficiaries) applied to the allowable

medical school costs incurred by the medical school for the services furnished to all patients of the hospital.

(d) *''Salary equivalent'' payments for direct medical and surgical services furnished by physicians on the voluntary staff of the hospital.* (1) CMS makes payments under the Medicare program to a fund as defined in § 415.164 for direct medical and surgical services furnished to beneficiaries on a regularly scheduled basis by physicians on the unpaid voluntary medical staff of the hospital (or medical school under arrangement with the hospital).

(i) These payments represent compensation for contributed medical staff time which, if not contributed, would have to be obtained through employed staff on a payable basis.

(ii) Payments for volunteer services are determined by applying to the regularly scheduled contributed time an hourly rate not to exceed the equivalent of the average direct salary (exclusive of fringe benefits) paid to all full-time, salaried physicians (other than interns and residents) on the hospital staff or, if the number of full-time salaried physicians is minimal in absolute terms or in relation to the number of physicians on the voluntary staff, to physicians at like institutions in the area.

(iii) This ''salary equivalent'' is a single hourly rate covering all physicians regardless of specialty and is applied to the actual regularly scheduled time contributed by the physicians in furnishing direct medical and surgical services to beneficiaries including supervision of interns and residents in that care.

(iv) A physician who receives any compensation from the hospital or a medical school related to the hospital by common ownership or control (within the meaning of § 413.17 of this chapter) for direct medical and surgical services furnished to any patient in the hospital is not considered an unpaid voluntary physician for purposes of this paragraph.

(v) If, however, a physician receives compensation from the hospital or related medical school or organization only for services that are other than direct medical and surgical services, a salary equivalent payment for the physician's regularly scheduled direct medical and surgical services to beneficiaries in the hospital may be imputed. However, the sum of the imputed value for volunteer services and the physician's actual compensation from the hospital and the related medical school (or organization) may not exceed the amount that would have been imputed if all of the physician's hospital and medical school services (compensated and volunteer) had been volunteer services, or paid at the rate of $30,000 per year, whichever is less.

(2) The following examples illustrate how the allowable imputed value for volunteer services is determined. In each example, it has been assumed that the average salary equivalent hourly rate is equal to the hourly rate for the individual physician's compensated services.

Example No: 1. Dr. Jones received $3,000 a year from Hospital X for services other than direct medical services to all patients, for example, utilization review and administrative services. Dr. Jones also voluntarily furnished direct medical services to beneficiaries. The imputed value of the volunteer services amounted to $10,000 for the cost reporting period. The full imputed value of Dr. Jones' volunteer direct medical services would be allowed since the total amount of the imputed value ($10,000) and the compensated services ($3,000) does not exceed $30,000.

Example No: 2. Dr. Smith received $25,000 from Hospital X for services as a department head in a teaching hospital. Dr. Smith also voluntarily furnished direct medical services to beneficiaries. The imputed value of the volunteer services amounted to $10,000. Only $5,000 of the imputed value of volunteer services would be allowed since the total amount of the imputed value ($10,000) and the compensated services ($25,000) exceeds the $30,000 maximum amount allowable for all of Dr. Smith's services.

COMPUTATION:

Maximum amount allowable for all services performed by Dr. Smith for purposes of this computation	$30,000
Less compensation received from Hospital X for other than direct medical services to individual patients	$25,000
Allowable amount of imputed value for the volunteer services furnished by Dr. Smith	$5,000

Example No. 3. Dr. Brown is not compensated by Hospital X for any services furnished in the hospital. Dr. Brown voluntarily

furnished direct surgical services to beneficiaries for a period of 6 months, and the imputed value of these services amounted to $20,000. The allowable amount of the imputed value for volunteer services furnished by Dr. Brown would be limited to $15,000 ($30,000 × 6/12).

(3) The amount of the imputed value for volunteer services applicable to beneficiaries and payable to a fund is determined in accordance with the aggregate per diem method described in paragraph (g) of this section.

(4) Medicare payments to a fund must be used by the fund solely for improvement of care of hospital patients or for educational or charitable purposes (which may include but are not limited to medical and other scientific research).

(i) No personal financial gain, either direct or indirect, from benefits of the fund may inure to any of the hospital staff physicians, medical school faculty, or physicians for whom Medicare imputes costs for purposes of payment into the fund.

(ii) Expenses met from contributions made to the hospital from a fund are not included as a reimbursable cost when expended by the hospital, and depreciation expense is not allowed with respect to equipment or facilities donated to the hospital by a fund or purchased by the hospital from monies in a fund.

(e) *Requirements for payment*—(1) *Physicians on the hospital staff.* The requirements under which the costs of physician direct medical and surgical services (including supervision of interns and residents) to beneficiaries are the same as those applicable to the cost of all other covered provider services except that the costs of these services are separately determined as provided by this section and are not subject to cost-finding as described in §413.24 of this chapter.

(2) *Physicians on the medical school faculty.* Payment is made to a hospital for the costs of services of physicians on the medical school faculty, provided that if the medical school is not related to the hospital (within the meaning of §413.17 of this chapter, concerning cost to related organizations), the hospital does not make payment to the medical school for services furnished to all patients and the following requirements are met: If the hospital makes payment to the medical school for services furnished to all patients, these requirements do not apply. (See paragraph (c)(1)(ii) of this section.)

(i) There is a written agreement between the hospital and the medical school or organization, specifying the types and extent of services to be furnished by the medical school and specifying that the hospital must pay to the medical school an amount at least equal to the reasonable cost (as defined in paragraph (c) of this section) of furnishing the services to beneficiaries.

(ii) The costs are paid to the medical school by the hospital no later than the date on which the cost report covering the period in which the services were furnished is due to CMS.

(iii) Payment for the services furnished under an arrangement would have been made to the hospital had the services been furnished directly by the hospital.

(3) *Physicians on the voluntary staff of the hospital (or medical school under arrangement with the hospital).* If the conditions for payment to a fund outlined in §415.164 are met, payments are made on a ''salary equivalent'' basis (as defined in paragraph (d) of this section) to a fund.

(f) *Requirements for payment for medical school faculty services other than physician direct medical and surgical services.* If the requirements for payment for physician direct medical and surgical services furnished to beneficiaries in a teaching hospital described in paragraph (e) of this section are met, payment is made to a hospital for the costs of medical school faculty services other than physician direct medical and surgical services furnished in a teaching hospital.

(g) *Aggregate per diem methods of apportionment*—(1) *For the costs of physician direct medical and surgical services.* The cost of physician direct medical and surgical services furnished in a teaching hospital to beneficiaries is determined on the basis of an average cost per diem as defined in paragraph (h)(1) of this section for physician direct medical and surgical services to all patients (see §§415.172 through 415.184) for each of the following categories of physicians:

(i) Physicians on the hospital staff.

(ii) Physicians on the medical school faculty.

(2) *For the imputed value of physician volunteer direct medical and surgical services.* The imputed value of physician direct medical and surgical services furnished to beneficiaries in a teaching hospital is determined on the basis of an average per diem, as defined in paragraph (h)(1) of this section, for physician direct medical and surgical services to all patients except that the average per diem is derived from the imputed value of the physician volunteer direct medical and surgical services furnished to all patients.

(h) *Definitions.* (1) *Average cost per diem for physician direct medical and surgical services (including supervision of interns and residents) furnished in a teaching hospital to patients in each category of physician services described in paragraph (g)(1) of this section* means the amount computed by dividing total reasonable costs of these services in each category by the sum of—

(i) Inpatient days (as defined in paragraph (h)(2) of this section); and

(ii) Outpatient visit days (as defined in paragraph (h)(3) of this section).

(2) *Inpatient days* are determined by counting the day of admission as 3.5 days and each day after a patient's day of admission, except the day of discharge, as 1 day.

(3) *Outpatient visit days* are determined by counting only one visit day for each calendar day that a patient visits an outpatient department or multiple outpatient departments.

(i) *Application.* (1) The following illustrates how apportionment based on the aggregate per diem method for costs of physician direct medical and surgical services furnished in a teaching hospital to patients is determined.

TEACHING HOSPITAL Y

Statistical and financial data:

Total inpatient days as defined in paragraph (h)(2) of this section and outpatient visit days as defined in paragraph (h)(3) of this section	75,000
Total inpatient Part A days	20,000
Total inpatient Part B days where Part A coverage is not available	1,000
Total outpatient Part B visit days	5,000
Total cost of direct medical and surgical services furnished to all patients by physicians on the hospital staff as determined in accordance with paragraph (i) of this section	$1,500,000
Total cost of direct medical and surgical services furnished to all patients by physicians on the medical school faculty as determined in accordance with paragraph (i) of this section	$1,650,000

Computation of cost applicable to program for physicians on the hospital staff:

Average cost per diem for direct medical and surgical services to patients by physicians on the hospital staff: $1,500,000 ÷ 75,000 = $20 per diem.

Cost of physician direct medical and surgical services furnished to inpatient beneficiaries covered under Part A: $20 per diem × 20,000	$400,000
Cost of physician direct medical and surgical services furnished to inpatient beneficiaries covered under Part B: $20 per diem × 1,000	$20,000
Cost of physician direct medical and surgical services furnished to outpatient beneficiaries covered under Part B: $20 per diem × 5,000	$100,000

Computation of cost applicable to program for physicians on the medical school faculty:

Average cost per diem for direct medical and surgical services to patients by physicians on the medical school faculty: $1,650,000 ÷ 75,000 = $22 per diem.

Cost of physician direct medical and surgical services furnished to inpatient beneficiaries covered under Part A: $22 per diem × 20,000	$440,000
Cost of physician direct medical and surgical services furnished to inpatient beneficiaries covered under Part B: $20 per diem × 1,000	$22,000
Cost of physician direct medical and surgical services furnished to outpatient beneficiaries covered under Part B: $22 per diem × 5,000	$110,000

(2) The following illustrates how the imputed value of physician volunteer direct medical and surgical services furnished in a teaching hospital to beneficiaries is determined.

Example: The physicians on the medical staff of Teaching Hospital Y donated a total of 5,000 hours in furnishing direct medical

and surgical services to patients of the hospital during a cost reporting period and did not receive any compensation from either the hospital or the medical school. Also, the imputed value for any physician volunteer services did not exceed the rate of $30,000 per year per physician.

STATISTICAL AND FINANCIAL DATA:

Total salaries paid to the full-time salaried physicians by the hospital (excluding interns and residents)	$800,000
Total physicians who were paid for an average of 40 hours per week or 2,080 (52 weeks × 40 hours per week) hours per year	20
Average hourly rate equivalent: $800,000 ÷ 41,600 (2,080 × 20)	$19.23

Computation of total imputed value of physician volunteer services applicable to all patients:

(Total donated hours × average hourly rate equivalent): 5,000 × $19.23	$96,150
Total inpatient days (as defined in paragraph (h)(2) of this section) and outpatient visit days (as defined in paragraph (h)(3) of this section)	75,000
Total inpatient Part A days	20,000
Total inpatient Part B days if Part A coverage is not available	1,000
Total outpatient Part B visit days	5,000

Computation of imputed value of physician volunteer direct medical and surgical services furnished to Medicare beneficiaries:

Average per diem for physician direct medical and surgical services to all patients: $96,150 ÷ 75,000 = $1.28 per diem

Imputed value of physician direct medical and surgical services furnished to inpatient beneficiaries covered under Part A: $1.28 per diem × 20,000	$25,600
Imputed value of physician direct medical and surgical services furnished to inpatient beneficiaries covered under Part B: $1.28 per diem × 1,000	$1,280
Imputed value of physician direct medical and surgical services furnished to outpatient beneficiaries covered under Part B: $1.28 per diem × 5,000	$6,400
Total	$33,280

(j) *Allocation of compensation paid to physicians in a teaching hospital.* (1) In determining reasonable cost under this section, the compensation paid by a teaching hospital, or a medical school or related organization under arrangement with the hospital, to physicians in a teaching hospital must be allocated to the full range of services implicit in the physician compensation arrangements. (However, see paragraph (d) of this section for the computation of the ''salary equivalent'' payments for volunteer services furnished to patients.)

(2) This allocation must be made and must be capable of substantiation on the basis of the proportion of each physician's time spent in furnishing each type of service to the hospital or medical school.

§415.164 Payment to a fund.

(a) *General rules.* Payment for certain voluntary services by physicians in teaching hospitals (as these services are described in §415.160) is made on a salary equivalent basis (as described in §415.162(d)) subject to the conditions and limitations contained in parts 405 and 413 of this chapter and this part 415, to a single fund (as defined in paragraph (b) of this section) designated by the organized medical staff of the hospital (or, if the services are furnished in the hospital by the faculty of a medical school, to a fund as may be designated by the faculty), if the following conditions are met:

(1) The hospital (or medical school furnishing the services under arrangement with the hospital) incurs no actual cost in furnishing the services.

(2) The hospital has an agreement with CMS under part 489 of this chapter.

(3) The intermediary, or CMS as appropriate, has received written assurances that—

(i) The payment is used solely for the improvement of care of hospital patients or for educational or charitable purposes; and

(ii) Neither the individuals who are furnished the services nor any other persons are charged for the services (and if charged, provision is made for the return of any monies incorrectly collected).

(b) *Definition of a fund.* For purposes of paragraph (a) of this section, a *fund* is an organization that meets either of the following requirements:

(1) The organization has and retains exemption, as a governmental entity or

under section 501(c)(3) of the Internal Revenue Code (nonprofit educational, charitable, and similar organizations), from Federal taxation.

(2) The organization is an organization of physicians who, under the terms of their employment by an entity that meets the requirements of paragraph (b)(1) of this section, are required to turn over to that entity all income that the physician organization derives from the physician services.

(c) *Status of a fund.* A fund approved for payment under paragraph (a) of this section has all the rights and responsibilities of a provider under Medicare except that it does not enter into an agreement with CMS under part 489 of this chapter.

§ 415.170 Conditions for payment on a fee schedule basis for physician services in a teaching setting.

Services meeting the conditions for payment in § 415.102(a) furnished in teaching settings are payable under the physician fee schedule if—

(a) The services are personally furnished by a physician who is not a resident; or

(b) The services are furnished by a resident in the presence of a teaching physician except as provided in § 415.172 (concerning physician fee schedule payment for services of teaching physicians), § 415.174 (concerning an exception for services furnished in hospital outpatient and certain other ambulatory settings), § 415.176 (concerning renal dialysis services), and § 415.184 (concerning psychiatric services), as applicable.

§ 415.172 Physician fee schedule payment for services of teaching physicians.

(a) *General rule.* If a resident participates in a service furnished in a teaching setting, physician fee schedule payment is made only if a teaching physician is present during the key portion of any service or procedure for which payment is sought. In residency training sites that are located outside a metropolitan statistical area, physician fee schedule payment may also be made if a teaching physician is present during the key portion of the service, including for Medicare telehealth services, through audio/video real-time communications technology for any service or procedure for which payment is sought. For all teaching settings during the Public Health Emergency, as defined in § 400.200 of this chapter, for the COVID–19 pandemic, if a resident participates in a service furnished in a teaching setting, physician fee schedule payment is made if a teaching physician is present during the key portion of the service including for Medicare telehealth services, through audio/video real-time communications technology for any service or procedure for which payment is sought.

(1) In the case of surgical, high-risk, or other complex procedures, the teaching physician must be present during all critical portions of the procedure and immediately available to furnish services during the entire service or procedure.

(i) In the case of surgery, the teaching physician's presence is not required during opening and closing of the surgical field.

(ii) In the case of procedures performed through an endoscope, the teaching physician must be present during the entire viewing.

(2) In the case of evaluation and management services, except as otherwise provided in this paragraph (a)(2), the teaching physician must be present in person during the portion of the service that determines the level of service billed. (However, in the case of evaluation and management services furnished in hospital outpatient departments and certain other ambulatory settings, the requirements of § 415.174 apply.)

(i) In residency training sites that are located outside of a metropolitan statistical area, the teaching physician may be present through audio/video real-time communications technology during the portion of the service that determines the level of service billed. (However, in the case of evaluation and management services furnished in hospital outpatient departments and certain other ambulatory settings, the requirements of § 415.174 apply.)

(ii) For all teaching settings during the Public Health Emergency, as defined in § 400.200 of this chapter, for the

COVID–19 pandemic, the teaching physician may be present through audio/video real-time communications technology during the portion of the service that determines the level of service billed. (However, in the case of evaluation and management services furnished in hospital outpatient departments and certain other ambulatory settings, the requirements of §415.174 apply.)

(b) *Documentation.* Except as otherwise provided in this paragraph (b), except for services furnished as set forth in §§415.174 (concerning an exception for services furnished in hospital outpatient and certain other ambulatory settings), §§415.176 (concerning renal dialysis services), and 415.184 (concerning psychiatric services), the medical records must document that the teaching physician was present at the time the service (including a Medicare telehealth service) is furnished. The presence of the teaching physician during procedures and evaluation and management services may be demonstrated by the notes in the medical records made by the physician or as provided in §410.20(e) of this chapter.

(1) In residency training sites that are located outside of a metropolitan statistical area only, except for services furnished as set forth in §§415.174 (concerning an exception for services furnished in hospital outpatient and certain other ambulatory settings), 415.176 (concerning renal dialysis services), and 415.184 (concerning psychiatric services), the medical records must document whether the teaching physician was physically present or present through audio/video real-time communications technology at the time the service (including a Medicare telehealth service) is furnished. The medical records must contain a notation describing the specific portion(s) of the service for which the teaching physician was present through audio/video real-time communications technology. The presence of the teaching physician during procedures and evaluation and management services may be demonstrated by the notes in the medical records made by the physician or as provided in §410.20(e) of this chapter.

(2) For all teaching settings during the Public Health Emergency, as defined in §400.200 of this chapter, for the COVID–19 pandemic, except for services furnished as set forth in §§415.174 (concerning an exception for services furnished in hospital outpatient and certain other ambulatory settings), 415.176 (concerning renal dialysis services), and 415.184 (concerning psychiatric services), the medical records must document whether the teaching physician was physically present or present through audio/video real-time communications technology at the time the service (including a Medicare telehealth service) is furnished. The medical records must contain a notation describing the specific portion(s) of the service for which the teaching physician was present through audio/video real-time communications technology. The presence of the teaching physician during procedures and evaluation and management services may be demonstrated by the notes in the medical records made by the physician or as provided in §410.20(e) of this chapter.

(c) *Payment level.* In the case of services such as evaluation and management for which there are several levels of service codes available for reporting purposes, the appropriate payment level must reflect the extent and complexity of the service when fully furnished by the teaching physician.

[60 FR 63178, Dec. 8, 1995, as amended at 83 FR 60091, Nov. 23, 2018; 84 FR 63201, Nov. 15, 2019; 85 FR 19288, Apr. 6, 2020; 85 FR 27623, May 8, 2020; 85 FR 85036, Dec. 28, 2020]

§415.174 Exception: Evaluation and management services furnished in certain centers.

(a) In the case of certain evaluation and management codes of lower and mid-level complexity (as specified by CMS in program instructions), carriers may make physician fee schedule payment for a service furnished by a resident without the presence of a teaching physician. For the exception to apply, all of the following conditions must be met:

(1) The services must be furnished in a center that is located in an outpatient department of a hospital or another ambulatory care entity in which the time spent by residents in patient

care activities is included in determining intermediary payments to a hospital under §§ 413.75 through 413.83.

(2) Any resident furnishing the service without the presence of a teaching physician must have completed more than 6 months of an approved residency program.

(3) The teaching physician must not direct the care of more than four residents at any given time and must direct the care from such proximity as to constitute immediate availability. The teaching physician must—

(i) Have no other responsibilities at the time;

(ii) Assume management responsibility for those beneficiaries seen by the residents;

(iii) Ensure that the services furnished are appropriate; and

(iv) Review with each resident during or immediately after each visit, the beneficiary's medical history, physical examination, diagnosis, and record of tests and therapies.

(4) The range of services furnished by residents in the center includes all of the following:

(i) Acute care for undifferentiated problems or chronic care for ongoing conditions.

(ii) Coordination of care furnished by other physicians and providers.

(iii) Comprehensive care not limited by organ system, or diagnosis.

(5) The patients seen must be an identifiable group of individuals who consider the center to be the continuing source of their health care and in which services are furnished by residents under the medical direction of teaching physicians.

(6) The medical records must document the extent of the teaching physician's participation in the review and direction of services furnished to each beneficiary. The extent of the teaching physician's participation may be demonstrated by the notes in the medical records made by the physician or as provided in § 410.20(e) of this chapter to each beneficiary in accordance with the documentation requirements at § 415.172(b).

(b) Nothing in paragraph (a) of this section may be construed as providing a basis for the coverage of services not determined to be covered under Medicare, such as routine physical checkups.

(c) For all teaching settings during the Public Health Emergency, as defined in § 400.200 of this chapter, for the COVID–19 pandemic, the requirements in paragraph (a)(3) of this section for a teaching physician to direct the care and then to review the services furnished by each resident during or immediately after each visit may be met through audio/video real-time communications technology.

(d) In residency training sites that are located outside of a metropolitan statistical area only, the requirements in paragraph (a)(3) of this section for a teaching physician to direct the care and then to review the services furnished by each resident during or immediately after each visit may be met through audio/video real-time communications technology.

[60 FR 63178, Dec. 8, 1995, as amended at 61 FR 59554, Nov. 22, 1996; 70 FR 47490, Aug. 12, 2005; 83 FR 60092, Nov. 23, 2018; 84 FR 63202, Nov. 15, 2019; 85 FR 19288, Apr. 6, 2020; 85 FR 27624, May 8, 2020; 85 FR 85037, Dec. 28, 2020]

§ 415.176 Renal dialysis services.

In the case of renal dialysis services, physicians who are not paid under the physician monthly capitation payment method (as described in § 414.314 of this chapter) must meet the requirements of §§ 415.170 and 415.172 (concerning physician fee schedule payment for services of teaching physicians).

§ 415.178 Anesthesia services.

(a) *General rule.* (1) *For services furnished prior to January 1, 2010*, an unreduced physician fee schedule payment may be made if a physician is involved in a single anesthesia procedure involving an anesthesia resident. In the case of anesthesia services, the teaching physician must be present during all critical portions of the procedure and immediately available to furnish services during the entire service or procedure. The teaching physician cannot receive an unreduced fee if he or she performs services involving other patients during the period the anesthesia resident is furnishing services in a single case. Additional rules for payment

of anesthesia services involving residents are specified in § 414.46(c)(1)(iii) of this chapter.

(2) *For services furnished on or after January 1, 2010*, payment made under § 414.46(e) of this chapter if the teaching anesthesiologist (or different teaching anesthesiologists in the same anesthesia group practice) is present during all critical or key portions of the anesthesia service or procedure involved; and the teaching anesthesiologist (or another anesthesiologist with whom the teaching anesthesiologist has entered into an arrangement) is immediately available to furnish anesthesia services during the entire procedure.

(b) *Documentation.* Documentation must indicate the teaching physician's presence during all critical or key portions of the anesthesia procedure and the immediate availability of another teaching anesthesiologist.

[74 FR 62014, Nov. 25, 2009]

§ 415.180 Teaching setting requirements for the interpretation of diagnostic radiology and other diagnostic tests.

(a) *General rule.* Physician fee schedule payment is made for the interpretation of diagnostic radiology and other diagnostic tests if the interpretation is performed or reviewed by a physician other than a resident.

(1) In residency training sites that are located outside of a metropolitan statistical area only, physician fee schedule payment may also be made for the interpretation of diagnostic radiology and other diagnostic tests if the interpretation is performed by a resident when the teaching physician is present through audio/video real-time communications technology. The medical records must document the extent of the teaching physician's participation in the interpretation of review of the diagnostic radiology test.

(2) For all teaching settings during the Public Health Emergency, as defined in § 400.200 of this chapter, for the COVID–19 pandemic, physician fee schedule payment may also be made for the interpretation of diagnostic radiology and other diagnostic tests if the interpretation is performed by a resident when the teaching physician is present through audio/video real-time communications technology. The medical records must document the extent of the teaching physician's participation in the interpretation or review of the diagnostic radiology or diagnostic test.

(b) [Reserved]

[85 FR 85037, Dec. 28, 2020]

§ 415.184 Psychiatric services.

(a) Physician fee schedule payment is made for psychiatric services furnished under an approved GME program if the requirements of §§ 415.170 and 415.172 are met, including documentation, except that the requirement for the presence of the teaching physician during the service in which a resident is involved may be met by observation of the service by use of a one-way mirror, video equipment, or similar device.

(b) In residency training sites that are located outside of a metropolitan statistical area, the requirement for the presence of the teaching physician during the service in which a resident is involved may be met through audio/video real-time communications technology. The medical records must document the extent of the teaching physician's participation in the service.

(c) For all teaching settings during the Public Health Emergency, as defined in § 400.200 of this chapter, for the COVID–19 pandemic, the requirement for the presence of the teaching physician during the service in which a resident is involved may also be met through audio/video real-time communications technology. The medical records must document the extent of the teaching physician's participation in the service.

[85 FR 85037, Dec. 28, 2020]

§ 415.190 Conditions of payment: Assistants at surgery in teaching hospitals.

(a) *Basis, purpose, and scope.* This section describes the conditions under which Medicare pays on a fee schedule basis for the services of an assistant at surgery in a teaching hospital. This section is based on section 1842(b)(7)(D)(I) of the Act and applies only to hospitals with an approved GME residency program. Except as

specified in paragraph (c) of this section, fee schedule payment is not available for assistants at surgery in hospitals with—

(1) A training program relating to the medical specialty required for the surgical procedure; and

(2) A resident in a training program relating to the specialty required for the surgery available to serve as an assistant at surgery.

(b) *Definition.* *Assistant at surgery* means a physician who actively assists the physician in charge of a case in performing a surgical procedure.

(c) *Conditions for payment for assistants at surgery.* Payment on a fee schedule basis is made for the services of an assistant at surgery in a teaching hospital only if the services meet one of the following conditions:

(1) Are required as a result of exceptional medical circumstances.

(2) Are complex medical procedures performed by a team of physicians, each performing a discrete, unique function integral to the performance of a complex medical procedure that requires the special skills of more than one physician.

(3) Constitute concurrent medical care relating to a medical condition that requires the presence of, and active care by, a physician of another specialty during surgery.

(4) Are medically required and are furnished by a physician who is primarily engaged in the field of surgery, and the primary surgeon does not use interns and residents in the surgical procedures that the surgeon performs (including preoperative and postoperative care).

(5) Are not related to a surgical procedure for which CMS determines that assistants are used less than 5 percent of the time.

Subpart E—Services of Residents

§ 415.200 Services of residents in approved GME programs.

(a) *General rules.* Services furnished in hospitals by residents in approved GME programs are specifically excluded from being paid as ''physician services'' defined in § 414.2 of this chapter and are payable as hospital services. This exclusion applies whether or not the resident is licensed to practice under the laws of the State in which he or she performs the service. The payment methodology for services of residents in hospitals and hospital-based providers is set forth in §§ 413.75 through 413.83 of this chapter.

(b) *Exception.* For low and mid-level evaluation and management services furnished under certain conditions in centers located in hospital outpatient departments and other ambulatory settings, see § 415.174.

(c) *Definitions.* See § 415.152 for definitions of terms used in this subpart E.

[60 FR 63178, Dec. 8, 1995, as amended at 70 FR 47490, Aug. 12, 2005]

§ 415.202 Services of residents not in approved GME programs.

(a) *General rules.* For services of a physician employed by a hospital who is authorized to practice only in a hospital setting and for the services of a resident who is not in any approved GME program, payment is made to the hospital on a Part B reasonable cost basis regardless of whether the services are furnished to hospital inpatients or outpatients.

(b) *Payment.* For services described in paragraph (a) of this section, payment is made under Part B by reducing the reasonable costs of furnishing the services by the beneficiary deductible and paying 80 percent of the remaining amount. No payment is made for other costs of unapproved programs, such as administrative costs related to teaching activities of physicians.

§ 415.204 Services of residents in skilled nursing facilities and home health agencies.

(a) *Medicare Part A payment.* Payment is made under Medicare Part A for interns' and residents' services furnished in the following settings that meet the specified requirements:

(1) *Skilled nursing facility.* Payment to a participating skilled nursing facility may include the cost of services of an intern or resident who is in an approved GME program in a hospital with which the skilled nursing facility has a transfer agreement that provides, in part, for the transfer of patients and the interchange of medical records.

(2) *Home health agency.* A participating home health agency may receive payment for the cost of the services of an intern or resident who is under an approved GME program of a hospital with which the home health agency is affiliated or under common control if these services are furnished as part of the home health visits for a Medicare beneficiary. (Nevertheless, see §§ 413.75 through 413.83 of this chapter for the costs of approved GME programs in hospital-based providers.)

(b) *Medicare Part B payment.* Medical services of a resident of a hospital that are furnished by a skilled nursing facility or home health agency are paid under Medicare Part B if payment is not provided under Medicare Part A. Payment is made under Part B for a resident's services by reducing the reasonable costs of furnishing the services by the beneficiary deductible and paying 80 percent of the remaining amount.

[60 FR 63178, Dec. 8, 1995, as amended at 70 FR 47490, Aug. 12, 2005]

§ 415.206 Services of residents in nonprovider settings.

Patient care activities of residents in approved GME programs that are furnished in nonprovider settings are payable in one of the following two ways:

(a) *Direct GME payments.* If the conditions in § 413.78 regarding patient care activities and training of residents are met, the time residents spend in nonprovider settings such as clinics, nursing facilities, and physician offices in connection with approved GME programs is included in determining the number of full-time equivalency residents in the calculation of a teaching hospital's resident count. The teaching physician rules on carrier payments in §§ 415.170 through 415.184 apply in these teaching settings.

(b) *Physician fee schedule.* (1) Services furnished by a resident in a nonprovider setting are covered as physician services and payable under the physician fee schedule if the following requirements are met:

(i) The resident is fully licensed to practice medicine, osteopathy, dentistry, or podiatry in the State in which the service is performed.

(ii) The time spent in patient care activities in the nonprovider setting is not included in a teaching hospital's full-time equivalency resident count for the purpose of direct GME payments.

(2) Payment may be made regardless of whether a resident is functioning within the scope of his or her GME program in the nonprovider setting.

(3) If fee schedule payment is made for the resident's services in a nonprovider setting, payment must not be made for the services of a teaching physician.

(4) The carrier must apply the physician fee schedule payment rules set forth in subpart A of part 414 of this chapter to payments for services furnished by a resident in a nonprovider setting.

[60 FR 63178, Dec. 8, 1995, as amended at 70 FR 47490, Aug. 12, 2005]

§ 415.208 Services of moonlighting residents.

(a) *Definition.* For purposes of this section, the term *services of moonlighting residents* refers to services that licensed residents perform that are outside the scope of an approved GME program.

(b) *Services in teaching hospitals.* (1) The services of residents to inpatients of hospitals in which the residents have their approved GME program are not covered as physician services and are payable under §§ 413.75 through 413.83 regarding direct GME payments.

(2) Services of residents that are not related to their approved GME programs and are performed in an outpatient department or emergency department of a hospital in which they have their training program are covered as physician services and payable under the physician fee schedule if criteria in paragraphs (b)(2)(i) through (iii) of this section are met. The services of residents that are not related to their approved GME programs and are furnished to inpatients of a hospital in which they have their training program are covered as physician services and payable under the physician fee schedule if criteria in paragraphs (b)(2)(i) through (iii) of this section are met. The medical record must include

documentation to demonstrate in each case that these criteria are satisfied.

(i) The services are identifiable physician services and meet the conditions for payment of physician services to beneficiaries in providers in §415.102(a).

(ii) The resident is fully licensed to practice medicine, osteopathy, dentistry, or podiatry by the State in which the services are performed.

(iii) The services performed can be separately identified from those services that are required as part of the approved GME program.

(3) If the criteria specified in paragraph (b)(2) of this section are met, the services of the moonlighting resident are considered to have been furnished by the individual in his or her capacity as a physician, rather than in the capacity of a resident. The carrier must review the contracts and agreements for these services to ensure compliance with the criteria specified in paragraph (b)(2) of this section.

(4) No payment is made for services of a ''teaching physician'' associated with moonlighting services, and the time spent furnishing these services is not included in the teaching hospital's full-time equivalency count for the indirect GME payment (§412.105 of this chapter) and for the direct GME payment (§§413.75 through 413.83 of this chapter).

(c) *Other settings.* Moonlighting services of a licensed resident in an approved GME program furnished outside the scope of that program in a hospital or other setting that does not participate in the approved GME program are payable under the physician fee schedule as set forth in §415.206(b)(1).

[60 FR 63178, Dec. 8, 1995, as amended at 70 FR 47490, Aug. 12, 2005; 85 FR 19289, Apr. 6, 2020; 85 FR 85037, Dec. 28, 2020]

PART 416—AMBULATORY SURGICAL SERVICES

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AUTHORITY: 42 U.S.C. 1302 and 1395hh.

SOURCE: 47 FR 34094, Aug. 5, 1982, unless otherwise noted.

Subpart A—General Provisions and Definitions

§416.1 Basis and scope.

(a) *Statutory basis.* (1) Section 1832(a)(2)(F)(i) of the Act provides for Medicare Part B coverage of facility services furnished in connection with surgical procedures specified by the Secretary under section 1833(i)(1) of the Act.

(2) Section 1833(i)(1)(A) of the Act requires the Secretary to specify the surgical procedures that can be performed safely on an ambulatory basis in an ambulatory surgical center.

(3) Sections 1833(i)(2)(A) and (D) and 1833(a)(1)(G) of the Act specify the amounts to be paid for facility services furnished in connection with the specified surgical procedures when they are performed in an ASC.

(4) Section 1833(i)(2)(C) of the Act provides that if the Secretary has not updated amounts for ASC facility services furnished during a fiscal year through 2005 or a calendar year beginning with 2006, the amounts shall be increased by the percentage increase in the Consumer Price Index for all urban consumers as estimated by the Secretary for the 12-month period ending with the midpoint of the year involved, except that, in fiscal year 2005, the last quarter of calendar year 2005, and each of the calendar years 2006 through 2009, the increase shall be zero percent.

(5) Section 1833(i)(2)(E) of the Act provides that, with respect to surgical procedures furnished on or after January 1, 2007, and before the effective date of the implementation of a revised payment system, the payment amount shall be the lesser of the ASC payment rate established under section 1833(i)(2)(A) of the Act or the prospective payment rate for hospital outpatient department services established under section 1833(t)(3)(D) of the Act. The lesser payment amount shall be determined prior to application of any geographic adjustment.

(b) *Scope.* This part sets forth—

(1) The conditions that an ASC must meet in order to participate in the Medicare program;

(2) The scope of covered services; and

(3) The conditions for Medicare payment for facility services.

[56 FR 8843, Mar. 1, 1991; 56 FR 23022, May 20, 1991, as amended at 71 FR 68226, Nov. 24, 2006]

§416.2 Definitions.

As used in this part:

Ambulatory surgical center or *ASC* means any distinct entity that operates exclusively for the purpose of providing surgical services to patients not

requiring hospitalization and in which the expected duration of services would not exceed 24 hours following an admission. The entity must have an agreement with CMS to participate in Medicare as an ASC, and must meet the conditions set forth in subparts B and C of this part.

ASC services means, for the period before January 1, 2008, facility services that are furnished in an ASC, and beginning January 1, 2008, means the combined facility services and covered ancillary services that are furnished in an ASC in connection with covered surgical procedures.

Covered ancillary services means items and services that are integral to a covered surgical procedure performed in an ASC as provided in §416.164(b), for which payment may be made under §416.171 in addition to the payment for the facility services.

Covered surgical procedures means those surgical procedures furnished before January 1, 2008, that meet the criteria specified in §416.65 and those surgical procedures furnished on or after January 1, 2008, that meet the criteria specified in §416.166.

Facility services means for the period before January 1, 2008, services that are furnished in connection with covered surgical procedures performed in an ASC, and beginning January 1, 2008, means services that are furnished in connection with covered surgical procedures performed in an ASC as provided in §416.164(a) for which payment is included in the ASC payment established under §416.171 for the covered surgical procedure.

[56 FR 8843, Mar. 1, 1991; 56 FR 23022, May 20, 1991, as amended at 71 FR 68226, Nov. 24, 2006; 72 FR 42544, Aug. 2, 2007; 73 FR 68811, Nov. 18, 2008]

Subpart B—General Conditions and Requirements

§416.25 Basic requirements.

Participation as an ASC is limited to facilities that—

(a) Meet the definition in §416.2; and

(b) Have in effect an agreement obtained in accordance with this subpart.

[56 FR 8843, Mar. 1, 1991]

§416.26 Qualifying for an agreement.

(a) *Deemed compliance.* CMS may deem an ASC to be in compliance with any or all of the conditions set forth in subpart C of this part if—

(1) The ASC is accredited by a national accrediting body, or licensed by a State agency, that CMS determines provides reasonable assurance that the conditions are met;

(2) In the case of deemed status through accreditation by a national accrediting body, where State law requires licensure, the ASC complies with State licensure requirements; and

(3) The ASC authorizes the release to CMS, of the findings of the accreditation survey.

(b) *Survey of ASCs.* (1) Unless CMS deems the ASC to be in compliance with the conditions set forth in subpart C of this part, the State survey agency must survey the facility to ascertain compliance with those conditions, and report its findings to CMS.

(2) CMS surveys deemed ASCs on a sample basis as part of CMS's validation process.

(c) *Acceptance of the ASC as qualified to furnish ambulatory surgical services.* If CMS determines, after reviewing the survey agency recommendation and other evidence relating to the qualification of the ASC, that the facility meets the requirements of this part, it sends to the ASC—

(1) Written notice of the determination; and

(2) Two copies of the ASC agreement.

(d) *Filing of agreement by the ASC.* If the ASC wishes to participate in the program, it must—

(1) Have both copies of the ASC agreement signed by its authorized representative; and

(2) File them with CMS.

(e) *Acceptance by CMS.* If CMS accepts the agreement filed by the ASC, returns to the ASC one copy of the agreement, with a notice of acceptance specifying the effective date.

(f) *Appeal rights.* If CMS refuses to enter into an agreement or if CMS terminates an agreement, the ASC is entitled to a hearing in accordance with part 498 of this chapter.

[56 FR 8843, Mar. 1, 1991]

§ 416.30 Terms of agreement with CMS.

As part of the agreement under § 416.26 the ASC must agree to the following:

(a) *Compliance with coverage conditions.* The ASC agrees to meet the conditions for coverage specified in subpart C of this part and to report promptly to CMS any failure to do so.

(b) *Limitation on charges to beneficiaries.*[1] The ASC agrees to charge the beneficiary or any other person only the applicable deductible and coinsurance amounts for facility services for which the beneficiary—

(1) Is entitled to have payment made on his or her behalf under this part; or

(2) Would have been so entitled if the ASC had filed a request for payment in accordance with § 410.165 of this chapter.

(c) *Refunds to beneficiaries.* (1) The ASC agrees to refund as promptly as possible any money incorrectly collected from beneficiaries or from someone on their behalf.

(2) As used in this section, *money incorrectly collected* means sums collected in excess of those specified in paragraph (b) of this section. It includes amounts collected for a period of time when the beneficiary was believed not to be entitled to Medicare benefits if—

(i) The beneficiary is later determined to have been entitled to Medicare benefits; and

(ii) The beneficiary's entitlement period falls within the time the ASC's agreement with CMS is in effect.

(d) *Furnishing information.* The ASC agrees to furnish to CMS, if requested, information necessary to establish payment rates specified in §§ 416.120–416.130 in the form and manner that CMS requires.

(e) *Acceptance of assignment.* The ASC agrees to accept assignment for all facility services furnished in connection with covered surgical procedures. For purposes of this section, assignment means an assignment under § 424.55 of this chapter of the right to receive payment under Medicare Part B and payment under § 424.64 of this chapter (when an individual dies before assigning the claim).

(f) *ASCs operated by a hopsital.* In an ASC operated by a hospital—

(1) The agreement is made effective on the first day of the next Medicare cost reporting period of the hospital that operates the ASC; and

(2) The ASC participates and is paid only as an ASC.

(3) Costs for the ASC are treated as a non-reimbursable cost center on the hopsital's cost report.

(g) *Additional provisions.* The agreement may contain any additional provisions that CMS finds necessary or desirable for the efficient and effective administration of the Medicare program.

[47 FR 34094, Aug. 5, 1982, as amended at 51 FR 41351, Nov. 14, 1986; 56 FR 8844, Mar. 1, 1991; 74 FR 60680, Nov. 20, 2009]

§ 416.35 Termination of agreement.

(a) *Termination by the ASC*—(1) *Notice to CMS.* An ASC that wishes to terminate its agreement must send CMS written notice of its intent.

(2) *Date of termination.* The notice may state the intended date of termination which must be the first day of a calendar month.

(i) If the notice does not specify a date, or the date is not acceptable to CMS, CMS may set a date that will not be more than 6 months from the date on the ASC's notice of intent.

(ii) CMS may accept a termination date that is less than 6 months after the date on the ASC's notice if it determines that to do so would not unduly disrupt services to the community or otherwise interfere with the effective and efficient administration of the Medicare program.

(3) *Voluntary termination.* If an ASC ceases to furnish services to the community, that shall be deemed to be a voluntary termination of the agreement by the ASC, effective on the last day of business with Medicare beneficiaries.

(b) *Termination by CMS*—(1) *Cause for termination.* CMS may terminate an agreement if it determines that the ASC—

[1] For facility services furnished before July 1987, the ASC had to agree to make no charge to the beneficiary, since those services were not subject to the part B deductible and coinsurance provisions.

(i) No longer meets the conditions for coverage as specified under § 416.26; or

(ii) Is not in substantial compliance with the provisions of the agreement, the requirements of this subpart, and other applicable regulations of subchapter B of this chapter, or any applicable provisions of title XVIII of the Act.

(2) *Notice of termination.* CMS sends notice of termination to the ASC at least 15 days before the effective date stated in the notice.

(3) *Appeal by the ASC.* An ASC may appeal the termination of its agreement in accordance with the provisions set forth in part 498 of this chapter.

(c) *Effect of termination.* Payment is not available for ASC services furnished on or after the effective date of termination.

(d) *Notice to the public.* Prompt notice of the date and effect of termination is given to the public by—

(1) The ASC, after CMS has approved or set a termination date; or

(2) CMS, when it has terminated the agreement.

(e) *Conditions for reinstatement after termination of agreement by CMS.* When an agreement with an ASC is terminated by CMS, the ASC may not file another agreement to participate in the Medicare program unless CMS—

(1) Finds that the reason for the termination of the prior agreement has been removed; and

(2) Is assured that the reason for the termination will not recur.

[47 FR 34094, Aug. 5, 1982, as amended at 52 FR 22454, June 12, 1987; 56 FR 8844, Mar. 1, 1991; 61 FR 40347, Aug. 2, 1996; 82 FR 38515, Aug. 14, 2017]

Subpart C—Specific Conditions for Coverage

§ 416.40 Condition for coverage—Compliance with State licensure law.

The ASC must comply with State licensure requirements.

§ 416.41 Condition for coverage—Governing body and management.

The ASC must have a governing body that assumes full legal responsibility for determining, implementing, and monitoring policies governing the ASC's total operation. The governing body has oversight and accountability for the quality assessment and performance improvement program, ensures that facility policies and programs are administered so as to provide quality health care in a safe environment, and develops and maintains a disaster preparedness plan.

(a) *Standard: Contract services.* When services are provided through a contract with an outside resource, the ASC must assure that these services are provided in a safe and effective manner.

(b) *Standard: Hospitalization.* (1) The ASC must have an effective procedure for the immediate transfer, to a hospital, of patients requiring emergency medical care beyond the capabilities of the ASC.

(2) This hospital must be a local, Medicare-participating hospital or a local, nonparticipating hospital that meets the requirements for payment for emergency services under § 482.2 of this chapter.

(3) The ASC must periodically provide the local hospital with written notice of its operations and patient population served.

[73 FR 68811, Nov. 18, 2008, as amended at 81 FR 64022, Sept. 16, 2016; 84 FR 51814, Sep. 30, 2019]

§ 416.42 Condition for coverage—Surgical services.

Surgical procedures must be performed in a safe manner by qualified physicians who have been granted clinical privileges by the governing body of the ASC in accordance with approved policies and procedures of the ASC.

(a) *Standard: Anesthetic risk and evaluation.* (1) Immediately before surgery—

(i) A physician must examine the patient to evaluate the risk of the procedure to be performed; and

(ii) A physician or anesthetist as defined at § 410.69(b) of this chapter must examine the patient to evaluate the risk of anesthesia.

(2) Before discharge from the ASC, each patient must be evaluated by a physician or by an anesthetist as defined at § 410.69(b) of this chapter, in accordance with applicable State health and safety laws, standards of practice,

and ASC policy, for proper anesthesia recovery.

(b) *Standard: Administration of anesthesia.* Anesthetics must be administered by only—

(1) A qualified anesthesiologist; or

(2) A physician qualified to administer anesthesia, a certified registered nurse anesthetist (CRNA), or an anesthesiologist's assistant as defined in § 410.69(b) of this chapter, or a supervised trainee in an approved educational program. In those cases in which a non-physician administers the anesthesia, unless exempted in accordance with paragraph (c) of this section, the anesthetist must be under the supervision of the operating physician, and in the case of an anesthesiologist's assistant, under the supervision of an anesthesiologist.

(c) *Standard: State exemption.* (1) An ASC may be exempted from the requirement for physician supervision of CRNAs as described in paragraph (b)(2) of this section, if the State in which the ASC is located submits a letter to CMS signed by the Governor, following consultation with the State's Boards of Medicine and Nursing, requesting exemption from physician supervision of CRNAs. The letter from the Governor must attest that he or she has consulted with State Boards of Medicine and Nursing about issues related to access to and the quality of anesthesia services in the State and has concluded that it is in the best interests of the State's citizens to opt-out of the current physician supervision requirement, and that the opt-out is consistent with State law.

(2) The request for exemption and recognition of State laws, and the withdrawal of the request may be submitted at any time, and are effective upon submission.

[57 FR 33899, July 31, 1992, as amended at 66 FR 56768, Nov. 13, 2001; 73 FR 68812, Nov. 18, 2008; 79 FR 27153, May 12, 2014; 84 FR 63202, Nov. 15, 2019]

§ 416.43 Conditions for coverage—Quality assessment and performance improvement.

The ASC must develop, implement and maintain an ongoing, data-driven quality assessment and performance improvement (QAPI) program.

(a) *Standard: Program scope.* (1) The program must include, but not be limited to, an ongoing program that demonstrates measurable improvement in patient health outcomes, and improves patient safety by using quality indicators or performance measures associated with improved health outcomes and by the identification and reduction of medical errors.

(2) The ASC must measure, analyze, and track quality indicators, adverse patient events, infection control and other aspects of performance that includes care and services furnished in the ASC.

(b) *Standard: Program data.* (1) The program must incorporate quality indicator data, including patient care and other relevant data regarding services furnished in the ASC.

(2) The ASC must use the data collected to—

(i) Monitor the effectiveness and safety of its services, and quality of its care.

(ii) Identify opportunities that could lead to improvements and changes in its patient care.

(c) *Standard: Program activities.* (1) The ASC must set priorities for its performance improvement activities that—

(i) Focus on high risk, high volume, and problem-prone areas.

(ii) Consider incidence, prevalence, and severity of problems in those areas.

(iii) Affect health outcomes, patient safety, and quality of care.

(2) Performance improvement activities must track adverse patient events, examine their causes, implement improvements, and ensure that improvements are sustained over time.

(3) The ASC must implement preventive strategies throughout the facility targeting adverse patient events and ensure that all staff are familiar with these strategies.

(d) *Standard: Performance improvement projects.* (1) The number and scope of distinct improvement projects conducted annually must reflect the scope and complexity of the ASC's services and operations.

(2) The ASC must document the projects that are being conducted. The documentation, at a minimum, must

include the reason(s) for implementing the project, and a description of the project's results.

(e) *Standard: Governing body responsibilities.* The governing body must ensure that the QAPI program—

(1) Is defined, implemented, and maintained by the ASC.

(2) Addresses the ASC's priorities and that all improvements are evaluated for effectiveness.

(3) Specifies data collection methods, frequency, and details.

(4) Clearly establishes its expectations for safety.

(5) Adequately allocates sufficient staff, time, information systems and training to implement the QAPI program.

[73 FR 68812, Nov. 18, 2008]

§ 416.44 Condition for coverage—Environment.

The ASC must have a safe and sanitary environment, properly constructed, equipped, and maintained to protect the health and safety of patients.

(a) *Standard: Physical environment.* The ASC must provide a functional and sanitary environment for the provision of surgical services.

(1) Each operating room must be designed and equipped so that the types of surgery conducted can be performed in a manner that protects the lives and assures the physical safety of all individuals in the area.

(2) The ASC must have a separate recovery room and waiting area.

(b) *Standard: Safety from fire.* (1) Except as otherwise provided in this section, the ASC must meet the provisions applicable to Ambulatory Health Care Occupancies, regardless of the number of patients served, and must proceed in accordance with the Life Safety Code (NFPA 101 and Tentative Interim Amendments TIA 12–1, TIA 12–2, TIA 12–3, and TIA 12–4).

(2) In consideration of a recommendation by the State survey agency or Accrediting Organization or at the discretion of the Secretary, may waive, for periods deemed appropriate, specific provisions of the Life Safety Code, which would result in unreasonable hardship upon an ASC, but only if the waiver will not adversely affect the health and safety of the patients.

(3) The provisions of the Life Safety Code do not apply in a State if CMS finds that a fire and safety code imposed by State law adequately protects patients in an ASC.

(4) An ASC may place alcohol-based hand rub dispensers in its facility if the dispensers are installed in a manner that adequately protects against inappropriate access.

(5) When a sprinkler system is shut down for more than 10 hours, the ASC must:

(i) Evacuate the building or portion of the building affected by the system outage until the system is back in service, or

(ii) Establish a fire watch until the system is back in service.

(6) Beginning July 5, 2017, an ASC must be in compliance with Chapter 21.3.2.1, Doors to hazardous areas.

(c) *Standard: Building Safety.* Except as otherwise provided in this section, the ASC must meet the applicable provisions and must proceed in accordance with the 2012 edition of the Health Care Facilities Code (NFPA 99, and Tentative Interim Amendments TIA 12–2, TIA 12–3, TIA 12–4, TIA 12–5 and TIA 12–6).

(1) Chapters 7, 8, 12, and 13 of the adopted Health Care Facilities Code do not apply to an ASC.

(2) If application of the Health Care Facilities Code required under paragraph (c) of this section would result in unreasonable hardship for the ASC, CMS may waive specific provisions of the Health Care Facilities Code, but only if the waiver does not adversely affect the health and safety of patients.

(d) *Standard: Emergency equipment.* The ASC medical staff and governing body of the ASC coordinates, develops, and revises ASC policies and procedures to specify the types of emergency equipment required for use in the ASC's operating room. The equipment must meet the following requirements:

(1) Be immediately available for use during emergency situations.

(2) Be appropriate for the facility's patient population.

(3) Be maintained by appropriate personnel.

(e) *Standard: Emergency personnel.* Personnel trained in the use of emergency equipment and in cardiopulmonary resuscitation must be available whenever there is a patient in the ASC.

(f) The standards incorporated by reference in this section are approved for incorporation by reference by the Director of the Office of the Federal Register in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. You may inspect a copy at the CMS Information Resource Center, 7500 Security Boulevard, Baltimore, MD or at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202–741–6030, or go to: *http://www.archives.gov/federal_register/code_of_federal_regulations/ibr_locations.html*. If any changes in this edition of the Code are incorporated by reference, CMS will publish a document in the FEDERAL REGISTER to announce the changes.

(1) National Fire Protection Association, 1 Batterymarch Park, Quincy, MA 02169, *www.nfpa.org*, 1.617.770.3000.

(i) NFPA 99, Standards for Health Care Facilities Code of the National Fire Protection Association 99, 2012 edition, issued August 11, 2011.

(ii) TIA 12–2 to NFPA 99, issued August 11, 2011.

(iii) TIA 12–3 to NFPA 99, issued August 9, 2012.

(iv) TIA 12–4 to NFPA 99, issued March 7, 2013.

(v) TIA 12–5 to NFPA 99, issued August 1, 2013.

(vi) TIA 12–6 to NFPA 99, issued March 3, 2014.

(vii) NFPA 101, Life Safety Code, 2012 edition, issued August 11, 2011;

(viii) TIA 12–1 to NFPA 101, issued August 11, 2011.

(ix) TIA 12–2 to NFPA 101, issued October 30, 2012.

(x) TIA 12–3 to NFPA 101, issued October 22, 2013.

(xi) TIA 12–4 to NFPA 101, issued October 22, 2013.

(2) [Reserved]

[47 FR 34094, Aug. 5, 1982, amended at 53 FR 11508, Apr. 7, 1988; 54 FR 4026, Jan. 27, 1989; 68 FR 1385, Jan. 10, 2003; 69 FR 18803, Apr. 9, 2004; 70 FR 15237, Mar. 25, 2005; 71 FR 55339, Sept. 22, 2006; 77 FR 29030, May 16, 2012; 81 FR 26896, May 4, 2016; 81 FR 42548, June 30, 2016]

§ 416.45 Condition for coverage—Medical staff.

The medical staff of the ASC must be accountable to the governing body.

(a) *Standard: Membership and clinical privileges.* Members of the medical staff must be legally and professionally qualified for the positions to which they are appointed and for the performance of privileges granted. The ASC grants privileges in accordance with recommendations from qualified medical personnel.

(b) *Standard: Reappraisals.* Medical staff privileges must be periodically reappraised by the ASC. The scope of procedures performed in the ASC must be periodically reviewed and amended as appropriate.

(c) *Standard: Other practitioners.* If the ASC assigns patient care responsibilities to practitioners other than physicians, it must have established policies and procedures, approved by the governing body, for overseeing and evaluating their clinical activities.

§ 416.46 Condition for coverage—Nursing services.

The nursing services of the ASC must be directed and staffed to assure that the nursing needs of all patients are met.

(a) *Standard: Organization and staffing.* Patient care responsibilities must be delineated for all nursing service personnel. Nursing services must be provided in accordance with recognized standards of practice. There must be a registered nurse available for emergency treatment whenever there is a patient in the ASC.

(b) [Reserved]

§ 416.47 Condition for coverage—Medical records.

The ASC must maintain complete, comprehensive, and accurate medical records to ensure adequate patient care.

(a) *Standard: Organization.* The ASC must develop and maintain a system for the proper collection, storage, and use of patient records.

(b) *Standard: Form and content of record.* The ASC must maintain a medical record for each patient. Every record must be accurate, legible, and

promptly completed. Medical records must include at least the following:

(1) Patient identification.

(2) Significant medical history and results of physical examination (as applicable).

(3) Pre-operative diagnostic studies (entered before surgery), if performed.

(4) Findings and techniques of the operation, including a pathologist's report on all tissues removed during surgery, except those exempted by the governing body.

(5) Any allergies and abnormal drug reactions.

(6) Entries related to anesthesia administration.

(7) Documentation of properly executed informed patient consent.

(8) Discharge diagnosis.

[47 FR 34094, Aug. 5, 1982, as amended at 84 FR 51814, Sept. 30, 2019]

§ 416.48 Condition for coverage—Pharmaceutical services.

The ASC must provide drugs and biologicals in a safe and effective manner, in accordance with accepted professional practice, and under the direction of an individual designated responsible for pharmaceutical services.

(a) *Standard: Administration of drugs.* Drugs must be prepared and administered according to established policies and acceptable standards of practice.

(1) Adverse reactions must be reported to the physician responsible for the patient and must be documented in the record.

(2) Blood and blood products must be administered by only physicians or registered nurses.

(3) Orders given orally for drugs and biologicals must be followed by a written order, signed by the prescribing physician.

(b) [Reserved]

§ 416.49 Condition for coverage—Laboratory and radiologic services.

(a) *Standard: Laboratory services.* If the ASC performs laboratory services, it must meet the requirements of part 493 of this chapter. If the ASC does not provide its own laboratory services, it must have procedures for obtaining routine and emergency laboratory services from a certified laboratory in accordance with part 493 of this chapter. The referral laboratory must be certified in the appropriate specialties and subspecialties of service to perform the referred tests in accordance with the requirements of Part 493 of this chapter.

(b) *Standard: Radiologic services.* (1) Radiologic services may only be provided when integral to procedures offered by the ASC and must meet the requirements specified in §482.26(b), (c)(2), and (d)(2) of this chapter.

(2) If radiologic services are utilized, the governing body must appoint an individual qualified in accordance with State law and ASC policies who is responsible for assuring all radiologic services are provided in accordance with the requirements of this section.

[73 FR 68812, Nov. 18, 2008, as amended at 79 FR 27153, May 12, 2014]

§ 416.50 Condition for coverage—Patient rights.

The ASC must inform the patient or the patient's representative or surrogate of the patient's rights and must protect and promote the exercise of these rights, as set forth in this section. The ASC must also post the written notice of patient rights in a place or places within the ASC likely to be noticed by patients waiting for treatment or by the patient's representative or surrogate, if applicable.

(a) *Standard: Notice of Rights.* An ASC must, prior to the start of the surgical procedure, provide the patient, the patient's representative, or the patient's surrogate with verbal and written notice of the patient's rights in a language and manner that ensures the patient, the representative, or the surrogate understand all of the patient's rights as set forth in this section. The ASC's notice of rights must include the address and telephone number of the State agency to which patients may report complaints, as well as the Web site for the Office of the Medicare Beneficiary Ombudsman.

(b) *Standard: Disclosure of physician financial interest or ownership.* The ASC must disclose, in accordance with Part 420 of this subchapter, and where applicable, provide a list of physicians who have financial interest or ownership in the ASC facility. Disclosure of information must be in writing.

(c) *Standard: Advance directives.* The ASC must comply with the following requirements:

(1) Provide the patient or, as appropriate, the patient's representative with written information concerning its policies on advance directives, including a description of applicable State health and safety laws and, if requested, official State advance directive forms.

(2) Inform the patient or, as appropriate, the patient's representative of the patient's right to make informed decisions regarding the patient's care.

(3) Document in a prominent part of the patient's current medical record, whether or not the individual has executed an advance directive.

(d) *Standard: Submission and investigation of grievances.* The ASC must establish a grievance procedure for documenting the existence, submission, investigation, and disposition of a patient's written or verbal grievance to the ASC. The following criteria must be met:

(1) All alleged violations/grievances relating, but not limited to, mistreatment, neglect, verbal, mental, sexual, or physical abuse, must be fully documented.

(2) All allegations must be immediately reported to a person in authority in the ASC.

(3) Only substantiated allegations must be reported to the State authority or the local authority, or both.

(4) The grievance process must specify timeframes for review of the grievance and the provisions of a response.

(5) The ASC, in responding to the grievance, must investigate all grievances made by a patient, the patient's representative, or the patient's surrogate regarding treatment or care that is (or fails to be) furnished.

(6) The ASC must document how the grievance was addressed, as well as provide the patient, the patient's representative, or the patient's surrogate with written notice of its decision. The decision must contain the name of an ASC contact person, the steps taken to investigate the grievance, the result of the grievance process and the date the grievance process was completed.

(e) *Standard: Exercise of rights and respect for property and person.* (1) The patient has the right to the following:

(i) Be free from any act of discrimination or reprisal.

(ii) Voice grievances regarding treatment or care that is (or fails to be) provided.

(iii) Be fully informed about a treatment or procedure and the expected outcome before it is performed.

(2) If a patient is adjudged incompetent under applicable State laws by a court of proper jurisdiction, the rights of the patient are exercised by the person appointed under State law to act on the patient's behalf.

(3) If a State court has not adjudged a patient incompetent, any legal representative or surrogate designated by the patient in accordance with State law may exercise the patient's rights to the extent allowed by State law.

(f) *Standard: Privacy and safety.* The patient has the right to—

(1) Personal privacy.

(2) Receive care in a safe setting.

(3) Be free from all forms of abuse or harassment.

(g) *Standard: Confidentiality of clinical records.* The ASC must comply with the Department's rules for the privacy and security of individually identifiable health information, as specified at 45 CFR parts 160 and 164.

[73 FR 68812, Nov. 18, 2008, as amended at 76 FR 65889, Oct. 24, 2011]

§ 416.51 Conditions for coverage—Infection control.

The ASC must maintain an infection control program that seeks to minimize infections and communicable diseases.

(a) *Standard: Sanitary environment.* The ASC must provide a functional and sanitary environment for the provision of surgical services by adhering to professionally acceptable standards of practice.

(b) *Standard: Infection control program.* The ASC must maintain an ongoing program designed to prevent, control, and investigate infections and communicable diseases. In addition, the infection control and prevention program must include documentation that the

ASC has considered, selected, and implemented nationally recognized infection control guidelines. The program is—

(1) Under the direction of a designated and qualified professional who has training in infection control;

(2) An integral part of the ASC's quality assessment and performance improvement program; and

(3) Responsible for providing a plan of action for preventing, identifying, and managing infections and communicable diseases and for immediately implementing corrective and preventive measures that result in improvement.

[73 FR 68813, Nov. 18, 2008, as amended at 86 FR 61616, Nov. 5, 2021; 88 FR 36510, June 5, 2023]

§ 416.52 Conditions for coverage—Patient admission, assessment and discharge.

The ASC must ensure each patient has the appropriate pre-surgical and post-surgical assessments completed and that all elements of the discharge requirements are completed.

(a) *Standard: Patient assessment and admission.* (1) The ASC must develop and maintain a policy that identifies those patients who require a medical history and physical examination prior to surgery. The policy must—

(i) Include the timeframe for medical history and physical examination to be completed prior to surgery.

(ii) Address, but is not limited to, the following factors: Patient age, diagnosis, the type and number of procedures scheduled to be performed on the same surgery date, known comorbidities, and the planned anesthesia level.

(iii) Be based on any applicable nationally recognized standards of practice and guidelines, and any applicable State and local health and safety laws.

(2) Upon admission, each patient must have a pre-surgical assessment completed by a physician who will be performing the surgery or other qualified practitioner in accordance with applicable State health and safety laws, standards of practice, and ASC policy.

(3) The pre-surgical assessment must include documentation of any allergies to drugs and biologicals.

(4) The patient's medical history and physical examination (if any) must be placed in the patient's medical record prior to the surgical procedure.

(b) *Standard: Post-surgical assessment.* (1) The patient's post-surgical condition must be assessed and documented in the medical record by a physician, other qualified practitioner, or a registered nurse with, at a minimum, post-operative care experience in accordance with applicable State health and safety laws, standards of practice, and ASC policy.

(2) Post-surgical needs must be addressed and included in the discharge notes.

(c) *Standard: Discharge.* The ASC must—

(1) Provide each patient with written discharge instructions and overnight supplies. When appropriate, make a followup appointment with the physician, and ensure that all patients are informed, either in advance of their surgical procedure or prior to leaving the ASC, of their prescriptions, post-operative instructions and physician contact information for followup care.

(2) Ensure each patient has a discharge order, signed by the physician who performed the surgery or procedure in accordance with applicable State health and safety laws, standards of practice, and ASC policy.

(3) Ensure all patients are discharged in the company of a responsible adult, except those patients exempted by the attending physician.

[73 FR 68813, Nov. 18, 2008, as amended at 84 FR 51814, Sept. 30, 2019]

§ 416.54 Condition for coverage—Emergency preparedness.

The Ambulatory Surgical Center (ASC) must comply with all applicable Federal, State, and local emergency preparedness requirements. The ASC must establish and maintain an emergency preparedness program that meets the requirements of this section. The emergency preparedness program must include, but not be limited to, the following elements:

(a) *Emergency plan.* The ASC must develop and maintain an emergency preparedness plan that must be reviewed, and updated at least every 2 years. The plan must do the following:

(1) Be based on and include a documented, facility-based and community-based risk assessment, utilizing an all-hazards approach.

(2) Include strategies for addressing emergency events identified by the risk assessment.

(3) Address patient population, including, but not limited to, the type of services the ASC has the ability to provide in an emergency; and continuity of operations, including delegations of authority and succession plans.

(4) Include a process for cooperation and collaboration with local, tribal, regional, State, and Federal emergency preparedness officials' efforts to maintain an integrated response during a disaster or emergency situation.

(b) *Policies and procedures.* The ASC must develop and implement emergency preparedness policies and procedures, based on the emergency plan set forth in paragraph (a) of this section, risk assessment at paragraph (a)(1) of this section, and the communication plan at paragraph (c) of this section. The policies and procedures must be reviewed and updated at least every 2 years. At a minimum, the policies and procedures must address the following:

(1) A system to track the location of on-duty staff and sheltered patients in the ASC's care during an emergency. If on-duty staff or sheltered patients are relocated during the emergency, the ASC must document the specific name and location of the receiving facility or other location.

(2) Safe evacuation from the ASC, which includes the following:

(i) Consideration of care and treatment needs of evacuees.

(ii) Staff responsibilities.

(iii) Transportation.

(iv) Identification of evacuation location(s).

(v) Primary and alternate means of communication with external sources of assistance.

(3) A means to shelter in place for patients, staff, and volunteers who remain in the ASC.

(4) A system of medical documentation that does the following:

(i) Preserves patient information.

(ii) Protects confidentiality of patient information.

(iii) Secures and maintains the availability of records.

(5) The use of volunteers in an emergency and other staffing strategies, including the process and role for integration of State and Federally designated health care professionals to address surge needs during an emergency.

(6) The role of the ASC under a waiver declared by the Secretary, in accordance with section 1135 of the Act, in the provision of care and treatment at an alternate care site identified by emergency management officials.

(c) *Communication plan.* The ASC must develop and maintain an emergency preparedness communication plan that complies with Federal, State, and local laws and must be reviewed and updated at least every 2 years. The communication plan must include all of the following:

(1) Names and contact information for the following:

(i) Staff.

(ii) Entities providing services under arrangement.

(iii) Patients' physicians.

(iv) Volunteers.

(2) Contact information for the following:

(i) Federal, State, tribal, regional, and local emergency preparedness staff.

(ii) Other sources of assistance.

(3) Primary and alternate means for communicating with the following:

(i) ASC's staff.

(ii) Federal, State, tribal, regional, and local emergency management agencies.

(4) A method for sharing information and medical documentation for patients under the ASC's care, as necessary, with other health care providers to maintain the continuity of care.

(5) A means, in the event of an evacuation, to release patient information as permitted under 45 CFR 164.510(b)(1)(ii).

(6) A means of providing information about the general condition and location of patients under the facility's

care as permitted under 45 CFR 164.510(b)(4).

(7) A means of providing information about the ASC's needs, and its ability to provide assistance, to the authority having jurisdiction, the Incident Command Center, or designee.

(d) *Training and testing.* The ASC must develop and maintain an emergency preparedness training and testing program that is based on the emergency plan set forth in paragraph (a) of this section, risk assessment at paragraph (a)(1) of this section, policies and procedures at paragraph (b) of this section, and the communication plan at paragraph (c) of this section. The training and testing program must be reviewed and updated at least every 2 years.

(1) *Training program.* The ASC must do all of the following:

(i) Initial training in emergency preparedness policies and procedures to all new and existing staff, individuals providing on-site services under arrangement, and volunteers, consistent with their expected roles.

(ii) Provide emergency preparedness training at least every 2 years.

(iii) Maintain documentation of all emergency preparedness training.

(iv) Demonstrate staff knowledge of emergency procedures.

(v) If the emergency preparedness policies and procedures are significantly updated, the ASC must conduct training on the updated policies and procedures.

(2) *Testing.* The ASC must conduct exercises to test the emergency plan at least annually. The ASC must do the following:

(i) Participate in a full-scale exercise that is community-based every 2 years; or

(A) When a community-based exercise is not accessible, conduct a facility-based functional exercise every 2 years; or

(B) If the ASC experiences an actual natural or man-made emergency that requires activation of the emergency plan, the ASC is exempt from engaging in its next required community-based or individual, facility-based functional exercise following the onset of the emergency event.

(ii) Conduct an additional exercise at least every 2 years, opposite the year the full-scale or functional exercise under paragraph (d)(2)(i) of this section is conducted, that may include, but is not limited to the following:

(A) A second full-scale exercise that is community-based, or an individual, facility-based functional exercise; or

(B) A mock disaster drill; or

(C) A tabletop exercise or workshop that is led by a facilitator and includes a group discussion using a narrated, clinically-relevant emergency scenario, and a set of problem statements, directed messages, or prepared questions designed to challenge an emergency plan.

(iii) Analyze the ASC's response to and maintain documentation of all drills, tabletop exercises, and emergency events and revise the ASC's emergency plan, as needed.

(e) *Integrated healthcare systems.* If an ASC is part of a healthcare system consisting of multiple separately certified healthcare facilities that elects to have a unified and integrated emergency preparedness program, the ASC may choose to participate in the healthcare system's coordinated emergency preparedness program. If elected, the unified and integrated emergency preparedness program must—

(1) Demonstrate that each separately certified facility within the system actively participated in the development of the unified and integrated emergency preparedness program.

(2) Be developed and maintained in a manner that takes into account each separately certified facility's unique circumstances, patient populations, and services offered.

(3) Demonstrate that each separately certified facility is capable of actively using the unified and integrated emergency preparedness program and is in compliance.

(4) Include a unified and integrated emergency plan that meets the requirements of paragraphs (a)(2), (3), and (4) of this section. The unified and integrated emergency plan must also be based on and include the following:

(i) A documented community-based risk assessment, utilizing an all-hazards approach.

(ii) A documented individual facility-based risk assessment for each separately certified facility within the health system, utilizing an all-hazards approach.

(5) Include integrated policies and procedures that meet the requirements set forth in paragraph (b) of this section, a coordinated communication plan and training and testing programs that meet the requirements of paragraphs (c) and (d) of this section, respectively.

[81 FR 64022, Sept. 16, 2016, as amended at 84 FR 51814, Sept. 30, 2019]

Subpart D—Scope of Benefits for Services Furnished Before January 1, 2008

§ 416.60 General rules.

(a) The services payable under this part are facility services furnished to Medicare beneficiaries, by a participating facility, in connection with covered surgical procedures specified in § 416.65.

(b) The surgical procedures, including all preoperative and post-operative services that are performed by a physician, are covered as physician services under part 410 of this chapter.

[56 FR 8844, Mar. 1, 1991]

§ 416.61 Scope of facility services.

(a) *Included services.* Facility services include, but are not limited to—

(1) Nursing, technician, and related services;

(2) Use of the facilities where the surgical procedures are performed;

(3) Drugs, biologicals, surgical dressings, supplies, splints, casts, and appliances and equipment directly related to the provision of surgical procedures;

(4) Diagnostic or therapeutic services or items directly related to the provision of a surgical procedure;

(5) Administrative, recordkeeping and housekeeping items and services; and

(6) Materials for anesthesia.

(7) Intra-ocular lenses (IOLs).

(8) Supervision of the services of an anesthetist by the operating surgeon.

(b) *Excluded services.* Facility services do not include items and services for which payment may be made under other provisions of part 405 of this chapter, such as physicians' services, laboratory, X-ray or diagnostic procedures (other than those directly related to performance of the surgical procedure), prosthetic devices (except IOLs), ambulance services, leg, arm, back and neck braces, artificial limbs, and durable medical equipment for use in the patient's home. In addition, they do not include anesthetist services furnished on or after January 1, 1989.

[56 FR 8844, Mar. 1, 1991, as amended at 57 FR 33899, July 31, 1992]

§ 416.65 Covered surgical procedures.

Effective for services furnished before January 1, 2008, covered surgical procedures are those procedures that meet the standards described in paragraphs (a) and (b) of this section and are included in the list published in accordance with paragraph (c) of this section.

(a) *General standards.* Covered surgical procedures are those surgical and other medical procedures that—

(1) Are commonly performed on an inpatient basis in hospitals, but may be safely performed in an ASC;

(2) Are not of a type that are commonly performed, or that may be safely performed, in physicians' offices;

(3) Are limited to those requiring a dedicated operating room (or suite), and generally requiring a post-operative recovery room or short-term (not overnight) convalescent room; and

(4) Are not otherwise excluded under § 411.15 of this chapter.

(b) *Specific standards.* (1) Covered surgical procedures are limited to those that do not generally exceed—

(i) A total of 90 minutes operating time; and

(ii) A total of 4 hours recovery or convalescent time.

(2) If the covered surgical procedures require anesthesia, the anesthesia must be—

(i) Local or regional anesthesia; or

(ii) General anesthesia of 90 minutes or less duration.

(3) Covered surgical procedures may not be of a type that—

(i) Generally result in extensive blood loss;

(ii) Require major or prolonged invasion of body cavities;

(iii) Directly involve major blood vessels; or

(iv) Are generally emergency or life-threatening in nature.

(c) *Publication of covered procedures.* CMS will publish in the FEDERAL REGISTER a list of covered surgical procedures and revisions as appropriate.

[47 FR 34094, Aug. 5, 1982, as amended at 71 FR 68226, Nov. 24, 2006]

§ 416.75 Performance of listed surgical procedures on an inpatient hospital basis.

The inclusion of any procedure as a covered surgical procedure under § 416.65 does not preclude its coverage in an inpatient hospital setting under Medicare.

§ 416.76 Applicability.

The provisions of this subpart apply to facility services furnished before January 1, 2008.

[71 FR 68226, Nov. 24, 2006]

Subpart E—Prospective Payment System for Facility Services Furnished Before January 1, 2008

§ 416.120 Basis for payment.

The basis for payment depends on where the services are furnished.

(a) *Hospital outpatient department.* Payment is in accordance with part 419 of this chapter.

(b) [Reserved]

(c) *ASC*—(1) *General rule.* Payment is based on a prospectively determined rate. This rate covers the cost of services such as supplies, nursing services, equipment, etc., as specified in § 416.61. The rate does not cover physician services or other medical services covered under part 410 of this chapter (for example, X-ray services or laboratory services) which are not directly related to the performance of the surgical procedures. Those services may be billed separately and paid on a reasonable charge basis.

(2) *Single and multiple surgical procedures.* (i) If one covered surgical procedure is furnished to a beneficiary in an operative session, payment is based on the prospectively determined rate for that procedure.

(ii) If more than one surgical procedure is furnished in a single operative session, payment is based on—

(A) The full rate for the procedure with the highest prospectively determined rate; and

(B) One half of the prospectively determined rate for each of the other procedures.

(3) *Deductibles and coinsurance.* Part B deductible and coinsurance amounts apply as specified in § 410.152 (a) and (i) of this chapter.

[56 FR 8844, Mar. 1, 1991; 56 FR 23022, May 20, 1991, as amended at 71 FR 68226, Nov. 24, 2006]

§ 416.121 Applicability.

The provisions of this subpart apply to facility services furnished before January 1, 2008.

[71 FR 68226, Nov. 24, 2006]

§ 416.125 ASC facility services payment rate.

(a) The payment rate is based on a prospectively determined standard overhead amount per procedure derived from an estimate of the costs incurred by ambulatory surgical centers generally in providing services furnished in connection with the performance of that procedure.

(b) The payment must be substantially less than would have been paid under the program if the procedure had been performed on an inpatient basis in a hospital.

(c) For services furnished on or after January 1, 2007, and before the effective date of implementation of a revised payment system, the ASC payment rate for a surgical procedure is the lesser of the ASC payment rate established under paragraph (a) of this section or the prospective payment rate for the procedure established under § 419.32 of this chapter. The lesser payment amount is determined prior to application of any geographic adjustment.

[56 FR 8844, Mar. 1, 1991, as amended at 71 FR 68226, Nov. 24, 2006]

§416.130 Publication of revised payment methodologies.

Whenever CMS proposes to revise the payment rate for ASCs, CMS publishes a notice in the FEDERAL REGISTER describing the revision. The notice also explains the basis on which the rates were established. After reviewing public comments, CMS publishes a notice establishing the rates authorized by this section. In setting these rates, CMS may adopt reasonable classifications of facilities and may establish different rates for different types of surgical procedures.

[47 FR 34094, Aug. 5, 1982, as amended at 56 FR 8844, Mar. 1, 1991]

§416.140 Surveys.

(a) *Timing, purpose, and procedures.* (1) No more often than once a year, CMS conducts a survey of a randomly selected sample of participating ASCs to collect data for analysis or reevaluation of payment rates.

(2) CMS notifies the selected ASCs by mail of their selection and of the form and content of the report the ASCs are required to submit within 60 days of the notice.

(3) If the facility does not submit an adequate report in response to CMS's survey request, CMS may terminate the agreement to participate in the Medicare program as an ASC.

(4) CMS may grant a 30-day postponement of the due date for the survey report if it determines that the facility has demonstrated good cause for the delay.

(b) *Requirements for ASCs.* ASCs must—

(1) Maintain adequate financial records, in the form and containing the data required by CMS, to allow determination of the payment rates for covered surgical procedures furnished to Medicare beneficiaries under this subpart.

(2) Within 60 days of a request from CMS submit, in the form and detail as may be required by CMS, a report of—

(i) Their operations, including the allowable costs actually incurred for the period and the actual number and kinds of surgical procedures furnished during the period; and

(ii) Their customary charges for each surgical procedure furnished for the period.

[47 FR 34094, Aug. 5, 1982, as amended at 56 FR 8845, Mar. 1, 1991]

Subpart F—Coverage, Scope of ASC Services, and Prospective Payment System for ASC Services Furnished on or After January 1, 2008

SOURCE: 72 FR 42545, Aug. 2, 2007, unless otherwise noted.

§416.160 Basis and scope.

(a) *Statutory basis.* (1) Section 1833(i)(2)(D) of the Act requires the Secretary to implement a revised payment system for payment of surgical services furnished in ASCs. The statute requires that, in the year such system is implemented, the system shall be designed to result in the same amount of aggregate expenditures for such services as would be made if there was no requirement for a revised payment system. The revised payment system shall be implemented no earlier than January 1, 2006, and no later than January 1, 2008. The statute provides that the Secretary may implement a reduction in any annual update for failure to report on quality measures as specified by the Secretary. The statute also requires that, for CY 2011 and each subsequent year, any annual update to the ASC payment system, after application of any reduction in the annual update for failure to report on quality measures as specified by the Secretary, be reduced by a productivity adjustment. There shall be no administrative or judicial review under section 1869 of the Act, section 1878 of the Act, or otherwise of the classification system, the relative weights, payment amounts, and the geographic adjustment factor, if any, of the revised payment system.

(2) Section 1833(a)(1)(G) of the Act provides that, beginning with the implementation date of a revised payment system for ASC facility services furnished in connection with a surgical procedure pursuant to section 1833(i)(1)(A) of the Act, the amount paid shall be 80 percent of the lesser of the actual charge for such services or

the amount determined by the Secretary under the revised payment system.

(3) Section 1833(i)(1)(A) of the Act requires the Secretary to specify the surgical procedures that can be performed safely on an ambulatory basis in an ASC.

(4) Section 1834(d) of the Act specifies that, when screening colonoscopies or screening flexible sigmoidoscopies are performed in an ASC or hospital outpatient department, payment shall be based on the lesser of the amount under the fee schedule that would apply to such services if they were performed in a hospital outpatient department in an area or the amount under the fee schedule that would apply to such services if they were performed in an ambulatory surgical center in the same area. Section 1834(d) of the Act also specifies that, in the case of screening flexible sigmoidoscopy and screening colonoscopy services, the payment amounts must not exceed the payment rates established for the related diagnostic services.

(5) Section 1833(a)(1) of the Act requires 100 percent payment for preventive services described in section 1861(ww)(2) of the Act (excluding electrocardiograms) to which the United States Preventive Services Task Force (USPSTF) has given a grade of A or B for any indication or population. Section 1833(b)(1) of the Act also specifies that the Part B deductible shall not apply with respect to preventive services described in section 1861(ww)(2) of the Act (excluding electrocardiograms) to which the USPSTF has given a grade of A or B for any indication or population.

(b) *Scope.* This subpart sets forth—

(1) The scope of ASC services and the criteria for determining the covered surgical procedures for which Medicare provides payment for the associated facility services and covered ancillary services;

(2) The basis of payment for facility services and for covered ancillary services furnished in an ASC in connection with a covered surgical procedure;

(3) The methodologies by which Medicare determines payment amounts for ASC services.

[72 FR 42545, Aug. 2, 2007, as amended at 75 FR 72264, Nov. 24, 2010; 77 FR 68558, Nov. 15, 2012]

§ 416.161 Applicability of this subpart.

The provisions of this subpart apply to ASC services furnished on or after January 1, 2008.

§ 416.163 General rules.

(a) Payment is made under this subpart for ASC services specified in §§ 416.164(a) and (b) furnished to Medicare beneficiaries by a participating ASC in connection with covered surgical procedures as determined by the Secretary in accordance with § 416.166.

(b) Payment for physicians' services and payment for anesthetists' services are made in accordance with part 414 of this subchapter.

(c) Payment for items and services other than physicians' and anesthetists' services, as specified in § 416.164(c), is made in accordance with § 410.152 of this subchapter.

§ 416.164 Scope of ASC services.

(a) *Included facility services.* ASC services for which payment is packaged into the ASC payment for a covered surgical procedure under § 416.166 include, but are not limited to—

(1) Nursing, technician, and related services;

(2) Use of the facility where the surgical procedures are performed;

(3) Any laboratory testing performed under a Clinical Laboratory Improvement Amendments of 1988 (CLIA) certificate of waiver;

(4) Drugs and biologicals for which separate payment is not allowed under the hospital outpatient prospective payment system (OPPS);

(5) Medical and surgical supplies not on pass-through status under subpart G of part 419 of this subchapter;

(6) Equipment;

(7) Surgical dressings;

(8) Implanted prosthetic devices, including intraocular lenses (IOLs), and related accessories and supplies not on pass-through status under subpart G of part 419 of this subchapter;

(9) Implanted DME and related accessories and supplies not on pass-through status under subpart G of part 419 of this subchapter;

(10) Splints and casts and related devices;

(11) Radiology services for which separate payment is not allowed under the OPPS and other diagnostic tests or interpretive services that are integral to a surgical procedure, except certain diagnostic tests for which separate payment is allowed under the OPPS;

(12) Administrative, recordkeeping and housekeeping items and services;

(13) Materials, including supplies and equipment for the administration and monitoring of anesthesia; and

(14) Supervision of the services of an anesthetist by the operating surgeon.

(b) *Covered ancillary services.* Ancillary items and services that are integral to a covered surgical procedure, as defined in §416.166, and for which separate payment is allowed include:

(1) Brachytherapy sources;

(2) Certain implantable items that have pass-through status under the OPPS;

(3) Certain items and services that CMS designates as contractor-priced, including, but not limited to, the acquisition or procurement of corneal tissue for corneal transplant procedures;

(4) Certain drugs and biologicals for which separate payment is allowed under the OPPS;

(5) Certain radiology services and certain diagnostic tests for which separate payment is allowed under the OPPS; and

(6) Non-opioid pain management drugs, biologicals, and medical devices as determined by CMS under §416.174.

(c) *Excluded services.* ASC services do not include items and services outside the scope of ASC services for which payment may be made under part 414 of this subchapter in accordance with §410.152, including, but not limited to—

(1) Physicians' services (including surgical procedures and all preoperative and postoperative services that are performed by a physician);

(2) Anesthetists' services;

(3) Radiology services (other than those integral to performance of a covered surgical procedure);

(4) Diagnostic procedures (other than those directly related to performance of a covered surgical procedure);

(5) Ambulance services;

(6) Leg, arm, back, and neck braces other than those that serve the function of a cast or splint;

(7) Artificial limbs;

(8) Nonimplantable prosthetic devices and DME.

[72 FR 42545, Aug. 2, 2007, as amended at 79 FR 67030, Nov. 10, 2014; 80 FR 70604, Nov. 13, 2015; 83 FR 59178, Nov. 21, 2018; 86 FR 63992, Nov. 16, 2021; 89 FR 94588, Nov. 27, 2024]

§416.166 Covered surgical procedures.

(a) *Covered surgical procedures.* Effective for services furnished on or after January 1, 2022, covered surgical procedures are those procedures that meet the general standards described in paragraph (b) of this section (whether commonly furnished in an ASC or a physician's office) and are not excluded under paragraph (c) of this section.

(b) *General standards.* Subject to the exclusions in paragraph (c) of this section, covered surgical procedures are surgical procedures specified by the Secretary and published in the FEDERAL REGISTER and/or via the internet on the CMS website that are separately paid under the OPPS, that would not be expected to pose a significant safety risk to a Medicare beneficiary when performed in an ASC, and for which standard medical practice dictates that the beneficiary would not typically be expected to require active medical monitoring and care at midnight following the procedure.

(c) *General exclusions.* Notwithstanding paragraph (b) of this section, covered surgical procedures do not include those surgical procedures that —

(1) Generally result in extensive blood loss;

(2) Require major or prolonged invasion of body cavities;

(3) Directly involve major blood vessels;

(4) Are generally emergent or life-threatening in nature;

(5) Commonly require systemic thrombolytic therapy;

(6) Are designated as requiring inpatient care under §419.22(n) of this chapter;

(7) Can only be reported using a CPT unlisted surgical procedure code; or

(8) Are otherwise excluded under § 411.15 of this chapter.

(d) *Additions to the list of ASC covered surgical procedures.* Surgical procedures are added to the list of ASC covered surgical procedures as follows:

(1) *Pre-proposed rule covered procedures list (CPL) recommendation process.* On or after January 1, 2024, an external party may recommend a surgical procedure by March 1 of a calendar year for the list of ASC covered surgical procedures for the following calendar year.

(2) *Inclusion in rulemaking.* If CMS identifies a surgical procedure that meets the requirements at paragraph (a) of this section, including a surgical procedure nominated under paragraph (d)(1) of this section, it will propose to add the surgical procedure to the list of ASC covered surgical procedures in the next available annual rulemaking.

[86 FR 63992, Nov. 16, 2021, as amended at 87 FR 72291, Nov. 23, 2022]

§ 416.167 Basis of payment.

(a) *Unit of payment.* Under the ASC payment system, prospectively determined amounts are paid for ASC services furnished to Medicare beneficiaries in connection with covered surgical procedures. Covered surgical procedures and covered ancillary services are identified by codes established under the Healthcare Common Procedure Coding System (HCPCS). The unadjusted national payment rate is determined according to the methodology described in § 416.171. The manner in which the Medicare payment amount and the beneficiary coinsurance amount for each ASC service is determined is described in § 416.172.

(b) *Ambulatory payment classification (APC) groups and payment weights.* (1) ASC covered surgical procedures are classified using the APC groups described in § 419.31 of this subchapter.

(2) For purposes of calculating ASC national payment rates under the methodology described in § 416.171, except as specified in paragraph (b)(3) of this section, an ASC relative payment weight is determined based on the APC relative payment weight for each covered surgical procedure and covered ancillary service that has an applicable APC relative payment weight described in § 419.31 of this subchapter.

(3) Notwithstanding paragraph (b)(2) of this section, the relative payment weights for services paid in accordance with § 416.171(d) are determined so that the national ASC payment rate does not exceed the unadjusted nonfacility practice expense amount paid under the Medicare physician fee schedule for such procedures under subpart B of part 414 of this subchapter.

§ 416.171 Determination of payment rates for ASC services.

(a) *Standard methodology.* The standard methodology for determining the national unadjusted payment rate for ASC services is to calculate the product of the applicable conversion factor and the relative payment weight established under § 416.167(b), unless otherwise indicated in this section.

(1) *Conversion factor for CY 2008.* CMS calculates a conversion factor so that payment for ASC services furnished in CY 2008 would result in the same aggregate amount of expenditures as would be made if the provisions in this Subpart F did not apply, as estimated by CMS.

(2) *Conversion factor for CY 2009 and subsequent calendar years.* The conversion factor for a calendar year is equal to the conversion factor calculated for the previous year, updated as follows:

(i) For CY 2009, the update is equal to zero percent.

(ii) For CY 2010 through CY 2018, the update is the Consumer Price Index for All Urban Consumers (U.S. city average) as estimated by the Secretary for the 12-month period ending with the midpoint of the year involved.

(iii) For CY 2019 through CY 2025, the update is the hospital inpatient market basket percentage increase applicable under section 1886(b)(3)(B)(iii) of the Act.

(iv) For CY 2026 and subsequent years, the update is the Consumer Price Index for All Urban Consumers (U.S. city average) as estimated by the Secretary for the 12-month period ending with the midpoint of the year involved.

(v) For CY 2014 through CY 2018, the Consumer Price Index for All Urban Consumers update determined under

paragraph (a)(2)(ii) of this section is reduced by 2.0 percentage points for an ASC that fails to meet the standards for reporting of ASC quality measures as established by the Secretary for the corresponding calendar year.

(vi) For CY 2019 through CY 2025, the hospital inpatient market basket update determined under paragraph (a)(2)(iii) of this section is reduced by 2.0 percentage points for an ASC that fails to meet the standards for reporting of ASC quality measures as established by the Secretary for the corresponding calendar year.

(vii) For CY 2026 and subsequent years, the Consumer Price Index for All Urban Consumers update determined under paragraph (a)(2)(iv) of this section is reduced by 2.0 percentage points for an ASC that fails to meet the standards for reporting of ASC quality measures as established by the Secretary for the corresponding calendar year.

(viii)(A) For CY 2011 through CY 2018, the Consumer Price Index for All Urban Consumers determined under paragraph (a)(2)(ii) of this section, after application of any reduction under paragraph (a)(2)(iv) of this section, is reduced by the productivity adjustment described in section 1886(b)(3)(B)(xi)(II) of the Act.

(B) For CY 2019 through CY 2025, the hospital inpatient market basket update determined under paragraph (a)(2)(iii) of this section, after application of any reduction under paragraph (a)(2)(vi) of this section, is reduced by the productivity adjustment described in section 1886(b)(3)(B)(xi)(II) of the Act.

(C) For CY 2026 and subsequent years, the Consumer Price Index for All Urban Consumers determined under paragraph (a)(2)(iv) of this section, after application of any reduction under paragraph (a)(2)(vii) of this section, is reduced by the productivity adjustment described in section 1886(b)(3)(B)(xi)(II) of the Act.

(D) The application of the provisions of paragraph (a)(2)(viii)(A), (B), or (C) of this section may result in the update being less than zero percent for a year, and may result in payment rates for a year being less than the payment rates for the preceding year.

(b) *Exception.* The national ASC payment rates for the following items and services are not determined in accordance with paragraph (a) of this section but are paid an amount derived from the payment rate for the equivalent item or service set under the payment system established in part 419 of this subchapter as updated annually in the FEDERAL REGISTER and/or via the Internet on the CMS Web site. If a payment rate is not available, the following items and services are designated as contractor-priced:

(1) Covered ancillary services specified in §416.164(b), with the exception of radiology services and certain diagnostic tests as provided in §416.164(b)(5) and non-opioid pain management drugs, biologicals, and medical devices as determined by CMS under §416.174.

(2) The device portion of device-intensive procedures, which are procedures that—

(i) Involve implantable devices assigned a CPT or HCPCS code;

(ii) Utilize devices (including single-use devices) that must be surgically inserted or implanted; and

(iii) Have a HCPCS code-level device offset of greater than 30 percent when calculated according to the standard OPPS ASC ratesetting methodology.

(3) Procedures using certain separately paid implantable devices that are approved for transitional pass-through payment in accordance with §419.66 of this subchapter.

(4) Notwithstanding paragraph (b)(2) of this section, procedures assigned to Low Volume APCs where the otherwise applicable payment rate calculated based on the standard methodology for such procedures described in paragraph (b) of this section would exceed the payment rate for the equivalent service set under the payment system established under part 419 of this chapter, for which the payment rate will be set at an amount equal to the amount under that payment system.

(c) *Transitional payment rates.* (1) ASC payment rates for CY 2008 are a transitional blend of 75 percent of the CY 2007 ASC payment rate for a covered surgical procedure on the CY 2007 ASC list of surgical procedures and 25 percent of

the payment rate for the procedure calculated under the methodology described in paragraph (a) of this section.

(2) ASC payment rates for CY 2009 are a transitional blend of 50 percent of the CY 2007 ASC payment rate for a covered surgical procedure on the CY 2007 ASC list of surgical procedures and 50 percent of the payment rate for the procedure calculated under the methodology described in paragraph (a) of this section.

(3) ASC payment rates for CY 2010 are a transitional blend of 25 percent of the CY 2007 ASC payment rate for a covered surgical procedure on the CY 2007 ASC list of surgical procedures and 75 percent of the payment rate for the procedure calculated under the methodology described in paragraph (a) of this section.

(4) The national ASC payment rate for CY 2011 and subsequent calendar years for a covered surgical procedure designated in accordance with § 416.166 is the payment rates for the procedure calculated under the methodology described in paragraph (a) of this section.

(5) Covered ancillary services described in § 416.164(b) and surgical procedures identified as covered when performed in an ASC under § 416.166 for the first time beginning on or after January 1, 2008, are not subject to the transitional payment rates applicable in CYs 2008 through 2010 for ASC facility services.

(d) *Limitation on payment rates for office-based surgical procedures and covered ancillary radiology services and certain diagnostic tests.* Notwithstanding the provisions of paragraph (a) of this section, for any covered surgical procedure under § 416.166 that CMS determines is commonly performed in physicians' offices or for any covered ancillary radiology service or diagnostic test under § 416.164(b)(5), excluding those listed in paragraphs (d)(1) and (d)(2) of this section, the national unadjusted ASC payment rates for these procedures and services will be the lesser of the amount determined under paragraph (a) of this section or the amount calculated at the nonfacility practice expense relative value units under § 414.22(b)(5)(i)(B) of this chapter multiplied by the conversion factor described in § 414.20(a)(3) of this chapter.

(1) The national unadjusted ASC payment rate for covered ancillary radiology services that involve certain nuclear medicine procedures will be the amount determined under paragraph (a) of this section.

(2) The national unadjusted ASC payment rate for covered ancillary radiology services that use contrast agents will be the amount determined under paragraph (a) of this section.

(e) *Budget neutrality.* (1) For CY 2008, CMS establishes the conversion factor to result in budget neutrality as estimated by CMS in accordance with paragraph (a)(1) of this section.

(2) For CY 2009 and subsequent calendar years, CMS adjusts the ASC relative payment weights under § 416.167(b)(2) as needed so that any updates and adjustments made under § 419.50(a) of this subchapter are budget neutral as estimated by CMS.

[72 FR 42545, Aug. 2, 2007, as amended at 75 FR 72264, Nov. 24, 2010; 76 FR 74582, Nov. 30, 2011; 77 FR 277, Jan. 4, 2012; 77 FR 68558, Nov. 15, 2012; 79 FR 67030, Nov. 10, 2014; 81 FR 79879, Nov. 14, 2016; 83 FR 59178, Nov. 21, 2018; 84 FR 61490, Nov. 12, 2019; 86 FR 63993, Nov. 16, 2021; 88 FR 82179, Nov. 22, 2023; 89 FR 94588, Nov. 27, 2024]

§ 416.172 Adjustments to national payment rates.

(a) *General rule.* Contractors adjust the payment rates established for ASC services to determine Medicare program payment and beneficiary coinsurance amounts in accordance with paragraphs (b) through (g) of this section.

(b) *Lesser of actual charge or geographically adjusted payment rate.* Payments to ASCs equal 80 percent of the lesser of—

(1) The actual charge for the service; or

(2) The geographically adjusted payment rate determined under this subpart.

(c) *Geographic adjustment*—(1) *General rule.* Except as provided in paragraph (c)(2) of this section, the national ASC payment rates established under § 416.171 for covered surgical procedures are adjusted for variations in ASC labor costs across geographic areas using wage index values, labor and

nonlabor percentages, and localities specified by the Secretary.

(2) *Exception.* The geographic adjustment is not applied to the payment rates set for drugs, biologicals, devices with OPPS transitional pass-through payment status, and brachytherapy sources.

(d) *Deductibles and coinsurance.* Part B deductible and coinsurance amounts apply as specified in §§410.152(a) and (i)(2) and 489.30(b)(6) of this chapter.

(e) *Payment reductions for multiple surgical procedures*—(1) *General rule.* Except as provided in paragraph (e)(2) of this section, when more than one covered surgical procedure for which payment is made under the ASC payment system is performed during an operative session, the Medicare program payment amount and the beneficiary coinsurance amount are based on—

(i) 100 percent of the applicable ASC payment amount for the procedure with the highest national unadjusted ASC payment rate; and

(ii) 50 percent of the applicable ASC payment amount for all other covered surgical procedures.

(2) *Exception: Procedures not subject to multiple procedure discounting.* CMS may apply any policies or procedures used with respect to multiple procedures under the prospective payment system for hospital outpatient department services under Part 419 of this subchapter as may be consistent with the equitable and efficient administration of this part.

(f) *Interrupted procedures.* (1) Subject to the provisions of paragraph (f)(2) of this section, when a covered surgical procedure or covered ancillary service is terminated prior to completion due to extenuating circumstances or circumstances that threaten the well-being of the patient, the Medicare program payment amount and the beneficiary coinsurance amount are based on one of the following:

(i) The full program and beneficiary coinsurance amounts if the procedure for which anesthesia is planned is discontinued after the induction of anesthesia or after the procedure is started;

(ii) One-half of the full program and beneficiary coinsurance amounts if the procedure for which anesthesia is planned is discontinued after the patient is prepared for surgery and taken to the room where the procedure is to be performed but before the anesthesia is induced; or

(iii) One-half of the full program and beneficiary coinsurance amounts if a covered surgical procedure or covered ancillary service for which anesthesia is not planned is discontinued after the patient is prepared and taken to the room where the service is to be provided.

(2) Beginning CY 2016, if the covered surgical procedure is a device-intensive procedure, the full device portion of the ASC device-intensive procedure is removed prior to determining the Medicare program payment amount and the beneficiary coinsurance amount identified in paragraph (f)(1)(ii) of this section.

(g) *Payment adjustment for new technology intraocular lenses (NTIOLs).* A payment adjustment will be made for insertion of an IOL approved as belonging to a class of NTIOLs as defined in subpart G.

(h) *Special payment for certain code combinations*—(1) *Eligibility.* A code combination is eligible for the payment specified in paragraph (h)(2) of this section if the code combination is—

(i) Eligible for a comprehensive APC (C–APC) complexity adjustment under the OPPS; and

(ii) Comprised of a separately payable surgical procedure, that is listed on the ASC Covered Procedures list (§416.166), and one or more packaged add-on codes that are listed on the ASC covered procedures or ancillary services lists (§416.164(b)).

(2) *Calculation of payment.* (i) Except as specified in paragraph (h)(2)(ii) of this section, CMS calculates the payment for code combinations that meet the eligibility requirements in paragraph (h)(1) of this section by applying the methodology specified in §416.171(a) to the OPPS C–APC complexity-adjusted relative weights.

(ii) For primary procedures assigned device-intensive status that are a component of a code combination that is eligible for payment under paragraph (h)(2) of this section, the primary procedure of the code combination retains its device-intensive status, and—

(A) The device portion is equivalent to the device portion of the device-intensive APC under the OPPS (§ 419.44(b) of this subchapter); and

(B) The non-device portion is calculated in accordance with the methodology specified in § 416.171(a).

[72 FR 42545, Aug. 2, 2007, as amended at 80 FR 70604, Nov. 13, 2015; 87 FR 72291, Nov. 23, 2022; 88 FR 82179, Nov. 22, 2023]

§ 416.173 Publication of revised payment methodologies and payment rates.

CMS publishes annually, through notice and comment rulemaking in the FEDERAL REGISTER and/or via the Internet on the CMS Web site, the payment methodologies and payment rates for ASC services and designates the covered surgical procedures and covered ancillary services for which CMS will make an ASC payment and other revisions as appropriate.

[76 FR 74582, Nov. 30, 2011]

§ 416.174 Payment for non-opioid pain management drugs, biologicals, and medical devices.

(a) *Eligibility for separate payment for non-opioid pain management drugs and biologicals.* From January 1, 2025, through December 31, 2027, a non-opioid drug or biological is eligible for separate payment for an applicable calendar year if CMS determines it meets the following requirements through that year's rulemaking:

(1) The drug is approved under a new drug application under section 505(c) of the Federal Food, Drug, and Cosmetic Act (FDCA), under an abbreviated new drug application under section 505(j) of the FDCA, or, in the case of a biological product, is licensed under section 351 of the Public Health Service Act. The product also has a label indication approved by the Food and Drug Administration to reduce postoperative pain, or produce postsurgical or regional analgesia, without acting upon the body's opioid receptors.

(2) The drug or biological does not have transitional pass-through payment status under § 419.64 of this subchapter. In the case where a drug or biological otherwise meets the requirements under this section and has transitional pass-through payment status that expires during the calendar year, the drug or biological will qualify for separate payment as specified in this paragraph (a) during such calendar year on the first day of the next quarter following the expiration of its pass-through status.

(3) The drug or biological has payment that is packaged into a payment for a covered outpatient department (OPD) service (or group of services) under a policy in this part.

(b) *Eligibility for separate payment for non-opioid medical devices.* From January 1, 2025, through December 31, 2027, a medical device is eligible for separate payment for an applicable calendar year if CMS determines it meets all of the following requirements through that year's rulemaking:

(1) The medical device is used to deliver a therapy to reduce postoperative pain, or produce postsurgical or regional analgesia, and has an application under section 515 of the FDCA that has been approved with respect to the device, has been cleared for market under section 510(k) of the FDCA, or is exempt from the requirements of section 510(k) of the FDCA pursuant to section 510(l) or (m) or 520(g) of the FDCA.

(2) The medical device has demonstrated the ability to replace, reduce, or avoid intraoperative or postoperative opioid use or the quantity of opioids prescribed in a clinical trial or through data published in a peer-reviewed journal.

(3) The medical device does not have transitional pass-through payment status under § 419.66 of this subchapter. In the case where a medical device otherwise meets the requirements under this section and has transitional pass-through payment status that expires during the calendar year, the medical device will qualify for separate payment as specified in this paragraph (b) during such calendar year on the first day of the next calendar year quarter following the expiration of its pass-through status.

(4) The medical device has payment that is packaged into a payment for a covered OPD service (or group of services) under a policy in this part.

(c) *Payment amount.* From January 1, 2025, through December 31, 2027, the

amount of payment for a qualifying non-opioid treatment for pain relief is as follows:

(1) For a qualifying drug or biological as defined in paragraph (a) of this section, the amount of payment is the amount determined under section 1847A of the Act for the drug or biological that exceeds the portion of the otherwise applicable Medicare OPD fee schedule amount, which is determined to be zero dollars for calendar year 2025, subject to paragraph (c)(3) of this section.

(2) For a qualifying medical device as defined in paragraph (b) of this section, the amount of payment is the amount of the hospital's charges for the device, adjusted to cost, that exceeds the portion of the otherwise applicable Medicare OPD fee schedule amount, which is determined to be zero dollars for calendar year 2025, subject to paragraph (c)(3) of this section.

(3) The payment amounts in paragraphs (c)(1) and (2) of this section shall not exceed the estimated average of 18 percent of the OPD fee schedule amount of the volume weighted average of the most frequent five OPD primary procedures into which a non-opioid treatment for pain relief would be packaged.

[89 FR 94588, Nov. 27, 2024]

§416.178 Limitations on administrative and judicial review.

There is no administrative or judicial review under section 1869 of the Act, section 1878 of the Act, or otherwise of the following:

(a) The classification system;

(b) Relative weights;

(c) Payment amounts; and

(d) Geographic adjustment factors.

§416.179 Payment and coinsurance reduction for devices replaced without cost or when full or partial credit is received.

(a) *General rule.* CMS reduces the amount of payment for a covered surgical procedure for which CMS determines that a significant portion of the payment is attributable to the cost of an implanted device not on pass-through status under subpart G of part 419 of this subchapter when one of the following situations occur:

(1) The device is replaced without cost to the ASC or the beneficiary;

(2) The ASC receives full credit for the cost of a replaced device; or

(3) The ASC receives partial credit for the cost of a replaced device but only where the amount of the device credit is greater than or equal to 50 percent of the cost of the new replacement device being implanted.

(b) *Amount of reduction to the ASC payment for the covered surgical procedure.* (1) The amount of the reduction to the ASC payment made under paragraphs (a)(1) and (a)(2) of this section is calculated in the same manner as the device payment reduction that would be applied to the ASC payment for the covered surgical procedure in order to remove predecessor device costs so that the ASC payment amount for a device with pass-through status under §419.66 of this subchapter represents the full cost of the device, and no packaged device payment is provided through the ASC payment for the covered surgical procedure.

(2) The amount of the reduction to the ASC payment made under paragraph (a)(3) of this section is 50 percent of the payment reduction that would be calculated under paragraph (b)(1) of this section.

(c) *Amount of beneficiary coinsurance.* The beneficiary coinsurance is calculated based on the ASC payment for the covered surgical procedure after application of the reduction under paragraph (b) of this section.

[72 FR 42545, Aug. 2, 2007, as amended at 72 FR 66932, No. 27, 2007]

Subpart G—Adjustment in Payment Amounts for New Technology Intraocular Lenses Furnished by Ambulatory Service Centers

SOURCE: 71 FR 68226, Nov. 24, 2006, unless otherwise noted.

§416.180 Basis and scope.

(a) *Basis.* This subpart implements section 141 of Public Law 103–432, which provides for adjustments to payment amounts for new technology intraocular lenses (IOLs) furnished at ambulatory surgical centers (ASCs).

(b) *Scope.* This subpart sets forth—

(1) The process for interested parties to request that CMS review the appropriateness of the ASC facility fee for insertion of an IOL. This process includes a review of whether that payment is reasonable and related to the cost of acquiring a lens determined by CMS as belonging to a class of new technology IOLs;

(2) Factors that CMS considers for determination of a new class of new technology IOLs; and

(3) Application of the payment adjustment.

§ 416.185 Process for establishing a new class of new technology IOLs.

(a) *Announcement of deadline for requests for review.* CMS announces the deadline for each year's requests for review of a new class of new technology IOLs in the final rule updating the ASC payment rates for that calendar year.

(b) *Announcement of new classes of new technology IOLs for which review requests have been made and solicitation of public comments.* CMS announces the requests for review received in a calendar year and the deadline for public comments regarding the requests in the proposed rule updating the ASC payment rates for the following calendar year. The deadline for submission of public comments is 30 days following the date of the publication of the proposed rule.

(c) *Announcement of determinations regarding requests for review.* CMS announces its determinations for a calendar year in the final rule updating the ASC payment rates for the following calendar year. CMS publishes the codes and effective dates allowed for those lenses recognized by CMS as belonging to a class of new technology IOLs. New classes of new technology IOLs are effective 30 days following the date of publication of the final rule.

§ 416.190 Request for review of payment amount.

(a) *When requests can be submitted.* A request for review of the appropriateness of ASC payment for insertion of an IOL that might qualify for a payment adjustment as belonging to a new class of new technology IOLs must be submitted to CMS in accordance with the annual published deadline.

(b) *Who may submit a request.* Any individual, partnership, corporation, association, society, scientific or academic establishment, or professional or trade organization able to furnish the information required in paragraph (c) of this section may request that CMS review the appropriateness of the payment amount provided under section 1833(i)(2)(A)(iii) of the Act with respect to an IOL that meets the criteria of a new technology IOL under § 416.195.

(c) *Content of a request.* In order to be accepted by CMS for review, a request for review of the ASC payment amount for insertion of an IOL must include all the information as specified by CMS.

(d) *Confidential information.* In order for CMS to invoke the protection allowed under Exemption 4 of the Freedom of Information Act (5 U.S.C. 552(b)(4)) and, with respect to trade secrets, the Trade Secrets Act (18 U.S.C. 1905), the requestor must clearly identify all information that is to be characterized as confidential.

§ 416.195 Determination of membership in new classes of new technology IOLs.

(a) *Factors to be considered.* CMS uses the following criteria to determine whether an IOL qualifies for a payment adjustment as a member of a new class of new technology IOLs when inserted at an ASC:

(1) The IOL is considered new. CMS will evaluate an application for a new technology IOL only if the IOL type has received initial FDA premarket approval within the 3 years prior to the new technology IOL application submission date.

(2) The IOL shall have a new lens characteristic in comparison to currently available IOLs. The labeling, which must be approved by FDA, shall contain a claim of a specific clinical benefit imparted by the new lens characteristic.

(3) The IOL is not described by an active or expired class of new technology IOLs; that is, it does not share a predominant, class-defining characteristic associated with improved clinical outcomes with members of an active or expired class.

(4) Any specific clinical benefit referred to in paragraph (a)(2) of this section must be supported by evidence that demonstrates that the IOL results in a measurable, clinically meaningful, improved outcome. Improved outcomes include:

(i) Reduced risk of intraoperative or postoperative complication or trauma;

(ii) Accelerated postoperative recovery;

(iii) Reduced induced astigmatism;

(iv) Improved postoperative visual acuity;

(v) More stable postoperative vision;

(vi) Other comparable clinical advantages.

(b) *CMS determination of eligibility for payment adjustment.* CMS reviews the information submitted with a completed request for review, public comments submitted timely, and other pertinent information and makes a determination as follows:

(1) The IOL is eligible for a payment adjustment as a member of a new class of new technology IOLs.

(2) The IOL is a member of an active class of new technology IOLs and is eligible for a payment adjustment for the remainder of the period established for that class.

(3) The IOL does not meet the criteria for designation as a new technology IOL and a payment adjustment is not appropriate.

[71 FR 68226, Nov. 24, 2006, as amended at 77 FR 68558, Nov. 15, 2012; 80 FR 70604, Nov. 13, 2015]

§ 416.200 Payment adjustment.

(a) CMS establishes the amount of the payment adjustment for classes of new technology IOLs through proposed and final rulemaking in connection with ASC facility services.

(b) CMS adjusts the payment for insertion of an IOL approved as belonging to a class of new technology IOLs for the 5-year period of time established for that class.

(c) Upon expiration of the 5-year period of the payment adjustment, payment reverts to the standard rate for IOL insertion procedures performed in ASCs.

(d) ASCs that furnish an IOL designated by CMS as belonging to a class of new technology IOLs must submit claims using billing codes specified by CMS to receive the new technology IOL payment adjustment.

Subpart H—Requirements Under the Ambulatory Surgical Center Quality Reporting (ASCQR) Program

SOURCE: 80 FR 70604, Nov. 13, 2015, unless otherwise noted.

§ 416.300 Basis and scope of subpart.

(a) *Statutory basis.* Section 1833(i)(2)(D)(iv) and (i)(7) of the Act authorizes the Secretary to implement a revised ASC payment system in a manner so as to provide for a 2.0 percentage point reduction in any annual update for an ASC's failure to report on quality measures in accordance with the Secretary's requirements.

(b) *Scope.* This subpart contains specific requirements and standards for the ASCQR Program.

§ 416.305 Participation and withdrawal requirements under the ASCQR Program.

(a) *Participation in the ASCQR Program.* Except as provided in paragraph (c) of this section, an ambulatory surgical center (ASC) is considered as participating in the ASCQR Program once the ASC submits any quality measure data to the ASCQR Program and has been designated as open in the Certification and Survey Provider Enhanced Reporting system for at least four months prior to the beginning of data collection for a payment determination.

(b) *Withdrawal from the ASCQR Program.* (1) An ASC may withdraw from the ASCQR Program by submitting to CMS a withdrawal of participation form that can be found in the secure portion of the CMS-designated information system.

(2) An ASC may withdraw from the ASCQR Program any time up to and including August 31 of the year preceding a payment determination.

(3) Except as provided in paragraph (c) of this section, an ASC will incur a 2.0 percentage point reduction in its ASC annual payment update for that payment determination year and any

subsequent payment determinations in which it is withdrawn.

(4) An ASC will be considered as rejoining the ASCQR Program if it begins to submit any quality measure data again to the ASCQR Program.

(c) *Minimum case volume for program participation.* ASCs with fewer than 240 Medicare claims (Medicare primary and secondary payer) per year during an annual reporting period for a payment determination year are not required to participate in the ASCQR Program for the subsequent annual reporting period for that subsequent payment determination year.

(d) *Indian Health Service hospital outpatient department participation.* Beginning with the CY 2017 payment determination, Indian Health Service hospital outpatient departments that bill Medicare under the Ambulatory Surgical Center payment system are not considered ASCs for the purposes of the ASCQR Program. These facilities are not required to meet ASCQR Program requirements and will not receive payment reductions under the ASCQR Program.

[80 FR 70604, Nov. 13, 2015, as amended at 88 FR 82179, Nov. 22, 2023]

§ 416.310 Data collection and submission requirements under the ASCQR Program.

(a) *Requirements for claims-based measures using quality data codes (QDCs).* (1) ASCs must submit complete data on individual claims-based quality measures through a claims-based reporting mechanism by submitting the appropriate QDCs on the ASC's Medicare claims.

(2) The data collection period for claims-based quality measures reported using QDCs is the calendar year 2 years prior to the payment determination year. Only claims for services furnished in each calendar year paid by the Medicare Administrative Contractor (MAC) by April 30 of the following year of the ending data collection period will be included in the data used for the payment determination year.

(3) For ASCQR Program purposes, data completeness for claims-based measures using QDCs is determined by comparing the number of Medicare claims (where Medicare is the primary or secondary payer) meeting measure specifications that contain the appropriate QDCs with the number of Medicare claims that meet measure specifications, but do not have the appropriate QDCs on the submitted Medicare claim. The minimum threshold for successful reporting is that at least 50 percent of Medicare claims meeting measure specifications contain the appropriate QDCs. ASCs that meet this minimum threshold are regarded as having provided complete data for the claims-based measures using QDCs for the ASCQR Program.

(b) *Requirements for claims-based measures not using QDCs.* The data collection period for claims-based quality measures not using QDCs is paid Medicare fee-for-service claims from the calendar year 2 years prior to the payment determination year. Only claims for services furnished in each calendar year paid by the MAC by April 30 of the following year of the ending data collection period will be included in the data used for the payment determination.

(c) *Requirements for data submitted via an online data submission tool*—(1) *Requirements for data submitted via a CMS online data submission tool*—(i) *CMS-designated information system account for web-based measures.* ASCs, and any agents submitting data on an ASC's behalf, must maintain an account for the CMS-designated information system in order to submit quality measure data to the CMS-designated information system for all web-based measures submitted via a CMS online data submission tool. A security official is necessary to set up such an account for the CMS-designated information system for the purpose of submitting this information.

(ii) *Data collection requirements.* The data collection period for quality measures for which data are submitted via a CMS online data submission tool is for services furnished during the calendar year 2 years prior to the payment determination year. Beginning with the CY 2017 payment determination year, data collected must be submitted during the period of January 1 to May 15 in the year prior to the payment determination year.

(iii) *Review and corrections period.* For measures submitted to CMS via a CMS online tool, ASCs have a review and corrections period, which runs concurrently with the data submission period. During this timeframe, ASCs can enter, review, and correct data submitted. After the submission deadline, this data cannot be changed.

(2) *Requirements for data submitted via a non-CMS online data submission tool.* The data collection period for ASC–8: Influenza Vaccination Coverage Among Healthcare Personnel is from October 1 of the year 2 years prior to the payment determination year to March 31 during the year prior to the payment determination year. Data collected must be submitted by May 15 in the year prior to the payment determination year.

(d) *Extraordinary circumstances exceptions.* CMS may grant an exception with respect to quality data reporting requirements in the event of extraordinary circumstances beyond the control of the hospital, such as when an act of nature affects an entire region or if CMS determines that a systemic problem with one of its data collection systems directly affected the ability of the hospitals to submit data. CMS may grant an exception as follows:

(1) *Upon request of the ASC.* Specific requirements for submission of a request for an exception are available on the CMS website.

(2) *At the discretion of CMS.* CMS may grant exceptions to ASCs that have not requested them when CMS determines that an extraordinary circumstance has occurred.

(e) *Requirements for Outpatient and Ambulatory Surgery Consumer Assessment of Healthcare Providers and Systems (OAS CAHPS) Survey.* OAS CAHPS is the Outpatient and Ambulatory Surgical Center Consumer Assessment of Healthcare Providers and Systems survey that measures patient experience of care after a recent surgery or procedure at either a hospital outpatient department or an ambulatory surgical center. Ambulatory surgical centers must use an approved OAS CAHPS survey vendor to administer and submit OAS CAHPS data to CMS.

(1) [Reserved]

(2) CMS approves an application for an entity to administer the OAS CAHPS survey as a vendor on behalf of one or more ambulatory surgical centers when the applicant has met the Minimum Survey Requirements and Rules of Participation that can be found on the official OAS CAHPS Web site, and agrees to comply with the current survey administration protocols that can be found on the official OAS CAHPS Web site. An entity must be an approved OAS CAHPS Survey vendor in order to administer the OAS CAPHS Survey and submit data to CMS on behalf of one or more ambulatory surgical centers.

(f) *Data submission deadlines.* All deadlines occurring on a Saturday, Sunday, or legal holiday, or on any other day all or part of which is declared to be a nonwork day for Federal employees by statute or Executive order are extended to the first day thereafter which is not a Saturday, Sunday, or legal holiday or any other day all or part of which is declared to be a nonwork day for Federal employees by statute or Executive order.

[80 FR 70604, Nov. 13, 2015, as amended at 81 FR 79879, Nov. 14, 2016; 82 FR 52636, Nov. 13, 2017; 82 FR 59496, Dec. 14, 2017; 85 FR 86302, Dec. 29, 2020; 88 FR 82179, Nov. 22, 2023]

§ 416.315 Public reporting of data under the ASCQR Program.

Data that an ASC submitted for the ASCQR Program will be made publicly available on a CMS Web site after providing the ASC an opportunity to review the data to be made public. CMS will publicly display ASC data by the National Provider Identifier (NPI) when data are submitted by the NPI. CMS will publicly display ASC data by the CMS Certification Number (CCN) when data are submitted by the CCNs.

§ 416.320 Retention and removal of quality measures under the ASCQR Program.

(a) *General rule for the retention of quality measures.* Quality measures adopted for an ASCQR Program measure set for a previous payment determination year are retained in the ASCQR Program for measure sets for subsequent payment determination years, except when they are removed,

suspended, or replaced as set forth in paragraphs (b) and (c) of this section.

(b) *Immediate measure suspension.* If CMS determines that the collection and reporting activities related to a measure potentially raise patient safety concerns, CMS will immediately suspend the measure from the ASCQR Program and promptly notify ASCs and the public of the suspension. CMS will propose to retain, modify, or remove the suspended measure in the next feasible rulemaking cycle.

(c) *Removal of quality measures*—(1) *General rule for the removal of quality measures.* Unless a measure raises specific safety concerns as set forth in paragraph (b) of this section, CMS will use the regular rulemaking process to remove, suspend, or replace quality measures in the ASCQR Program to allow for public comment.

(2) *Factors for consideration of removal of quality measures.* CMS will weigh whether to remove measures based on the following factors:

(i) *Factor 1.* Measure performance among ASCs is so high and unvarying that meaningful distinctions and improvements in performance can no longer be made (topped-out measures);

(ii) *Factor 2.* Performance or improvement on a measure does not result in better patient outcomes;

(iii) *Factor 3.* A measure does not align with current clinical guidelines or practice;

(iv) *Factor 4.* The availability of a more broadly applicable (across settings, populations, or conditions) measure for the topic;

(v) *Factor 5.* The availability of a measure that is more proximal in time to desired patient outcomes for the particular topic;

(vi) *Factor 6.* The availability of a measure that is more strongly associated with desired patient outcomes for the particular topic;

(vii) *Factor 7.* Collection or public reporting of a measure leads to negative unintended consequences other than patient harm; and

(viii) *Factor 8.* The costs associated with a measure outweigh the benefit of its continued use in the program.

(3) *Criteria to determine topped-out measures.* For the purposes of the ASCQR Program, a measure is considered to be topped-out under paragraph (c)(2)(i) of this section when it meets both of the following criteria:

(i) Statistically indistinguishable performance at the 75th and 90th percentiles (defined as when the difference between the 75th and 90th percentiles for an ASC's measure is within two times the standard error of the full data set); and

(ii) A truncated coefficient of variation less than or equal to 0.10.

(4) *Application of measure removal factors.* The benefits of removing a measure from the ASCQR Program will be assessed on a case-by-case basis. A measure will not be removed solely on the basis of meeting any specific factor or criterion.

[80 FR 70604, Nov. 13, 2015, as amended at 83 FR 59178, Nov. 21, 2018; 88 FR 82179, Nov. 22, 2023; 89 FR 94589, Nov. 27, 2024]

§ 416.325 Measure maintenance under the ASCQR Program.

(a) *Measure maintenance under the ASCQR Program.* CMS follows different procedures to update the measure specifications under the ASCQR Program based on whether the change is substantive or nonsubstantive. CMS will determine what constitutes a substantive versus a nonsubstantive change to a measure's specifications on a case-by-case basis.

(b) *Substantive changes.* CMS will continue to use rulemaking to adopt substantive updates to measures in the ASCQR Program.

(c) *Non-substantive changes.* If CMS determines that a change to a measure previously adopted in the ASCQR Program is non-substantive, CMS will use a sub-regulatory process to revise the ASCQR Program Specifications Manual so that it clearly identifies the changes to that measure and provide links to where additional information on the changes can be found. When a measure undergoes sub-regulatory maintenance, CMS will provide notification of the measure specification update on the CMS website and in the ASCQR Program Specifications Manual, and will provide sufficient lead

time for ASCs to implement the revisions where changes to the data collection systems would be necessary.

[80 FR 70604, Nov. 13, 2015, as amended at 88 FR 82180, Nov. 22, 2023]

§ 416.330 Reconsiderations under the ASCQR Program.

(a) *Reconsiderations of ASCQR Program decisions.* An ASC may request reconsideration of a decision by CMS that it has not met the requirements of the ASCQR Program for a particular payment determination year. An ASC must submit a reconsideration request to CMS by no later than the first business day on or after March 17 of the affected payment year.

(b) *Requirements for reconsideration requests.* A reconsideration request must contain the following information:

(1) The ASC CCN and related NPI(s);

(2) The name of the ASC;

(3) The CMS-identified reason for not meeting the requirements of the ASCQR Program for the affected payment determination year as provided in any CMS notification to the ASC;

(4) The ASC's basis for requesting reconsideration. The ASC must identify its specific reason(s) for believing it met the ASCQR Program requirements for the affected payment determination year and should not be subject to the reduced ASC annual payment update;

(5) The ASC-designated personnel contact information, including name, email address, telephone number, and mailing address (must include physical mailing address, not just a post office box); and

(6) A copy of all materials that the ASC submitted to comply with the requirements of the affected ASCQR Program payment determination year. With regard to information on claims, ASCs are not required to submit copies of all submitted claims, but instead may focus on the specific claims at issue. For these claims, ASCs should submit relevant information, which could include copies of the actual claims at issue.

(c) *Reconsideration process.* Upon receipt of a request for reconsideration, CMS will do the following:

(1) Provide an email acknowledgement, using the contact information provided in the reconsideration request, notifying the ASC that the request has been received; and

(2) Provide a formal response to the ASC contact using the information provided in the reconsideration request notifying the ASC of the outcome of the reconsideration process.

(d) *Final ASCQR Program payment determination.* For an ASC that submits a timely reconsideration request, the reconsideration determination is the final ASCQR Program payment determination. For an ASC that does not submit a timely reconsideration request, the CMS determination is the final payment determination. There is no appeal of any final ASCQR Program payment determination.

PART 417—HEALTH MAINTENANCE ORGANIZATIONS, COMPETITIVE MEDICAL PLANS, AND HEALTH CARE PREPAYMENT PLANS

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AUTHORITY: 42 U.S.C. 1302 and 1395hh, and 300e, 300e–5, and 300e–9, and 31 U.S.C. 9701.

Subpart A—General Provisions

§ 417.1 Definitions.

As used in this part, unless the context indicates otherwise—

Basic health services means health services described in § 417.101(a).

Community rating system means a system of fixing rates of payments for health services that meets the requirements of § 417.104(a)(3).

Comprehensive health services means as a minimum the following services which may be limited as to time and cost:

(1) Physician services (§ 417.101(a)(1));

(2) Outpatient services and inpatient hospital services (§ 417.101(a)(2));

(3) Medically necessary emergency health services (§ 417.101(a)(3)); and

(4) Diagnostic laboratory and diagnostic and therapeutic radiologic services (§ 417.101(a)(6)).

Direct service contract means a contract for the provision of basic or supplemental health services or both between an HMO and (1) a health professional other than a member of the staff of the HMO, or (2) an entity other than a medical group or an IPA.

Enrollee means an individual for whom an HMO, CMP, or HCPP assumes the responsibility, under a contract or agreement, for the furnishing of health care services on a prepaid basis.

Full-time student means a student who is enrolled for a sufficient number of credit hours in a semester or other academic term to enable the student to complete the course of study within not more than the number of semesters or other academic terms normally required to complete that course of study on a full-time basis at the school in which the student is enrolled.

Furnished, when used in connection with prepaid health care services, means services that are maid available to an enrollee either dierctly by, or under arrangements made by, the HMO, CMP, or HCPP.

Health maintenance organization (HMO) means a legal entity that provides or arranges for the provision of basic and supplemental health services to its enrollees in the manner prescribed by, is organized and operated in the manner prescribed by, and otherwise meets the requirements of, section 1301 of the PHS Act and the regulations in subparts B and C of this part.

Health professionals means physicians (doctors of medicine and doctors of osteopathy), dentists, nurses, podiatrists, optometrists, physicians' assistants, clinical psychologists, social workers, pharmacists, nutritionists, occupational therapists, physical therapists, and other professionals engaged in the delivery of health services who are licensed, practice under an institutional license, are certified, or practice under authority of the HMO, a medical group, individual practice association, or other authority consistent with State law.

Individual practice association (IPA) means a partnership, association, corporation, or other legal entity that delivers or arranges for the delivery of health services and which has entered into written services arrangement or arrangements with health professionals, a majority of whom are licensed to practice medicine or osteopathy. The written services arrangement must provide:

(1) That these health professionals will provide their professional services in accordance with a compensation arrangement established by the entity; and

(2) To the extent feasible, for the sharing by these health professionals of health (including medical) and other records, equipment, and professional, technical, and administrative staff.

Medical group means a partnership, association, corporation, or other group:

(1) That is composed of health professionals licensed to practice medicine or osteopathy and of such other licensed health professionals (including dentists, optometrists, and podiatrists) as are necessary for the provision of health services for which the group is responsible;

(2) A majority of the members of which are licensed to practice medicine or osteopathy; and

(3) The members of which:

(i) After the end of the 48 month period beginning after the month in which the HMO for which the group provides health services becomes a

qualified HMO, as their principal professional activity (over 50 percent individually) engage in the coordinated practice of their profession and as a group responsibility have substantial responsibility (over 35 percent in the aggregate of their professional activity) for the delivery of health services to enrollees of an HMO;

(ii) Pool their income from practice as members of the group and distribute it among themselves according to a prearranged salary or drawing account or other similar plan unrelated to the provision of specific health services;

(iii) Share health (including medical) records and substantial portions of major equipment and of professional, technical, and administrative staff;

(iv) Establish an arrangement whereby an enrollee's enrollment status is not known to the health professional who provides health services to the enrollee.

Medical group members means (1) a health professional engaged as a partner, associate, or shareholder in the medical group, or (2) any other health professional employed by the group who may be designated as a medical group member by the medical group.

Medically underserved population means the population of an urban or rural area as described in Sec. 417.912(d).

Nonmetropolitan area means an area no part of which is within a standard metropolitan statistical area as designated by the Office of Management and Budget and which does not contain a city whose population exceeds 50,000 individuals.

Party in interest means: (1) Any director, officer, partner, or employee responsible for management or administration of an HMO, any person who is directly or indirectly the beneficial owner of more than 5 percent of the equity of the HMO, any person who is the beneficial owner of a mortgage, deed of trust, note, or other interest secured by, and valuing more than 5 percent of the assets of the HMO, and, in the case of an HMO organized as a nonprofit corporation, an incorporator or member of the corporation under applicable State corporation law;

(2) Any entity in which a person described in paragraph (1):

(i) Is an officer or director;

(ii) Is a partner (if the entity is organized as a partnership);

(iii) Has directly or indirectly a beneficial interest of more than 5 percent of the equity; or

(iv) Has a mortgage, deed of trust, note, or other interest valuing more than 5 percent of the assets of such entity;

(3) Any spouse, child, or parent of an individual described in paragraph (1).

Policymaking body of an HMO means a board of directors, governing body, or other body of individuals that has the authority to establish policy for the HMO.

Qualified HMO means an HMO found by CMS to be qualified within the meaning of section 1310 of the PHS Act and subpart D of this part.

Rural area means any area not listed as a place having a population of 2,500 or more in Document #PC(1)A, ''Number of Inhabitants,'' Table VI, ''Population of Places,'' and not listed as an urbanized area in Table XI, ''Population of Urbanized Areas'' of the same document (1970 Census or most recent update of this document, Bureau of Census, U.S. Department of Commerce).

Secretary means the Secretary of Health and Human Services and any other officer or employee of the Department of Health and Human Services to whom the authority involved has been delegated.

Service area means a geographic area, defined through zip codes, census tracts, or other geographic measurements, that is the area, as determined by CMS, within which the HMO furnishes basic and supplemental health services and makes them available and accessible to all its enrollees in accordance with §417.106(b). Facilities in which individuals are incarcerated are not included in the geographic service area of an HMO or CMP plan.

Significant business transaction means any business transaction or series of transactions during any one fiscal year of the HMO, the total value of which exceeds the lesser of $25,000 or 5 percent of the total operating expenses of the HMO.

Staff of the HMO means health professionals who are employees of the HMO and who—

(1) Provide services to HMO enrollees at an HMO facility subject to the staff policies and operational procedures of the HMO;

(2) Engage in the coordinated practice of their profession and provide to enrollees of the HMO the health services that the HMO has contracted to provide;

(3) Share medical and other records, equipment, and professional, technical, and administrative staff of the HMO; and

(4) Provide their professional services in accordance with a compensation arrangement, other than fee-for-service, established by the HMO. This arrangement may include, but is not limited to, fee-for-time, retainer or salary.

Subscriber means an enrollee who has entered into a contractual relationship with the HMO or who is responsible for making payments for basic health services (and contracted for supplemental health services) to the HMO or on whose behalf these payments are made.

Supplemental health services means the health services described in § 417.102(a).

Unusual or infrequently used health services means:

(1) Those health services that are projected to involve fewer than 1 percent of the encounters per year for the entire HMO enrollment, or,

(2) Those health services the provision of which, given the enrollment projection of the HMO and generally accepted staffing patterns, is projected will require less than 0.25 full time equivalent health professionals.

[45 FR 72528, Oct. 31, 1980, as amended at 47 FR 19338, May 5, 1982; 52 FR 22321, June 11, 1987. Redesignated at 52 FR 36746, Sept. 30, 1987. Redesignated and amended at 56 FR 51985, Oct. 17, 1991; 58 FR 38067, July 15, 1993; 60 FR 34887, July 5, 1995; 60 FR 45674, Sept. 1, 1995; 79 FR 29955, May 23, 2014]

§ 417.2 Basis and scope.

(a) Subparts B through F of this part pertain to the Federal qualification of HMOs under title XIII of the Public Health Service (PHS) Act.

(b) Subparts G through R of this part set forth the rules for Medicare contracts with, and payment to, HMOs and competitive medical plans (CMPs) under section 1876 of the Act and 8 U.S.C. 1611.

(c) Subpart U of this part pertains to Medicare payment to health care prepayment plans under section 1833(a)(1)(A) of the Act.

(d) Subpart V of this part applies to the administration of outstanding loans and loan guarantees previously granted under title XIII of the PHS Act.

[56 FR 51985, Oct. 17, 1991, as amended at 60 FR 45675, Sept. 1, 1995; 80 FR 7958, Feb. 12, 2015]

Subpart B—Qualified Health Maintenance Organizations: Services

§ 417.101 Health benefits plan: Basic health services.

(a) An HMO must provide or arrange for the provision of basic health services to its enrollees as needed and without limitations as to time and cost other than those prescribed in the PHS Act and these regulations, as follows:

(1) Physician services (including consultant and referral services by a physician), which must be provided by a licensed physician, or if a service of a physician may also be provided under applicable State law by other health professionals, an HMO may provide the service through these other health professionals;

(2)(i) Outpatient services, which must include diagnostic services, treatment services and x-ray services, for patients who are ambulatory and may be provided in a non-hospital based health care facility or at a hospital;

(ii) Inpatient hospital services, which must include but not be limited to, room and board, general nursing care, meals and special diets when medically necessary, use of operating room and related facilities, use of intensive care unit and services, x-ray services, laboratory, and other diagnostic tests, drugs, medications, biologicals, anesthesia and oxygen services, special duty nursing when medically necessary, radiation therapy, inhalation therapy, and administration of whole blood and blood plasma;

(iii) Outpatient services and inpatient hospital services must include short-term rehabilitation services and physical therapy, the provision of which the HMO determines can be expected to result in the significant improvement of a member's condition within a period of two months;

(3) Instructions to its enrollees on procedures to be followed to secure medically necessary emergency health services both in the service area and out of the service area;

(4) Twenty outpatient visits per enrollee per year, as may be necessary and appropriate for short-term evaluative or crisis intervention mental health services, or both;

(5) Diagnosis, medical treatment and referral services (including referral services to appropriate ancillary services) for the abuse of or addiction to alcohol and drugs:

(i) Diagnosis and medical treatment for the abuse of or addiction to alcohol and drugs must include detoxification for alcoholism or drug abuse on either an outpatient or inpatient basis, whichever is medically determined to be appropriate, in addition to the other required basic health services for the treatment of other medical conditions;

(ii) Referral services may be either for medical or for nonmedical ancillary services. Medical services must be a part of basic health services; nonmedical ancillary services (such as vocational rehabilitation and employment counseling) and prolonged rehabilitation services in a specialized inpatient or residential facility need not be a part of basic health services;

(6) Diagnostic laboratory and diagnostic and therapeutic radiologic services in support of basic health services;

(7) Home health services provided at an enrollee's home by health care personnel, as prescribed or directed by the responsible physician or other authority designated by the HMO; and

(8) Preventive health services, which must be made available to members and must include at least the following:

(i) A broad range of voluntary family planning services;

(ii) Services for infertility;

(iii) Well-child care from birth;

(iv) Periodic health evaluations for adults;

(v) Eye and ear examinations for children through age 17, to determine the need for vision and hearing correction; and

(vi) Pediatric and adult immunizations, in accord with accepted medical practice.

(b) In addition, an HMO may include a health service described in §417.102 as a supplemental health service in the basic health services that it provides or arranges for its enrollees for a basic health services payment.

(c) To the extent that a natural disaster, war, riot, civil insurrection, epidemic or any other emergency or similar event not within the control of an HMO results in the facilities, personnel, or financial resources of an HMO being unavailable to provide or arrange for the provision of a basic or supplemental health service in accordance with the requirements of §§417.101 through 417.106 and §§417.168 and 417.169, the HMO is required only to make a good-faith effort to provide or arrange for the provision of the service, taking into account the impact of the event. For purposes of this paragraph, an event is not within the control of an HMO if the HMO cannot exercise influence or dominion over its occurrence.

(d) The following are not required to be provided as basic health services:

(1) Corrective appliances and artificial aids;

(2) Mental health services, except as required under section 1302(1)(D) of the PHS Act and paragraph (a)(4) of this section;

(3) Cosmetic surgery, unless medically necessary;

(4) Prescribed drugs and medicines incidental to outpatient care;

(5) Ambulance services, unless medically necessary;

(6) Care for military service connected disabilities for which the enrollee is legally entitled to services and for which facilities are reasonably available to this enrollee;

(7) Care for conditions that State or local law requires be treated in a public facility;

(8) Dental services;

(9) Vision and hearing care except as required by sections 1302(1)(A) and

1302(1)(H)(vi) of the PHS Act and paragraphs (a)(1) and (a)(8) of this section;

(10) Custodial or domiciliary care;

(11) Experimental medical, surgical, or other experimental health care procedures, unless approved as a basic health service by the policymaking body of the HMO;

(12) Personal or comfort items and private rooms, unless medically necessary during inpatient hospitalization;

(13) Whole blood and blood plasma;

(14) Long-term physical therapy and rehabilitation;

(15) Durable medical equipment for home use (such as wheel chairs, surgical beds, respirators, dialysis machines); and

(16) Health services that are unusual and infrequently provided and not necessary for the protection of individual health, as approved by CMS upon application by the HMO.

(e) An HMO may not offer to provide or arrange for the provision of basic health services on a prepayment basis that do not include all the basic health services set forth in paragraph (a) of this section or that are limited as to time and cost except in a manner prescribed by this subpart.

[45 FR 72528, Oct. 31, 1980. Redesignated at 52 FR 36746, Sept. 30, 1987, and amended at 58 FR 38077, July 15, 1993]

§ 417.102 Health benefits plan: Supplemental health services.

(a) An HMO may provide to its enrollees any health service that is not included as a basic health service under § 417.101(a). These health services may be limited as to time and cost.

(b) An HMO must determine the level and scope of supplemental health services included with basic health services provided to its enrollees for a basic health services payment or those services offered to its enrollees as supplemental health services.

[45 FR 72528, Oct. 31, 1980, as amended at 47 FR 19339, May 5, 1982. Redesignated at 52 FR 36746, Sept. 30, 1987, as amended at 58 FR 38082, 38083, July 15, 1993]

§ 417.103 Providers of basic and supplemental health services.

(a)(1) The HMO must provide that the services of health professionals that are provided as basic health services will, except as provided in paragraph (c) of this section, be provided or arranged for through (i) health professionals who are staff of the HMO, (ii) a medical group or groups, (iii) an IPA or IPAs, (iv) physicians or other health professionals under direct service contracts with the HMO for the provision of these services, or (v) any combination of staff, medical group or groups, IPA or IPAs, or physicians or other health professionals under direct service contracts with the HMO.

(2) A staff or medical group model HMO may have as providers of basic health services physicians who have also entered into written services arrangements with an IPA or IPAs, but only if either (i) these physicians number less than 50 percent of the physicians who have entered into arrangements with the IPA or IPAs, or (ii) if the sharing is 50 percent or greater, CMS approves the sharing as being consistent with the purposes of section 1310(b) of the PHS Act.

(3) After the 4 year period beginning with the month following the month in that an HMO becomes a qualified HMO, an entity that meets the requirements of the definition of medical group in § 417.100, except for subdivision (3)(i) of that definition, may be considered a medical group if CMS determines that the principal professional activity (over 50 percent individually) of the entity's members is the coordinated practice of their profession, and if the HMO has demonstrated to the satisfaction of CMS that the entity is committed to the delivery of medical services on a prepaid group practice basis by either:

(i) Presenting a reasonable time-phased plan for the entity to achieve compliance with the ''substantial responsibility'' requirement of subdivision (3)(i) of the definition of ''medical group'' in § 417.100. The HMO must update the plan annually and must demonstrate to the satisfaction of CMS that the entity is making continuous efforts and progress towards compliance with the requirements of the definition of ''medical group,'' or

(ii) Demonstrating that compliance by the entity with the ''substantial responsibility'' requirement is unreasonable or impractical because (A) the

HMO serves a non-metropolitan or rural area as defined in §417.100, or (B) the entity is a multi-speciality group that provides medical consultation upon referral on a regional or national basis, or (C) the majority of the residents of the HMO's service area are not eligible for employer-employee health benefits plans and the HMO has an insufficient number of enrollees to require utilization of at least 35 percent of the entity's services.

(b) HMOs must have effective procedures to monitor utilization and to control cost of basic and supplemental health services and to achieve utilization goals, which may include mechanisms such as risk sharing, financial incentives, or other provisions agreed to by providers.

(c) Paragraph (a) of this section does not apply to the provision of the services of a physician:

(1) Which the HMO determines are unusual or infrequently used services; or

(2) Which, because of an emergency, it was medically necessary to provide to the enrollee other than as required by paragraph (a) of this section; or

(3) Which are provided as part of the inpatient hospital services by employees or staff of a hospital or provided by staff of other entities such as community mental health centers, home health agencies, visiting nurses' associations, independent laboratories, or family planning agencies.

(d) Supplemental health services must be provided or arranged for by the HMO and need not be provided by providers of basic health services under contract with the HMO.

(e) Each HMO must:

(1) Pay the provider, or reimburse its enrollees for the payment of reasonable charges for basic health services (or supplemental health services that the HMO agreed to provide on a prepayment basis) for which its enrollees have contracted, which were medically necessary and immediately required to be obtained other than through the HMO because of an unforeseen illness, injury, or condition, as determined by the HMO;

(2) Adopt procedures to review promptly all claims from enrollees for reimbursement for the provision of health services described in paragraph (e)(1) of this section, including a procedure for the determination of the medical necessity for obtaining the services other than through the HMO; and

(3) Provide instructions to its enrollees on procedures to be followed to secure these health services.

(Sec. 215 of the Public Health Service Act, as amended, 58 Stat. 690, 67 Stat. 631 (42 U.S.C. 216); secs. 1301–1318, as amended, Pub. L. 97–35, 95 Stat. 572–578 (42 U.S.C. 300e–300e–17)

[45 FR 72528, Oct. 31, 1980; 45 FR 77031, Nov. 21, 1980, as amended at 47 FR 19339, May 5, 1982; 50 FR 6174, Feb. 14, 1985. Redesignated at 52 FR 36746, Sept. 30, 1987, as amended at 58 FR 38082, 38083, July 15, 1993]

§417.104 Payment for basic health services.

(a) *Basic health services payment.* Each HMO must provide or arrange for the provision of basic health services for a basic health services payment that:

(1) Is to be paid on a periodic basis without regard to the dates these services are provided;

(2) Is fixed without regard to the frequency, extent, or kind of basic health services actually furnished;

(3) Except as provided in paragraph (c) of this section, is fixed under a community rating system, as described in paragraph (b) of this section; and

(4) May be supplemented by nominal copayments which may be required for the provision of specific basic health services. Each HMO may establish one or more copayment options calculated on the basis of a community rating system.

(i) An HMO may not impose copayment charges that exceed 50 percent of the total cost of providing any single service to its enrollees, nor in the aggregate more than 20 percent of the total cost of providing all basic health services.

(ii) To insure that copayments are not a barrier to the utilization of health services or enrollment in the HMO, an HMO may not impose copayment charges on any subscriber (or enrollees covered by the subscriber's contract with the HMO) in any calendar year, when the copayments made by the subscriber (or enrollees) in that calendar year total 200 percent of the total annual premium cost which that

subscriber (or enrollees) would be required to pay if he (or they) were enrolled under an option with no copayments. This limitation applies only if the subscriber (or enrollees) demonstrates that copayments in that amount have been paid in that year.

(b) *Community rating system.* Under a community rating system, rates of payment for health services may be determined on a per person or per family basis, as described in paragraph (b)(1) of this section or on a per group basis as described in paragraph (b)(2) of this section. An HMO may fix its rates of payment under the system described in paragraph (b)(1) or (b)(2) of this section or under both such systems, but an HMO may use only one such system for fixing its rates of payment for any one group.

(1) A system of fixing rates of payment for health services may provide that the rates will be fixed on a per person or per family basis and may vary with the number of persons in a family. Except as otherwise authorized in this paragraph, these rates must be equivalent for all individuals and for all families of similar composition. Rates of payment may be based on either a schedule of rates charged to each subscriber group or on a per-enrollee-per-month (or per-subscriber-per-month) revenue requirement for the HMO. In the former event, rates may vary from group to group if the projected total revenue from each group is substantially equivalent to the revenue that would be derived if the schedule of rates were uniform for all groups. In the latter event, the payments from each group of subscribers must be calculated to yield revenues substantially equivalent to the product of the total number of enrollees (or subscribers) expected to be enrolled from the group and the per-enrollee-per-month (or per-subscriber-per-month) revenue requirement for the HMO. Under the system described in this paragraph, rates of payment may not vary because of actual or anticipated utilization of services by individuals associated with any specific group of subscribers. These provisions do not preclude changes in the rates of payment that are established for new enrollments or re-enrollments and that do not apply to existing contracts until the renewal of these contracts.

(2) A system of fixing rates of payment for health services may provide that the rates will be fixed for individuals and families by groups. Except as otherwise authorized in this paragraph, such rates must be equivalent for all individuals in the same group and for all families of similar composition in the same group. If an HMO is to fix rates of payment for individuals and families by groups, it must:

(i) Classify all of the enrollees of the organization into classes based on factors that the HMO determines predict the differences in the use of health services by the individuals or families in each class and which have not been disapproved by CMS,

(ii) Determine its revenue requirements for providing services to the enrollees of each class established under paragraph (b)(2)(i) of this section, and

(iii) Fix the rates of payment for the individuals and families of a group on the basis of a composite of the organization's revenue requirements determined under paragraph (b)(2)(ii) of this section for providing services to them as members of the classes established under paragraph (b)(2)(i) of this section. CMS will review the factors used by each HMO to establish classes under paragraph (b)(2)(i) of this section. If CMS determines that any such factor may not reasonably be used to predict the use of the health services by individuals and families, CMS will disapprove the factor for that purpose.

(3)(i) Nominal differentials in rates may be established to reflect differences in marketing costs and the different administrative costs of collecting payments from the following categories of potential subscribers:

(A) Individual (non-group) subscribers (including their families).

(B) Small groups of subscribers (100 subscribers or fewer).

(C) Large groups of subscribers (over 100 subscribers).

(ii) Differentials in rates may be established for subscribers enrolled in an HMO: (A) Under a contract with a governmental authority under section 1079 (''Contracts for Medical Care for

Spouses and Children: Plans'') or section 1086 (''Contracts for Health Benefits for Certain Members, Former Members and their Dependents'') of title 10 (''Armed Forces''), United States Code; or (B) under any other governmental program (other than the health benefits program authorized by chapter 89 (''Health Insurance'') of title 5 (''Government Organization and Employees''), United States Code; or (C) under any health benefits program for employees of States, political subdivisions of states, and other public entities.

(4) An HMO may establish a separate community rate for separate regional components of the organization upon satisfactory demonstration to CMS of the following:

(i) Each regional component is geographically distinct and separate from any other regional component; and

(ii) Each regional component provides substantially the full range of basic health services to its enrollees, without extensive referral between components of the organization for these services, and without substantial utilization by any two components of the same health care facilities. The separate community rate for each regional component of the HMO must be based on the different costs of providing health services in the respective regions.

(c) *Exceptions to community rating requirement.* (1) In the case of an HMO that provided comprehensive health services on a prepaid basis before it became a qualifed HMO, the requirement of community rating shall not apply to the HMO during the forty-eight month period beginning with the month following the month in which it became a qualifed HMO.

(2) The requirement of community rating does not apply to the basic health services payment for basic health services provided an enrollee who is a full-time student at an accredited institution of higher education.

(d) *Late payment penalty.* HMOs may charge a late payment penalty on accounts receivable that are in arrears.

(e) *Review procedures for evaluating the community rating by class system under paragraph (b)(2).*[1] An HMO may establish a community rating system under paragraph (b)(2) of this section or revised factors used to establish classes after it receives written approval of the factors from CMS. CMS will give approval if it concludes that the factors can reasonably be used to predict the use of health services by individuals and families.

(1) An HMO must make a written request to CMS, listing the factors to be used in the community rating by class system under paragraph (b)(2) of this section.

(2) CMS will notify each HMO within 30 days of receipt of the request and application of one of the following:

(i) The application is approved;

(ii) Additional information or data are required and CMS will notify the HMO of its decision within 30 days from the date of receipt of this information or data; or

(iii) CMS needs additional time to review the written request and the HMO will be notified of CMS's decision within 90 days.

(Approved by the Office of Management and Budget under control number 0915–0051)

(Sec. 215 of the Public Health Service Act, as amended, 58 Stat. 690, 67 Stat. 631 (42 U.S.C. 216); secs. 1301–1318, as amended, Pub. L. 97–35, 95 Stat. 572–578 (42 U.S.C. 300e–300e–17)

[45 FR 72528, Oct. 31, 1980, as amended at 47 FR 19339, May 5, 1982; 50 FR 6175, Feb. 14, 1985. Redesignated at 52 FR 36746, Sept. 30, 1987, as amended at 56 FR 8853, Mar. 1, 1991; 58 FR 38082, 38083, July 15, 1993]

§417.105 Payment for supplemental health services.

(a) An HMO may require supplemental health services payments, in addition to the basic health services payments, for the provision of each health service included in the supplemental health services set forth in §417.102 for which subscribers have contracted, or it may include supplemental health services in the basic health services provided its enrollees for a basic health services payment.

(b) Supplemental health services payments may be made in any agreed upon manner, such as prepayment or fee-for-

[1] Further information entitled ''Guidelines for Rating by Class'' may be obtained from the Office of Prepaid Health Care, Division of Qualification Analysis, HHS Cohen Bldg., room 4360, 330 Independence Ave. SW., Washington, DC 20201.

service. Supplemental health services payments that are fixed on a prepayment basis, however, must be fixed under a community rating system, unless the supplemental health services payment is for a supplemental health service provided an enrollee who is a full-time student at an accredited institution of higher education. In the case of an HMO that provided comprehensive health services on a prepaid basis before it became a qualifed HMO, the community rating requirement shall not apply to that HMO during the forty-eight month period beginning with the month following the month in which it became a qualifed HMO.

(Sec. 215 of the Public Health Service Act, as amended, 58 Stat. 690, 67 Stat. 631 (42 U.S.C. 216); secs. 1301–1318, as amended, Pub. L. 97–35, 95 Stat. 572–578 (42 U.S.C. 300e–300e–17)

[45 FR 72528, Oct. 31, 1980, as amended at 50 FR 6175, Feb. 14, 1985. Redesignated at 52 FR 36746, Sept. 30, 1987, as amended at 58 FR 38082, 38083, July 15, 1993]

§ 417.106 Quality assurance program; Availability, accessibility, and continuity of basic and supplemental health services.

(a) *Quality assurance program.* Each HMO or CMP must have an ongoing quality assurance program for its health services that meets the following conditions:

(1) Stresses health outcomes to the extent consistent with the state of the art.

(2) Provides review by physicians and other health professionals of the process followed in the provision of health services.

(3) Uses systematic data collection of performance and patient results, provides interpretation of these data to its practitioners, and institutes needed change.

(4) Includes written procedures for taking appropriate remedial action whenever, as determined under the quality assurance program, inappropriate or substandard services have been provided or services that ought to have been furnished have not been provided.

(b) *Availability and accessibility of health care services.* Basic health services and those supplemental health services for which enrollees have contracted must be provided or arranged for by the HMO in accordance with the following rules:

(1) Except as provided in paragraph (b)(2) of this section, the services must be available to each enrollee within the HMO's service area.

(2) *Exception.* If the HMO's service area is located wholly within a nonmetropolitan area, the HMO may make available outside its service area any basic health service that is not a primary care or emergency care service, if the number of providers of that basic health service who will provide the service to the HMO's enrollees is insufficient to meet the demand. As used in this paragraph, primary care includes general practice, family practice, general internal medicine, general pediatrics, and general obstetrics and gynecology. An HMO that provides the services covered by these fields through at least a general or family practitioner, or a pediatrician and a general internist, is considered to be providing primary care.

(3) The services must be available and accessible with reasonable promptness to each of the HMO's enrollees as ensured through—

(i) Staffing patterns within generally accepted norms for meeting the projected enrollment needs; and

(ii) Geographic location, hours of operation, and arrangements for afterhours services. (Medically necessary emergency services must be available 24 hours a day, 7 days a week.)

(c) *Continuity of care.* The HMO must ensure continuity or care through arrangements that include but are not limited to the following:

(1) Use of a health professional who is primarily responsible for coordinating the enrollee's overall health care.

(2) A system of health and medical records that accumulates pertinent information about the enrollee's health care and makes it available to appropriate professionals.

(3) Arrangements made directly or through the HMO's providers to ensure that the HMO or the health professional who coordinates the enrollee's overall health care is kept informed about the services that the referral resources furnish to the enrollee.

(d) *Confidentiality of health records.* Each HMO must establish adequate procedures to ensure the confidentiality of the health and medical records of its enrollees.

[58 FR 38068, July 15, 1993]

Subpart C—Qualified Health Maintenance Organizations: Organization and Operation

SOURCE: 58 FR 38068, July 15, 1993, unless otherwise noted.

§417.120 Fiscally sound operation and assumption of financial risk.

(a) *Fiscally sound operation*—(1) *General requirements.* Each HMO must have a fiscally sound operation, as demonstrated by the following:

(i) Total assets greater than total unsubordinated liabilities. In evaluating assets and liabilities, loan funds awarded or guaranteed under section 1306 of the PHS Act are not included as liabilities.

(ii) Sufficient cash flow and adequate liquidity to meet obligations as they become due.

(iii) A net operating surplus, or a financial plan that meets the requirements of paragraph (a)(2) of this section.

(iv) An insolvency protection plan that meets the requirements of §417.122(b) for protection of enrollees.

(v) A fidelity bond or bonds, procured and maintained by the HMO, in an amount fixed by its policymaking body but not less than $100,000 per individual, covering each officer and employee entrusted with the handling of its funds. The bond may have reasonable deductibles, based upon the financial strength of the HMO.

(vi) Insurance policies or other arrangements, secured and maintained by the HMO and approved by CMS to insure the HMO against losses arising from professional liability claims, fire, theft, fraud, embezzlement, and other casualty risks.

(2) *Financial plan requirement.* (i) If an HMO has not earned a cumulative net operating surplus during the three most recent fiscal years, did not earn a net operating surplus during the most recent fiscal year or does not have positive net worth, the HMO must submit a financial plan satisfactory to CMS to achieve net operating surplus within available fiscal resources.

(ii) This plan must include—

(A) A detailed marketing plan;

(B) Statements of revenue and expense on an accrual basis;

(C) Sources and uses of funds statements; and

(D) Balance sheets.

(b) *Assumption of financial risk.* Each HMO must assume full financial risk on a prospective basis for the provision of basic health services, except that it may obtain insurance or make other arrangements as follows:

(1) For the cost of providing to any enrollee basic health services with an aggregate value of more than $5,000 in any year.

(2) For the cost of basic health services obtained by its enrollees from sources other than the HMO because medical necessity required that they be furnished before they could be secured through the HMO.

(3) For not more than 90 percent of the amount by which its costs for any of its fiscal years exceed 115 percent of its income for that fiscal year.

(4) For physicians or other health professionals, health care institutions, or any other combination of such individuals or institutions to assume all or part of the financial risk on a prospective basis for their furnishing of basic health services to the HMO's enrollees.

§417.122 Protection of enrollees.

(a) *Liability protection.* (1) Each HMO must adopt and maintain arrangements satisfactory to CMS to protect its enrollees from incurring liability for payment of any fees that are the legal obligation of the HMO. These arrangements may include any of the following:

(i) Contractual arrangements that prohibit health care providers used by the enrollees from holding any enrollee liable for payment of any fees that are the legal obligation of the HMO.

(ii) Insurance, acceptable to CMS.

(iii) Financial reserves, acceptable to CMS, that are held for the HMO and restricted for use only in the event of insolvency.

(iv) Any other arrangements acceptable to CMS.

(2) The requirements of this paragraph do not apply to an HMO if CMS determines that State law protects the HMO enrollees from liability for payment of any fees that are the legal obligation of the HMO.

(b) *Protection against loss of benefits if the HMO becomes insolvent.* The insolvency protection plan required under §417.120(a) must provide for continuation of benefits as follows:

(1) For all enrollees, for the duration of the contract period for which payment has been made.

(2) For enrollees who are in an inpatient facility on the date of insolvency, until they are discharged from the facility.

§ 417.124 Administration and management.

(a) *General requirements.* Each HMO must have administrative and managerial arrangements satisfactory to CMS, as demonstrated by at least the following:

(1) A policymaking body that exercises oversight and control over the HMO's policies and personnel to ensure that management actions are in the best interest of the HMO and its enrollees.

(2) Personnel and systems sufficient for the HMO to organize, plan, control and evaluate the financial, marketing, health services, quality assurance program, administrative and management aspects of the HMO.

(3) At a minimum, management by an executive whose appointment and removal are under the control of the HMO's policymaking body.

(b) *Full and fair disclosure*—(1) *Basic rule.* Each HMO must prepare a written description of the following:

(i) Benefits (including limitations and exclusions).

(ii) Coverage (including a statement of conditions on eligibility for benefits).

(iii) Procedures to be followed in obtaining benefits and a description of circumstances under which benefits may be denied.

(iv) Rates.

(v) Grievance procedures.

(vi) Service area.

(vii) Participating providers.

(viii) Financial condition including at least the following most recently audited information: Current assets, other assets, total assets; current liabilities, long term liabilities; and net worth.

(2) *Requirements for the description.* (i) The description must be written in a way that can be easily understood by the average person who might enroll in the HMO.

(ii) The description of benefits and coverage may be in general terms if reference is made to a detailed statement of benefits and coverage that is available without cost to any person who enrolls in the HMO or to whom the opportunity for enrollment is offered.

(iii) The HMO must provide the description to any enrollee or person who is eligible to elect the HMO option and who requests the material from the HMO or the administrator of a health benefits plan. For purposes of this requirement, ''administrator'' (of a health benefits plan) has the meaning it is given in the Employment Retirement Income Security Act of 1974 (ERISA) at 29 U.S.C. 1002(16)(A).

(iv) If the HMO provides health services through individual practice associations (IPAs), the HMO must specify the number of member physicians by specialty, and a listing of the hospitals where HMO enrollees will receive basic and supplemental health services.

(v) If the HMO provides health services other than through IPAs, the HMO must specify, for each ambulatory care facility, the facility's address, days and hours of operation, and the number of physicians by specialty, and a listing of the hospitals where HMO enrollees will receive basic and supplemental health services.

(c) *Broadly representative enrollment.* (1) Each HMO must offer enrollment to persons who are broadly representative of the various age, social, and income groups within its service area.

(2) If an HMO has a medically underserved population located in its service area, not more than 75 percent of its enrollees may be from the medically underserved population unless the area in which that population resides is a rural area.

(d) *Health status and enrollment.* (1) The HMO may not, on the basis of health status, health care needs, or age of the individual—

(i) Expel or refuse to reenroll any enrollee; or

(ii) Refuse to enroll individual members of a group.

(2) For purposes of this paragraph, a ''group'' is composed of individuals who enroll in the HMO under a contract or other arrangement that covers two or more subscribers. Examples of groups are employees who enroll under a contract between their employer and the HMO, or members of an organization that arranges coverage for its membership.

(3) Nothing in this subpart prohibits an HMO from requiring that, as a condition for continued eligibility for enrollment, enrolled dependent children, upon reaching a specified age, convert to individual enrollment, consistent with paragraph (e) of this section.

(e) *Conversion of enrollment.* (1) Each HMO must offer individual enrollment to the following:

(i) Each enrollee (and his or her enrolled dependents) leaving a group.

(ii) Each enrollee who would otherwise cease to be eligible for HMO enrollment because of his or her age, or the death or divorce of an enrollee.

(2) The individual enrollment offered must meet the conditions of subpart B of this part and this subpart C.

(3) The HMO is not required to offer individual enrollment except to the enrollees specified in this paragraph.

(4) The HMO must offer the enrollment on the same terms and conditions that it makes available to other nongroup enrollees.

(f) [Reserved]

(g) *Grievance procedures.* Each HMO must have and use meaningful procedures for hearing and resolving grievances between the HMO's enrollees and the HMO, including the HMO staff and medical groups and IPAs that furnish services. These procedures must ensure that:

(1) Grievances and complaints are transmitted in a timely manner to appropriate HMO decisionmaking levels that have authority to take corrective action; and

(2) Appropriate action is taken promptly, including a full investigation if necessary and notification of concerned parties as to the results of the HMO's investigation.

(h) *Certification of institutional providers.* Each HMO must ensure that its affiliated institutional providers meet one of the following conditions:

(1) In the case of hospitals, are either accredited by the Joint Commission on Accreditation of Health Care Organizations, or certified by Medicare.

(2) In the case of laboratories, are either CLIA-exempt, or have in effect a valid certificate of one of the following types, issued by CMS in accordance with section 353 of the PHS Act and part 493 of this chapter:

(i) Registration certificate.

(ii) Certificate.

(iii) Certificate of waiver.

(iv) Certificate of accreditation.

(3) In the case of other affiliated institutional providers, are certified for participation in Medicare and Medicaid in accordance with part 405, 416, 418, 488, or 491 of this chapter, as appropriate.

[58 FR 38068, July 15, 1993, as amended at 59 FR 49843, Sept. 30, 1994]

§417.126 Recordkeeping and reporting requirements.

(a) *General reporting and disclosure requirements.* Each HMO must have an effective procedure to develop, compile, evaluate, and report to CMS, to its enrollees, and to the general public, at the times and in the manner that CMS requires, and while safeguarding the confidentiality of the doctor-patient relationship, statistics and other information with respect to the following:

(1) The cost of its operations.

(2) The patterns of utilization of its services.

(3) The availability, accessibility, and acceptability of its services.

(4) To the extent practical, developments in the health status of its enrollees.

(5) Information demonstrating that the HMO has a fiscally sound operation.

(6) Other matters that CMS may require.

(b) *Significant business transactions.* Each HMO must report to CMS annually, within 120 days of the end of its fiscal year (unless for good cause shown, CMS authorizes an extension of time), the following:

(1) A description of significant business transactions (as defined in paragraph (c) of this section) between the HMO and a party in interest.

(2) With respect to those transactions—

(i) A showing that the costs of the transactions listed in paragraph (c) of this section do not exceed the costs that would be incurred if these transactions were with someone who is not a party in interest; or

(ii) If they do exceed, a justification that the higher costs are consistent with prudent management and fiscal soundness requirements.

(3) A combined financial statement for the HMO and a party in interest if either of the following conditions is met:

(i) Thirty-five percent or more of the costs of operation of the HMO go to a party in interest.

(ii) Thirty-five percent or more of the revenue of a party in interest is from the HMO.

(c) *''Significant business transaction'' defined.* As used in paragraph (b) of this section—

(1) Business transaction means any of the following kinds of transactions:

(i) Sale, exchange or lease of property.

(ii) Loan of money or extension of credit.

(iii) Goods, services, or facilities furnished for a monetary consideration, including management services, but not including—

(A) Salaries paid to employees for services performed in the normal course of their employment; or

(B) Health services furnished to the HMO's enrollees by hospitals and other providers, and by HMO staff, medical groups, or IPAs, or by any combination of those entities.

(2) *Significant business transaction* means any business transaction or series of transactions of the kind specified in paragraph (c)(1) of this section that, during any fiscal year of the HMO, have a total value that exceeds $25,000 or 5 percent of the HMO's total operating expenses, whichever is less.

(d) *Requirements for combined financial statements.* (1) The combined financial statements required by paragraph (b)(3) of this section must display in separate columns the financial information for the HMO and each of these parties in interest.

(2) Inter-entity transactions must be eliminated in the consolidated column.

(3) These statements must have been examined by an independent auditor in accordance with generally accepted accounting principles, and must include appropriate opinions and notes.

(4) Upon written request from an HMO showing good cause, CMS may waive the requirement that its combined financial statement include the financial information required in this paragraph (d) with respect to a particular entity.

(e) *Reporting and disclosure under ERISA.* (1) For any employees' health benefits plan that includes an HMO in its offerings, the HMO must furnish, upon request, the information the plan needs to fulfill its reporting and disclosure obligations (with respect to the particular HMO) under the Employee Retirement Income Security Act of 1974 (ERISA).

(i) The HMO must furnish the information to the employer or the employer's designee, or to the plan administrator, as the term ''administrator'' is defined in ERISA.

(ii) Loan of money or extension of credit.

(iii) Goods, services, or facilities furnished for a monetary consideration, including management services, but not including—

(A) Salaries paid to employees for services performed in the normal course of their employment; or

(B) Health services furnished to the HMO's enrollees by hospitals and other providers, and by HMO staff, medical groups, or IPAs, or by any combination of those entities.

(2) *Significant business transaction* means any business transaction or series of transactions of the kind specified in paragraph (c)(1) of this section that, during any fiscal year of the HMO, have a total value that exceeds

$25,000 or 5 percent of the HMO's total operating expenses, whichever is less.

(d) *Requirements for combined financial statements.* (1) The combined financial statements required by paragraph (b)(3) of this section must display in separate columns the financial information for the HMO and each of these parties in interest.

(2) Inter-entity transactions must be eliminated in the consolidated column.

(3) These statements must have been examined by an independent auditor in accordance with generally accepted accounting principles, and must include appropriate opinions and notes.

(4) Upon written request from an HMO showing good cause, CMS may waive the requirement that its combined financial statement include the financial information required in this paragraph (d) with respect to a particular entity.

(e) *Reporting and disclosure under ERISA.* (1) For any employees' health benefits plan that includes an HMO in its offerings, the HMO must furnish, upon request, the information the plan needs to fulfill its reporting and disclosure obligations (with respect to the particular HMO) under the Employee Retirement Income Security Act of 1974 (ERISA).

(2) The HMO must furnish the information to the employer or the employer's designee, or to the plan administrator, as the term ''administrator'' is defined in ERISA.

Subpart D—Application for Federal Qualification

§ 417.140 Scope.

This subpart sets forth—

(a) The requirements for—

(1) Entities that seek qualification as HMOs under title XIII of the PHS Act; and

(2) HMOs that seek—

(i) Qualification for their regional components; or

(ii) Expansion of their service areas;

(b) The procedures that CMS follows to make determinations; and

(c) Other related provisions, including application fees.

[59 FR 49836, Sept. 30, 1994]

§ 417.142 Requirements for qualification.

(a) *General rules.* (1) An entity seeking qualification as an HMO must meet the requirements and provide the assurances specified in paragraphs (b) through (f) of this section, as appropriate.

(2) CMS determines whether the entity is an HMO on the basis of the entity's application and any additional information and investigation (including site visits) that CMS may require.

(3) CMS may determine that an entity is any of the following:

(i) An operational qualified HMO.

(ii) A preoperational qualified HMO.

(iii) A transitional qualified HMO.

(b) *Operational qualified HMO.* CMS determines that an entity is an operational qualified HMO if—

(1) CMS finds that the entity meets the requirements of subparts B and C of this part.

(2) The entity, within 30 days of CMS's determination, provides written assurances, satisfactory to CMS, that it—

(i) Provides and will provide basic health services (and any supplemental health services included in any contract) to its enrollees;

(ii) Provides and will provide these services in the manner prescribed in sections 1301(b) and 1301(c) of the PHS Act and subpart B of this part;

(iii) Is organized and operated and will continue to be organized and operated in the manner prescribed in section 1301(c) of the PHS Act and subpart C of this part;

(iv) Under arrangements that safeguard the confidentiality of patient information and records, will provide access to CMS and the Comptroller General or any of their duly authorized representatives for the purpose of audit, examination or evaluation to any books, documents, papers, and records of the entity relating to its operation as an HMO, and to any facilities that it operates; and

(v) Will continue to comply with any other assurances that it has given to CMS.

(c) *Preoperational qualified HMO.* (1) CMS may determine that an entity is a

preoperational qualified HMO if it provides, within 30 days of CMS's determination, satisfactory assurances that it will become operational within 60 days following that determination and will, when it becomes operational, meet the requirements of subparts B and C of this part.

(2) Within 30 days after receiving notice that the entity has begun operation, CMS determines whether it is an operational qualified HMO. In the absence of this determination, the entity is not an operational qualified HMO even though it becomes operational.

(d) *Transitional qualified HMO: General rules*—(1) *Basic requirements.* CMS may determine that an entity is a transitional qualified HMO if the entity—

(i) Meets the requirements of paragraph (d)(2) through (d)(4) of this section; and

(ii) Provides the assurances specified in paragraphs (d)(5) through (d)(7) of this section within 30 days of CMS's determination.

(2) *Organization and operation.* The entity is organized and operated in accordance with subpart C of this part, except that it need not—

(i) Assume full financial risk for the provision of basic health services as required by § 417.120(b); or

(ii) Comply with the limitations that are imposed on insurance by § 417.120(b)(1).

(3) *Range of services.* The entity is currently providing the following services on a prepaid basis:

(i) Physician services.

(ii) Outpatient services and inpatient hospital services. (The entity need not provide or pay for hospital inpatient or outpatient services that it can show are being provided directly, through insurance, or under arrangements, by other entities.)

(iii) Medically necessary emergency services.

(iv) Diagnostic laboratory services and diagnostic and therapeutic radiologic services.

These services must meet the requirement of § 417.101, but may be limited in time and cost without regard to the constraints imposed by § 417.101(a).

(4) *Payment for services*—(i) *General rule.* The entity pays for basic health services in accordance with § 417.104, except that it need not comply with the copayments limitations imposed by § 417.104(a)(4).

(ii) *Determination of payment rates.* In determining payment rates, the entity need not comply with the community rating requirements of §§ 417.104(b) and 417.105(b).

(5) *Contracts in effect on the date of CMS's determination.* The entity gives assurances that it will meet the following conditions with respect to its group and individual contracts that are in effect on the date of CMS's determination, and which are renewed or renegotiated during the period approved by CMS under paragraph (d)(6) of this section:

(i) Continue to provide services in accordance with paragraph (d)(3) of this section.

(ii) Continue to be organized and operated and to pay for basic health services in accordance with paragraphs (d)(2) and (d)(4) of this section, respectively.

(6) *Time-phased plan.* The entity gives assurances as follows:

(i) It will implement a time-phased plan acceptable to CMS that—

(A) May not extend for more than 3 years from the date of CMS's determination; and

(B) Specifies definite steps for meeting, at the time of renewal of each group or individual contract, all the requirements of subparts B and C of this part.

(ii) Upon completion of this time-phased plan, it will—

(A) Provide basic and supplemental services to all of its enrollees; and

(B) Be organized and operated, and provide services, in accordance with subparts B and C of this part.

(7) *Contracts entered into after the date of CMS's determination.* The entity gives assurances that, with respect to any group or individual contract entered into after the date of CMS's determination, it will—

(i) Be organized and operated in accordance with subpart C of this part; and

(ii) Provide basic health services and any supplemental health services included in the contract, in accordance with subpart B of this part.

(e) *Failure to sign assurances timely.* If CMS determines that an entity meets the requirements for qualification and the entity fails to sign its assurances within 30 days following the date of the determination, CMS gives the entity written notice that its application is considered withdrawn and that it is not a qualified HMO.

(f) *Qualification of regional components.* An HMO that has more than one regional component is considered qualified for those regional components for which assurances have been signed in accordance with this section.

(g) *Special rules: Enrollees entitled to Medicare or Medicaid.* For an HMO that accepts enrollees entitled to Medicare or Medicaid, the following rules apply:

(1) The requirements of titles XVIII and XIX of the Act, as appropriate, take precedence over conflicting requirements of sections 1301(b) and 1301(c) of the PHS Act.

(2) The HMO must, with respect to its enrollees entitled to Medicare or Medicaid, comply with the applicable requirement of title XVIII or XIX, including those that pertain to—

(i) Deductibles and coinsurance;

(ii) Enrollment mix and enrollment practices;

(iii) State plan rules on copayment options; and

(iv) Grievance procedures.

(3) An HMO that complies with paragraph (g)(2) of this section may obtain and retain Federal qualification if, for its other enrollees, the HMO meets the requirements of sections 1301(b) and 1301(c) of the PHS Act and implementing regulations in this subpart D and in subparts B and C of this part.

(h) *Special rules: Enrollees under the Federal employee health benefits program (FEHBP).* An HMO that accepts enrollees under the FEHBP (Chapter 89 of title 5 of the U.S.C.) may obtain and retain Federal qualification if, for its other enrollees, it complies with the requirements of section 1301(b) and 1301(c) of the PHS Act and implementing regulations in this subpart D and subparts B and C of this part.

[59 FR 49836, Sept. 30, 1994]

§417.143 Application requirements.

(a) *General requirements.* This section sets forth application requirements for entities that seek qualification as HMOs; HMOs that seek expansion of their service areas; and HMOs that seek qualification of their regional components as HMOs.

(b) *Completion of an application form.* (1) In order to receive a determination concerning whether an entity is a qualified HMO, an individual authorized to act for the entity (the applicant) must complete an application form provided by CMS.

(2) The authorized individual must describe thoroughly how the entity meets, or will meet, the requirements for qualified HMOs described in the PHS Act and in subparts B and C of this part, this subpart D, and 417.168 and 417.169 of subpart F.

(c) *Collection of an application fee.* In accordance with the requirements of 31 U.S.C. 9701, Fees and charges for Government services and things of value, CMS determines the amount of the application fee that must be submitted with each type of application.

(1) The fee is reasonably related to the Federal government's cost of qualifying an entity and may vary based on the type of application.

(2) Each type of application has one set fee rather than a charge based on the specific cost of each determination. (For example, each Federally qualified HMO applicant seeking Federal qualification of one of its regional components as an HMO is charged the same amount, unless the amount of the fee has been changed under paragraph (f) of this section.)

(d) *Application fee amounts.* The application fee amounts for applications completed on or after July 13, 1987 are as follows:

(1) $18,400 for an entity seeking qualification as an HMO or qualification of a regional component of an HMO.

If, in the case of an HMO seeking qualification of a regional component, CMS determines that there is no need for a site visit, $8,000 will be returned to the applicant.

(2) $6,900 for an HMO seeking expansion of its service area.

(3) $3,100 for a CMP seeking qualification as an HMO.

(e) *Refund of an application fee.* CMS refunds an application fee only if the entity withdraws its application within

10 working days after receipt by CMS. Application fees are not returned in any other circumstance, even if qualification or certification is denied.

(f) *Procedure for changing the amount of an application fee.* If CMS determines that a change in the amount of a fee is appropriate, CMS issues a notice of proposed rulemaking in the FEDERAL REGISTER to announce the proposed new amount.

(g) *New application after denial.* An entity may not submit another application under this subpart for the same type of determination for four full months after the date of the notice in which CMS denied the application.

(h) *Disclosure of application information under the Freedom of Information Act.* An applicant submitting material that he or she believes is protected from disclosure under 5 U.S.C. 552, the Freedom of Information Act, or because of exceptions provided in 45 CFR part 5, the Department's regulations providing exceptions to disclosure, should label the material ''privileged'' and include an explanation of the applicability of an exception described in 45 CFR part 5.

[52 FR 22321, June 11, 1987. Redesignated at 52 FR 36746, Sept. 30, 1987, as amended at 58 FR 38077, July 15, 1993]

§ 417.144 Evaluation and determination procedures.

(a) *Basis for evaluation and determination.* (1) CMS evaluates an application for Federal qualification on the basis of information contained in the application itself and any additional information that CMS obtains through onsite visits, public hearings, and any other appropriate procedures.

(2) If the application is incomplete, CMS notifies the entity and allows 60 days from the date of the notice for the entity to furnish the missing information.

(3) After evaluating all relevant information, CMS determines whether the entity meets the applicable requirements of §§ 417.142 and 417.143.

(b) *Notice of determination.* CMS notifies each entity that applies for qualification under this subpart of its determination and the basis for the determination. The determination may be granting of qualification, intent to deny, or denial.

(c) *Intent to deny.* (1) If CMS finds that the entity does not appear to meet the requirements for qualification and appears to be able to meet those requirements within 60 days, CMS gives the entity notice of intent to deny qualification and a summary of the basis for this preliminary finding.

(2) Within 60 days from the date of the notice, the entity may respond in writing to the issues or other matters that were the basis for CMS's preliminary finding, and may revise its application to remedy any defects identified by CMS.

(d) *Denial and reconsideration of denial.* (1) If CMS denies an application for qualification under this subpart, CMS gives the entity written notice of the denial and an opportunity to request reconsideration of that determination.

(2) A request for reconsideration must—

(i) Be submitted in writing, within 60 days following the date of the notice of denial;

(ii) Be addressed to the CMS officer or employee who denied the application; and

(iii) Set forth the grounds upon which the entity requests reconsideration, specifying the material issues of fact and of law upon which the entity relies.

(3) CMS bases its reconsideration upon the record compiled during the qualification review proceedings, materials submitted in support of the request for reconsideration, and other relevant materials available to CMS.

(4) CMS gives the entity written notice of the reconsidered determination and the basis for the determination.

(e) *Information on qualified HMOs*—(1) FEDERAL REGISTER *notices.* In quarterly FEDERAL REGISTER notices, CMS gives the names, addresses, and service areas of newly qualified HMOs and describes the expanded service areas of other qualified HMOs.

(2) *Listings.* A cumulative list of qualified HMOs is available from the following office, which is open from 8:30 a.m. to 5 p.m., Monday through Friday: Office of Managed Care, room 4360,

Cohen Building, 400 Independence Avenue SW., Washington, DC 20201.

[59 FR 49837, Sept. 30, 1994]

Subpart E—Inclusion of Qualified Health Maintenance Organizations in Employee Health Benefits Plans

SOURCE: 45 FR 72517, Oct. 31, 1980, unless otherwise noted. Redesignated at 52 FR 36746, Sept. 30, 1987.

§417.150 Definitions.

As used in this subpart, unless the context indicates otherwise—

Agreement means a collective bargaining agreement.

Bargaining representative means an individual or entity designated or selected, under any applicable Federal, State, or local law, or public entity collective bargaining agreement, to represent employees in collective bargaining, or any other employee representative designated or selected under any law.

Carrier means a voluntary association, corporation, partnership, or other organization that is engaged in providing, paying for, or reimbursing all or part of the cost of health benefits under group insurance policies or contracts, medical or hospital service agreements, enrollment or subscription contracts, or similar group arrangements, in consideration of premiums or other periodic charges payable to the carrier.

Collective bargaining agreement means an agreement entered into between an employing entity and the bargaining representative of its employees.

Contract means an employer-employee or public entity-employee contract, or a contract for health benefits.

Designee means any person or entity authorized to act on behalf of an employing entity or a group of employing entities to offer the option of enrollment in a qualified health maintenance organization to their eligible employees.

Eligible employee means an employee who meets the employer's requirements for participation in the health benefits plan.

Employee means any individual employed by an employer or public entity on a full-time or part-time basis.

Employer has the meaning given that term in section 3(d) of the Fair Labor Standards Act of 1938, except that it—

(1) Includes non-appropriated fund instrumentalities of the United States Government; and

(2) Excludes the following:

(i) The governments of the United States, the District of Columbia and the territories and possessions of the United States, the 50 States and their political subdivisions, and any agencies or instrumentalities of any of the foregoing, including the United States Postal Service and Postal Rate Commission.

(ii) Any church, or convention or association of churches, and any organization operated, supervised, or controlled by a church, or convention or association of churches that meets the following conditions:

(A) Is an organization that is described in section 501(c)(3) of the Internal Revenue Code of 1954.

(B) Does not discriminate, in the employment, compensation, promotion or termination of employment of any personnel, or in the granting of staff and other privileges to physicians or other health personnel, on the grounds that the individuals obtain health care through HMOs, or participate in furnishing health care through HMOs.

Employing entity means an employer or public entity.

Employing entity-employee contract means a legally enforceable agreement (other than a collective bargaining agreement) between an employing entity and its employees for the provision of, or payment for, health benefits for its employees, or for its employees and their eligible dependents.

Group enrollment period means the period of at least 10 working days each calendar year during which each eligible employee is given the opportunity to select among the alternatives included in a health benefits plan.

Health benefits contract means a contract or other agreement between an employing entity or a designee and a carrier for the provision of, or payment

for, health benefits to eligible employees or to eligible employees and their eligible dependents.

Health benefits plan means any arrangement, to provide or pay for health services, that is offered to eligible employees, or to eligible employees and their eligible dependents, by or on behalf of an employing entity.

Public entity means the 50 states, Puerto Rico, Guam, the Virgin Islands, the Northern Mariana Islands and American Samoa and their political subdivisions, the District of Columbia, and any agency or instrumentality of the foregoing, and *political subdivisions* include counties, parishes, townships, cities, municipalities, towns, villages, and incorporated villages.

Qualified HMO means an HMO that has in effect a determination, made under subpart D of this part, that the HMO is an operational, preoperational, or transitional qualified HMO.

To offer a health benefits plan means to make participation in a health benefits plan available to eligible employees, or to eligible employees and their eligible dependents regardless of whether the employing entity makes a financial contribution to the plan on behalf of these employees, directly or indirectly, for example, through payments on any basis into a health and welfare trust fund.

[45 FR 72517, Oct. 31, 1980, as amended at 47 FR 19341, May 5, 1982. Redesignated at 52 FR 36746, Sept. 30, 1987, as amended at 58 FR 38077, July 15, 1993; 59 FR 49837, 49843, Sept. 30, 1994]

§ 417.151 Applicability.

(a) *Basic rule.* Effective October 24, 1995,[1] this subpart applies to any employing entity that offers a health benefits plan to its employees, meets the conditions specified in paragraphs (b) through (e) of this section, and elects to include one or more qualified HMOs in the health plan alternatives it offers its employees.

(b) *Number of employees.* During any calendar quarter of the preceding calendar year, the employer or public entity employed an average of not less than 25 employees.

(c) *Minimum wage.* During any calendar quarter of the preceding calendar year, the employer was required to pay the minimum wage specified in section 6 of the Fair Labor Standards Act of 1938, or would have been required to pay that wage but for section 13(a) of that Act.

(d) *Federal assistance under section 317 of the PHS Act.* The public entity has a pending application for, or is receiving, assistance under section 317 of the PHS Act.

(e) *Employees in HMO's service area.* At least 25 of the employing entity's employees reside within the HMO's service area.

[59 FR 49838, Sept. 30, 1994, as amended at 61 FR 27287, May 31, 1996]

§ 417.153 Offer of HMO alternative.

(a) *Basic rule.* An employing entity that is subject to this subpart and that elects to include one or more qualified HMOs must offer the HMO alternative in accordance with this section.

(b) *Employees to whom the HMO option must be offered.* Each employing entity must offer the option of enrollment in a qualified HMO to each eligible employee and his or her eligible dependents who reside in the HMO's service area.

(c) *Manner of offering the HMO option.* (1) For employees who are represented by a bargaining representative, the option of enrollment in a qualified HMO—

(i) Must first be presented to the bargaining representative; and

(ii) If the representative accepts the option, must then be offered to each represented employee.

(2) For employees not represented by a bargaining representative, the option must be offered directly to those employees.

[59 FR 49839, Sept. 30, 1994, as amended at 61 FR 27287, May 31, 1996]

[1] Before October 24, 1995, an employing entity that met the conditions specified in § 417.151 was required to include one or more qualified HMOs, if it received from at least one qualified HMO a written request for inclusion and that request met the timing, content, and procedural requirements specified in § 417.152.

§417.155 How the HMO option must be included in the health benefits plan.

(a) *HMO access to employees*—(1) *Purpose and timing*—(i) *Purpose.* The employing entity must provide each HMO included in its health benefits plan fair and reasonable access to all employees specified in §417.153(b), so that the HMO can explain its program in accordance with §417.124(b).

(ii) *Timing.* The employing entity must provide access beginning at least 30 days before, and continuing during, the group enrollment period.

(2) *Nature of access.* (i) Access must include, at a minimum, opportunity to distribute educational literature, brochures, announcements of meetings, and other relevant printed materials that meet the requirements of §417.124(b).

(ii) Access may not be more restrictive or less favorable than the access the employing entity provides to other offerors of options included in the health benefits plan, whether or not those offerors elect to avail themselves of that access.

(b) *Review of HMO offering materials.* (1) The HMO must give the employing entity or designee opportunity to review, revise, and approve HMO educational and offering materials before distribution.

(2) Revisions must be limited to correcting factual errors and misleading or ambiguous statements, unless—

(i) The HMO and the employing entity agree otherwise; or

(ii) Other revisions are required by law.

(3) The employing entity or designee must complete revision of the materials promptly so as not to delay or otherwise interfere with their use during the group enrollment period.

(c) *Group enrollment period; prohibition of restrictions; effective date of HMO coverage*—(1) *Prohibition of restrictions.* If an employing entity or designee includes the option of enrollment in a qualified HMO in the health benefits plan offered to its eligible employees, it must provide a group enrollment period before the effective date of HMO coverage. The employing entity may not impose waiting periods as a condition of enrollment in the HMO or of transfer from HMO to non-HMO coverage, or exclusions, or limitations based on health status.

(2) *Effective date of coverage.* Unless otherwise agreed to by the employing entity, or designee, and the HMO, coverage under the HMO contract for employees selecting the HMO option begins on the day the non-HMO contract expires or is renewed without lapse.

(3) *Coordination of benefits.* Nothing in this subpart precludes the uniform application of coordination of benefits agreements between the HMOs and the other carriers that are included in the health benefits plan.

(d) *Continued eligibility for ''free-standing'' health benefits*—(1) *Basic requirement.* At the request of a qualified HMO, the employing entity or its designee must provide that employees selecting the option of HMO membership will not, because of this selection, lose their eligibility for free-standing dental, optical, or prescription drug benefits for which they were previously eligible or would be eligible if selecting a non-HMO option and that are not included in the services provided by the HMO to its enrollees as part of the HMO prepaid benefit package.

(2) *''Free-standing'' defined.* For purposes of this paragraph, the term ''free-standing'' refers to a benefit that—

(i) Is not integrated or incorporated into a basic health benefits package or major medical plan, and

(ii) Is—

(A) Offered by a carrier other than the one offering the basic health benefits package or major medical plan; or

(B) Subject to a premium separate from the premium for the basic health benefits package or major medical plan.

(3) *Examples of the employing entity's obligation with respect to the continued eligibility.* (i) The health benefits plan includes a free-standing dental benefit. The HMO does not offer any dental coverage as part of its health services provided to members on a prepaid basis. The employing entity must provide that employees who select the HMO option continue to be eligible for dental coverage. (If the dental coverage is not optional for employees selecting the non-HMO option, nothing in this regulation requires that the coverage be

made optional for employees selecting the HMO option. Conversely, if this coverage is optional for employees selecting the non-HMO option, nothing in this regulation requires that the coverage be mandatory for employees selecting the non-HMO option.) -

(ii) The non-HMO option provides free-standing coverage for optical services (such as refraction and the provision of eyeglasses), and the HMO does not. The employing entity must provide that employees who select the HMO option continue to be eligible for optical coverage.

(iii) The non-HMO option includes dental coverage in its major medical package, with a common deductible applied to dental as well as non-dental benefits. The HMO provides no dental coverage as part of its pre-paid health services. Because the dental coverage is not free-standing, the employing entity is not required to provide that employees who select the HMO option continue to be eligible for dental coverage, but is free to do so.

(e) *Opportunity to select among coverage options: Requirement for affirmative written selection*—(1) *Opportunity other than during a group enrollment period.* The employing entity or designee must provide opportunity (in addition to the group enrollment period) for selection among coverage options, by eligible employees who meet any of the following conditions:

(i) Are new employees.

(ii) Have been transferred or have changed their place of residence, resulting in—

(A) Eligibility for enrollment in a qualified HMO for which they were not previously eligible by place of residence; or

(B) Residence outside the service area of a qualified HMO in which they were previously enrolled.

(iii) Are covered by any coverage option that ceases operation.

(2) *Prohibition of restrictions.* When the employees specified in paragraph (e)(1) of this section are eligible to participate in the health benefits plan, the employing entity or designee must make available, without waiting periods or exclusions based on health status as a condition, the opportunity to enroll in an HMO, or transfer from HMO coverage to non-HMO coverage.

(3) *Affirmative written selection.* The employing entity or designee must require that the eligible employee make an affirmative written selection in any of the following circumstances:

(i) Enrollment in a particular qualified HMO is offered for the first time.

(ii) The eligible employee elects to change from one option to another.

(iii) The eligible employee is one of those specified in paragraph (e)(1) of this section.

(f) *Determination of copayment levels and supplemental health services.* The selection of a copayment level and of supplemental health services to be contracted for must be made as follows:

(1) For employees represented by a collective bargaining representative, the selection of copayment levels and supplemental health services is subject to the collective bargaining process.

(2) For employees not represented by a bargaining representative, the selection of copayment levels and supplemental health services is subject to the same decisionmaking process used by the employing entity with respect to the non-HMO option in its health benefits plan.

(3) In all cases, the HMO has the right to include, with the basic benefits package it provides to its enrollees for a basic health services payment, on a non-negotiable basis, those supplemental health services that meet the following conditions:

(i) Are required to be offered under State law.

(ii) Are included uniformly by the HMO in its prepaid benefit package.

(iii) Are available to employees who select the non-HMO option but not available to those who select the HMO option.

[59 FR 49840, Sept. 30, 1994, as amended at 61 FR 27288, May 31, 1996]

§ 417.156 When the HMO must be offered to employees.

(a) *General rules.* (1) The employing entity or designee must offer eligible employees the option of enrollment in a qualified HMO at the earliest date permitted under the terms of existing agreements or contracts.

(2) If the HMO's request for inclusion in a health benefits plan is received at a time when existing contracts or agreements do not provide for inclusion, the employing entity must include the HMO option in the health benefits plan at the time that new agreements or contracts are offered or negotiated.

(b) *Specific requirements.* Unless mutually agreed otherwise, the following rules apply:

(1) *Collective bargaining agreement.* The employing entity or designee must raise the HMO's request during the collective bargaining process—

(i) When a new agreement is negotiated;

(ii) At the time prescribed, in an agreement with a fixed term of more than 1 year, for discussion of change in health benefits; or

(iii) In accordance with a specific process for review of HMO offers.

(2) *Contracts.* For employees not covered by a collective bargaining agreement, the employing entity or designee must include the HMO option in any health benefits plan offered to eligible employees when the existing contract is renewed or when a new health benefits contract or other arrangement is negotiated.

(i) If a contract has no fixed term or has a term in excess of 1 year, the contract must be treated as renewable on its earliest anniversary date.

(ii) If the employing entity or designee is self-insured, the budget year must be treated as the term of the existing contract.

(3) *Multiple arrangements.* In the case of a health benefits plan that includes multiple contracts or other arrangements with varying expiration or renewal dates, the employing entity must include the HMO option, in accordance with paragraphs (b)(1) and (b)(2) of this section,—

(i) At the time each contract or arrangement is renewed or reissued; or

(ii) The benefits provided under the contract or arrangement are offered to employees.

[59 FR 49841, Sept. 30, 1994]

§417.157 Contributions for the HMO alternative.

(a) *General principles*—(1) *Nondiscrimination.* The employer contribution to an HMO must be in an amount that does not discriminate financially against an employee who enrolls in an HMO. A contribution does not discriminate financially if the method of determining the contribution is reasonable and is designed to ensure that employees have a fair choice among health benefits plan alternatives.

(2) *Effect of agreements or contracts.* The employing entity or designee is not required to pay more for health benefits as a result of offering the HMO alternative than it would otherwise be required to pay under a collective bargaining agreement or contract that provides for health benefits and is in effect at the time the HMO alternative is included.

(3) *Examples of acceptable employer contributions.* The following are methods that are considered nondiscriminatory:

(i) The employer contribution to the HMO is the same, per employee, as the contribution to non-HMO alternatives.

(ii) The employer contribution reflects the composition of the HMO's enrollment in terms of enrollee attributes that can reasonably be used to predict utilization, experience, costs, or risk. For each enrollee in a given class established on the basis of those attributes, the employer contributes an equal amount, regardless of the health benefits plan chosen by the employee.

(iii) The employer contribution is a fixed percentage of the premium for each of the alternatives offered.

(iv) The employer contribution is determined under a mutually acceptable arrangement negotiated by the HMO and the employer. In negotiating the arrangement, the employer may not insist on terms that would cause the HMO to violate any of the requirements of this part.

(4) *Adjustment of employer contribution.* An employer contribution determined by an acceptable method may in some cases be adjusted if it would result in a nominal payment or no payment at all by HMO enrollees (because the HMO premium is lower than the

premiums for the other alternatives offered). If, for example the employer has a policy of requiring all employees to contribute to their health benefits plan, the employer may require HMO enrollees who would otherwise pay little or nothing at all, to make a payment that does not exceed 50 percent of the employee contribution to the principal non-HMO alternative. The principal non-HMO alternative is the one that covers the largest number of enrollees from the particular employer.

(b) *Administrative expenses.* (1) In determining the amount of its contribution to the HMO, the employing entity or designee may not consider administrative expenses incurred in connection with offering any alternative in the health benefits plan.

(2) However, if the employing entity or designee has special requirements for other than standard solicitation brochures and enrollment literature, it must, in the case of the HMO alternative, determine and distribute any administrative costs attributable to those requirements in a manner consistent with its method of determining and distributing those costs for the non-HMO alternatives.

(c) *Exclusion for contribution for certain benefits.* In determining the amount of the employing entity's contribution or the designee's cost for the HMO alternative, the employing entity or designee may exclude those portions of the contribution allocable to benefits (such as life insurance or insurance for supplemental health benefits)—

(1) For which eligible employees and their eligible dependents are covered notwithstanding selection of the HMO alternative; and

(2) That are not offered on a prepayment basis by the HMO to the employing entity's employees.

(d) *Contributions determined by agreements or contracts or by law.* If the specific amount of the employing entity's contribution for health benefits is fixed by an agreement or contract, or by law, that amount constitutes the employing entity's obligation for contribution toward the HMO premiums.

(e) *Allocation of portion of a contribution determined by an agreement.* In some cases, the employing entity's contribution for health benefits is determined by an agreement that also provides for benefits other than health benefits. In that case, the employing entity must determine, or instruct its designee to determine, what portion of its contribution is applicable to health benefits.

(f) *Retention and availability of data.* Each employing entity or designee must retain the following data for three years and make it available to CMS upon request:

(1) The data used to compute the level of contribution for each of the plans offered to employees.

(2) Related data about the employees who are eligible to enroll in a plan.

(3) A description of the methodology for computation.

(g) *CMS review of data.* (1) CMS may request and review the data specified in paragraph (f) of this section on its own initiative or in response to requests from HMOs or employees.

(2) The purpose of CMS's review is to determine whether the methodology and the level of contribution comply with the requirements of this subpart.

(3) HMOs and employees that request CMS to review must set forth reasonable grounds for making the request.

[61 FR 27287, May 31, 1996]

§ 417.158 Payroll deductions.

Each employing entity that provides payroll deductions as a means of paying employees' contributions for health benefits or provides a health benefits plan that does not require an employee contribution must, with the consent of an employee who selects the HMO option, arrange for the employee's contribution, if any, to be paid through payroll deductions.

[59 FR 49841, Sept. 30, 1994]

§ 417.159 Relationship of section 1310 of the Public Health Service Act to the National Labor Relations Act and the Railway Labor Act.

The decision of an employing entity subject to this subpart to include the HMO alternative in any health benefits plan offered to its eligible employees must be carried out consistently with the obligations imposed on that employing entity under the National Labor Relations Act, the Railway

Labor Act, and other laws of similar effect.

[59 FR 49841, Sept. 30, 1994, as amended at 61 FR 27288, May 31, 1996]

Subpart F—Continued Regulation of Federally Qualified Health Maintenance Organizations

SOURCE: 43 FR 32255, July 25, 1978, unless otherwise noted. Redesignated at 52 FR 36746, Sept. 30, 1987.

§417.160 Applicability.

This subpart applies to any entity that has been determined to be a qualified HMO under subpart D of this part.

[59 FR 49841, Sept. 30, 1994]

§417.161 Compliance with assurances.

Any entity subject to this subpart must comply with the assurances that it provided to CMS, unless compliance is waived under §417.166.

[58 FR 38071, July 15, 1993]

§417.162 Reporting requirements.

Entities subject to this subpart must submit:

(a) The reports that may be required by CMS under §417.126, and

(b) Any additional reports CMS may reasonably require.

[58 FR 38071, July 15, 1993]

§417.163 Enforcement procedures.

(a) *Complaints.* Any person, group, association, corporation, or other entity may file with CMS a written complaint with respect to an HMO's compliance with assurances it gave under subpart D of this part. A complaint must—

(1) State the grounds and underlying facts of the complaint;

(2) Give the names of all persons involved; and

(3) Assure that all appropriate grievance and appeals procedures established by the HMO and available to the complainant have been exhausted.

(b) *Investigations.* (1) CMS may initiate investigations when, based on a report, a complaint, or any other information, CMS has reason to believe that a Federally qualified HMO is not in compliance with any of the assurances it gave under subpart D of this part.

(2) When CMS initiates an investigation, it gives the HMO written notice that includes a full statement of the pertinent facts and of the matters being investigated and indicates that the HMO may submit, within 30 days of the date of the notice, a written report concerning these matters.

(3) CMS obtains any information it considers necessary to resolve issues related to the assurances, and may use site visits, public hearings, or any other procedures that CMS considers appropriate in seeking this information.

(c) *Determination and notice by CMS*—(1) *Determination.* (i) On the basis of the investigation, CMS determines whether the HMO has failed to comply with any of the assurances it gave under subpart D of this part.

(ii) CMS publishes in the FEDERAL REGISTER a notice of each determination of non-compliance.

(2) *Notice of determination: Corrective action.* (i) CMS gives the HMO written notice of the determination.

(ii) The notice specifies the manner in which the HMO has not complied with its assurances and directs the HMO to initiate the corrective action that CMS considers necessary to bring the HMO into compliance.

(iii) The HMO must initiate this corrective action within 30 days of the date of the notice from CMS, or within any longer period that CMS determines to be reasonable and specifies in the notice. The HMO must carry out the corrective action within the time period specified by CMS in the notice.

(iv) The notice may provide the HMO an opportunity to submit, for CMS's approval, proposed methods for achieving compliance.

(d) *Remedy: Revocation of qualification.* If CMS determines that a qualified HMO has failed to initiate or to carry out corrective action in accordance with paragraph (c)(2) of this section—

(1) CMS revokes the HMO's qualification and notifies the HMO of this action.

(2) In the notice, CMS provides the HMO with an opportunity for reconsideration of the revocation, including, at the HMO's election, a fair hearing.

(3) The revocation of qualification is effective on the tenth calendar day

after the day of the notice unless CMS receives a request for reconsideration by that date.

(4) If after reconsideration CMS again determines to revoke the HMO's qualification, this revocation is effective on the tenth calendar day after the date of the notice of reconsidered determination.

(5) CMS publishes in the FEDERAL REGISTER each determination it makes under this paragraph (d).

(6) A revocation under this paragraph (d) has the effect described in § 417.164.

(e) *Notice by the HMO.* Within 15 days after the date CMS issues a notice of revocation, the HMO must prepare a notice that explains, in readily understandable language, the reasons for the determination that it is not a qualified HMO, and send the notice to the following:

(1) The HMO's enrollees.

(2) Each employer or public entity that has offered enrollment in the HMO in accordance with subpart E of this part.

(3) Each lawfully recognized collective bargaining representative or other representative of the employees of the employer or public entity.

(f) *Reimbursement of enrollees for services improperly denied, or for charges improperly imposed.* (1) If CMS determines, under paragraph (c)(1) of this section, that an HMO is out of compliance, CMS may require the HMO to reimburse its enrollees for the following—

(i) Expenses for basic or supplemental health services that the enrollee obtained from other sources because the HMO failed to provide or arrange for them in accordance with its assurances.

(ii) Any amounts the HMO charged the enrollee that are inconsistent with its assurances. (Rules applicable to charges for all enrollees are set forth in §§ 417.104 and 417.105. The additional rules applicable to Medicare enrollees are in § 415.454.)

(2) This paragraph applies regardless of when the HMO failed to comply with the appropriate assurances.

(g) *Remedy: Civil suit*—(1) *Applicability.* This paragraph applies to any HMO or other entity to which a grant, loan, or loan guarantee was awarded, as set forth in subpart V of this part, on the basis of its assurances regarding the furnishing of basic and supplemental services or its operation and organization, as the case may be.

(2) *Basis for action.* If CMS determines that the HMO or other entity has failed to initiate or refuses to carry out corrective action in accordance with paragraph (c)(2) of this section, CMS may bring civil action in the U.S. district court for the district in which the HMO or other entity is located, to enforce compliance with the assurances it gave in applying for the grant, loan, or loan guarantee.

[59 FR 49841, Sept. 30, 1994]

§ 417.164 Effect of revocation of qualification on inclusion in employee's health benefit plans.

When an HMO's qualification is revoked under § 417.163(d), the following rules apply:

(a) The HMO may not seek inclusion in employees health benefits plans under subpart E of this part.

(b) Inclusion of the HMO in an employer's health benefits plan—

(1) Is disregarded in determining whether the employer is subject to the requirements of subpart E of this part; and

(2) Does not constitute compliance with subpart E of this part by the employer.

[59 FR 49842, Sept. 30, 1994, as amended at 61 FR 27288, May 31, 1996]

§ 417.165 Reapplication for qualification.

An entity whose qualification as an HMO has been revoked by CMS for purposes of section 1310 of the PHS Act may, after completing the corrective action required under § 417.163(c)(2), reapply for a determination of qualification in accordance with the procedures specified in subpart D of this part.

[43 FR 32255, July 25, 1978. Redesignated at 52 FR 36746, Sept. 30, 1987, and amended at 58 FR 38078, July 15, 1993]

§ 417.166 Waiver of assurances.

(a) *General rule.* CMS may release an HMO from compliance with any assurances the HMO gives under subpart D of this part if—

(1) The qualification requirements are changed by Federal law; or

(2) The HMO shows good cause, consistent with the purposes of title XIII of the PHS Act.

(b) *Basis for finding of good cause.* (1) Grounds upon which CMS may find good cause include but are not limited to the following:

(i) The HMO has filed for reorganization under Federal bankruptcy provisions and the reorganization can only be approved with the waiver of the assurances.

(ii) State laws governing the entity have been changed after it signed the assurances so as to prohibit the HMO from being organized and operated in a manner consistent with the signed assurances.

(2) Changes in State laws do not constitute good cause to the extent that the changes are preempted by Federal law under section 1311 of the PHS Act.

(c) *Consequences of waiver.* If CMS waives any assurances regarding compliance with section 1301 of the PHS Act, CMS concurrently revokes the HMO's qualification unless the waiver is based on paragraph (a)(1) of this section.

[59 FR 49842, Sept. 30, 1994, as amended at 61 FR 27288, May 31, 1996]

Subparts G–I [Reserved]

Subpart J—Qualifying Conditions for Medicare Contracts

SOURCE: 50 FR 1346, Jan. 10, 1985, unless otherwise noted.

§417.400 Basis and scope.

(a) *Statutory basis.* The regulations in this subpart implement section 1876 of the Act, which authorizes Medicare payment to HMOs and CMPs that contract with CMS to furnish covered services to Medicare beneficiaries.

(b) *Scope.* (1) This subpart sets forth the requirements an HMO or CMP must meet in order to enter into a contract with CMS under section 1876 of the Act. It also specifies the procedures that CMS follows to evaluate applications and make determinations.

(2) The rules for payment to HMOs and CMPs are set forth in subparts N, O, and P of this part.

(3) The rules for HCPP participation in Medicare under section 1833(a)(1)(A) of the Act are set forth in subpart U of this part.

[60 FR 45675, Sept. 1, 1995]

§417.401 Definitions.

As used in this subpart and subparts K through R of this part, unless the context indicates otherwise—

Adjusted average per capita cost (AAPCC) means an actuarial estimate made by CMS in advance of an HMO's or CMP's contract period that represents what the average per capita cost to the Medicare program would be for each class of the HMO's or CMP's Medicare enrollees if they had received covered services other than through the HMO or CMP in the same geographic area or in a similar area.

Adjusted community rate (ACR) is the equivalent of the premium that a risk HMO or CMP would charge Medicare enrollees independently of Medicare payments if the HMO or CMP used the same rates it charges non-Medicare enrollees for a benefit package limited to covered Medicare services.

Arrangement means a written agreement between an HMO or CMP and another entity, under which—

(1) The other entity agrees to furnish specified services to the HMO's or CMP's Medicare enrollees;

(2) The HMO or CMP retains responsibility for the services; and

(3) Medicare payment to the HMO or CMP discharges the beneficiary's obligation to pay for the services.

Benefit stabilization fund means a fund established by CMS, at the request of a risk HMO or CMP, to withhold a portion of the per capita payments available to the HMO or CMP and pay that portion in a subsequent contract period for the purpose of stabilizing fluctuations in the availability of the additional benefits the HMO or CMP provides to its Medicare enrollees.

Cost contract means a Medicare contract under which CMS pays the HMO or CMP on a reasonable cost basis.

Cost HMO or CMP means an HMO or CMP that has in effect a cost contract

with CMS under section 1876 of the Act and subpart L of this part.

Demonstration project means a demonstration project under section 402 of the Social Security Amendments of 1967 (42 U.S.C. 1395b–1) or section 222(a) of the Social Security Amendments of 1972 (42 U.S.C. 1395b–1 (note)), relating to the provision of services for which payment is made under Medicare on a prospectively determined basis.

Emergency services means covered inpatient or outpatient services that are furnished by an appropriate source other than the HMO or CMP and that meet the following conditions:

(1) Are needed immediately because of an injury or sudden illness.

(2) Are such that the time required to reach the HMO's or CMP's providers or suppliers (or alternatives authorized by the HMO or CMP) would mean risk of permanent damage to the enrollee's health.

Once initiated, the services continue to be considered emergency services as long as transfer of the enrollee to the HMO's or CMP's source of health care or authorized alternative is precluded because of risk to the enrollee's health or because transfer would be unreasonable, given the distance and the nature of the medical condition.

Geographic area means the area found by CMS to be the area within which the HMO or CMP furnishes, or arranges for furnishing, the full range of services that it offers to its Medicare enrollees.

Medicare enrollee means a Medicare beneficiary who has been identified on CMS records as an enrollee of an HMO or CMP that has a contract with CMS under section 1876 of the Act and subpart L of this part.

New Medicare enrollee means a Medicare beneficiary who—

(1) Enrolls with an HMO or CMP after the date on which the HMO or CMP first enters into a risk contract under subpart L of this part; and

(2) Was not enrolled with the HMO or CMP at the time he or she became entitled to benefits under Part A or eligible to enroll in Part B of Medicare.

Risk contract means a Medicare contract under which CMS pays the HMO or CMP on a risk basis for Medicare covered services.

Risk HMO or CMP means an HMO or CMP that has in effect a risk contract with CMS under section 1876 of the Act and subpart L of this part.

Urgently needed services means covered services that are needed by an enrollee who is temporarily absent from the HMO's or CMP's geographic area and that—

(1) Are required in order to prevent serious deterioration of the enrollee's health as a result of unforeseen injury or illness; and

(2) Cannot be delayed until the enrollee returns to the HMO's or CMP's geographic area.

[50 FR 1346, Jan. 10, 1985, as amended at 56 FR 51986, Oct. 17, 1991; 58 FR 38072, July 15, 1993; 60 FR 45675, Sept. 1, 1995]

§ 417.402 Effective date of initial regulations.

(a) The changes made to section 1876 of the Act by section 114 of the Tax Equity and Fiscal Responsibility Act of 1982 became effective on February 1, 1985, the effective date of the initial implementing regulations.

(b) No new cost plan contracts are accepted by CMS. CMS will, however, accept and approve applications to modify cost plan contracts in order to expand service areas, provided they are submitted on or before September 1, 2006, and CMS determines that the organization continues to meet regulatory requirements and the requirements in its cost plan contract. Section 1876 cost plan contracts will not be extended or renewed beyond December 31, 2007, where conditions in paragraph (c) of this section are present.

(c) *Mandatory HMO or CMP and contract non-renewal or service area reduction.* CMS will non-renew all or a portion of an HMO's or CMP's contracted service area using procedures in § 417.492(b) and § 417.494(a) for any period beginning on or after January 1, 2013, where—

(1) There were two or more coordinated care plan-model MA regional plans not offered by the same MA organization in the same service area or portion of a service area for the entire previous calendar year meeting the conditions in paragraph(c)(3) of this section; or

(2) There were two or more coordinated care plan-model MA local plans not offered by the same MA organization in the same service area or portion of a service area for the entire previous calendar year meeting the conditions in paragraph (c)(3) of this section.

(3) *Minimum enrollment requirements.* With respect to any service area or portion of a service area that is within a Metropolitan Statistical Area (MSA) with a population of more than 250,000 and counties contiguous to the MSA that are not in another MSA with a population of more than 250,000, 5000 enrolled individuals. If the service area includes a portion in more than one MSA with a population of more than 250,000, the minimum enrollment determination is made with respect to each such MSA and counties contiguous to the MSA that are not in another MSA with a population of more than 250,000.

[63 FR 35066, June 26, 1998, as amended at 65 FR 40314, June 29, 2000; 67 FR 13288, Mar. 22, 2002; 70 FR 4713, Jan. 28, 2005; 73 FR 54248, Sept. 18, 2008; 76 FR 21560, Apr. 15, 2011; 76 FR 54633, Sept. 1, 2011]

§417.404 General requirements.

(a) In order to contract with CMS under the Medicare program, an entity must—

(1) Be determined by CMS to be an HMO or CMP (in accordance with §§117.142 and 417.407, respectively); and

(2) Comply with the contract requirements set forth in subpart L of this part.

(b) CMS enters into or renews a contract only if it determines that action would be consistent with the effective and efficient implementation of section 1876 of the Act.

[60 FR 45675, Sept. 1, 1995]

§417.406 Application and determination.

(a) *Responsibility for making determinations.* CMS is responsible for determining whether an entity meets the requirements to be an HMO or CMP.

(b) *Application requirements.* (1) The application requirements for HMOs are set forth in §417.143.

(2) The requirements of §417.143 also apply to CMPs except that there are no application fees.

(c) *Determination.* CMS uses the procedures set forth in §417.144(a) through (d) to determine whether an entity is an HMO or CMP.

(d) *Oversight of continuing compliance.* (1) CMS oversees an entity's continued compliance with the requirements for an HMO as defined in §417.1 or for a CMP as set forth in §417.407.

(2) If an entity no longer meets those requirements, CMS terminates the contract of that entity in accordance with §417.494.

[60 FR 45675, Sept. 1, 1995]

§417.407 Requirements for a Competitive Medical Plan (CMP).

(a) *General rule.* To qualify as a CMP, an entity must be organized under the laws of a State and must meet the requirements of paragraphs (b) through (f) of this section.

(b) *Required services*—(1) *Basic rule.* Except as provided in paragraph (b)(2) of this section, the entity furnishes to its enrollees at least the following services:

(i) Physicians' services performed by physicians.

(ii) Laboratory, x-ray, emergency, and preventive services.

(iii) Out-of-area coverage.

(iv) Inpatient hospital services.

(2) Exception for Medicaid prepayment risk contracts. An entity that had, before 1970, a Medicaid prepayment risk contract that did not include provision of inpatient hospital services is not required to provide those services.

(c) *Compensation for services.* The entity receives compensation (except for deductibles, coinsurance, and copayments) for the health care services it provides to enrollees on a periodic, prepaid capitation basis regardless of the frequency, extent, or kind of services provided to any enrollee.

(d) *Source of physicians' services.* The entity provides physicians' services primarily through—

(1) Physicians who are employees or partners of the entity; or

(2) Physicians or groups of physicians (organized on a group or individual practice basis) under contract with the entity to provide physicians' services.

(e) *Assumption of financial risk.* The rules set forth in §417.120(b) for HMOs

apply also to CMPs except that reference to ''basic services'' must be read as reference to the required services listed in paragraph (b) of this section.

(f) *Protection of enrollees.* The entity provides adequately against the risk of insolvency by meeting the requirements of §§ 417.120(a) and 417.122 for protection of enrollees against loss of benefits and liability for payment of any fees that are the legal responsibility of the entity.

[60 FR 45675, Sept. 1, 1995]

§ 417.408 Contract application process.

(a) *Contents of application.* (1) The application for a contract must include supporting information in the form and detail required by CMS. (2) Whenever feasible, CMS exempts the HMO or CMP from resubmittal of information it has already submitted to CMS in connection with a determination made under the provisions of § 417.406.

(b) *Approval of application.* (1) If CMS approves the application, it gives written notice to the HMO or CMP, indicating that it meets the requirements for either a risk or reasonable cost contract or only for a reasonable cost contract.

(2) If the HMO or CMP is dissatisfied with a determination that it meets the requirements only for a reasonable cost contract, it may request reconsideration in accordance with the procedures specified in subpart R of this part.

(c) *Denial of application.* If CMS denies the application, it gives written notice to the HMO or CMP indicating—

(1) That it does not meet the contract requirements under section 1876 of the Act;

(2) The reasons why the HMO or CMP does not meet the contract requirements; and

(3) The HMO's or CMP's right to request reconsideration in accordance with the procedures specified in subpart R of this part.

[50 FR 1346, Jan. 10, 1985, as amended at 56 FR 8853, Mar. 1, 1991; 58 FR 38078, July 15, 1993; 60 FR 45676, Sept. 1, 1995]

§ 417.410 Qualifying conditions: General rules.

(a) *Basic requirement.* In order to qualify for a contract with CMS under this subpart, an HMO or CMP must demonstrate its ability to enroll Medicare beneficiaries and other individuals and groups and to deliver a specified comprehensive range of high quality services efficiently, effectively, and economically to its Medicare enrollees.

(b) *Other qualifying conditions.* An HMO or CMP must meet qualifying conditions that pertain to operating experience, enrollment, range of services, furnishing of services, and a quality assurance program.

(c) *Standards.* Generally, each qualifying condition is interpreted by a series of standards that are used in surveying an HMO or CMP to determine its qualifications for a Medicare contract.

(d) *Application of standards.* Application of the standards enables the surveyor to determine—

(1) The HMO's or CMP's activities;

(2) The extent to which the HMO or CMP complies with each condition;

(3) The nature and extent of any deficiencies; and

(4) The need for improvement if CMS should enter into a contract with the HMO or CMP.

(e) *Requirements for a risk contract.* An HMO or CMP may enter into a risk contract with CMS if it—

(1) Meets all the applicable requirements in the statute and regulations;

(2) Has at least 5,000 enrollees or 1,500 enrollees if it serves a primarily rural area as defined in § 417.413(b)(3);

(3) Has at least 75 Medicare enrollees or has an acceptable plan to achieve this Medicare membership within 2 years;

(4) Satisfies CMS that it can bear the potential losses of a risk contract; and

(5) Has not previously terminated or failed to renew a risk contract within the preceding 5 years, unless CMS determines that circumstances warrant special consideration.

(f) *Requirements for a reasonable cost sontract.* An HMO or CMP may enter into a reasonable cost contract if it meets one of the following:

(1) The HMO or CMP qualifies for a risk contract, but chooses a reasonable cost contract.

(2) The HMO or CMP meets the conditions for entering into a risk contract specified in paragraph (e) of this section except that CMS does not judge the HMO or CMP capable of bearing the potential losses of a risk contract.

(g) Regulations on reasonable cost and risk reimbursement are set forth in subparts O and P of this part.

[50 FR 20570, May 17, 1985, as amended at 58 FR 38078, July 15, 1993; 60 FR 45676, Sept. 1, 1995]

§417.412 Qualifying condition: Administration and management.

The HMO or CMP must demonstrate that it—

(a) Has sufficient administrative capability to carry out the requirements of the contract; and

(b) Does not have any agents or management staff or persons with ownership or control interests who have been convicted of criminal offenses related to their involvement in Medicaid, Medicare, or social service programs under title XX of the Act.

[50 FR 1346, Jan. 10, 1985, as amended at 58 FR 38082, July 15, 1993; 60 FR 45676, Sept. 1, 1995]

§417.413 Qualifying condition: Operating experience and enrollment.

(a) *Condition.* The HMO or CMP must demonstrate that it has operating experience and an enrolled population sufficient to provide a reasonable basis for establishing a prospective per capita reimbursement rate or a reasonable cost reimbursement rate, as appropriate.

(b) *Standard: Enrollment and operating experience for HMOs or CMPs to contract on a risk basis.* To be eligible to contract on a risk basis—

(1) A nonrural HMO or CMP must currently have the following:

(i) At least 5,000 enrollees; and

(ii) At least 75 Medicare enrollees or a plan acceptable to CMS for achieving a Medicare enrollment of 75 within 2 years from the beginning of its initial contract period.

(2) A rural HMO or CMP must currently have—

(i) At least 1,500 enrollees; and

(ii) At least 75 Medicare enrollees or a plan acceptable to CMS for achieving a Medicare enrollment of 75 within 2 years from the beginning of its initial contract period.

(3) For purposes of this paragraph, an HMO or CMP is considered rural if at least 50 percent of its enrollees reside in nonmetropolitan areas. A nonmetropolitan area is an area—

(i) No part of which is within a metropolitan statistical area (MSA) as designated by the Executive Office of Management and Budget; and

(ii) That does not contain a city whose population exceeds 50,000 individuals.

(4) A subdivision or subsidiary of an HMO or CMP that meets the requirements of paragraph (b)(1) or (b)(2) of this section need not demonstrate that it meets those requirements as an independent unit if the HMO or CMP assumes responsibility for the financial risk, and adequate management and supervision of health care services furnished by its subdivision or subsidiary.

(c) *Standard: Enrollment and operating experience for HMOs or CMPs to contract on a cost basis.* To be eligible to contract on a reasonable cost basis, an HMO or CMP must currently have enrollees sufficient in number to provide a reasonable basis for entering into a contract, as follows:

(1) At least 1,500 enrollees.

(2) At least 75 Medicare enrollees, or a plan acceptable to CMS for achieving—

(i) A Medicare enrollment of 75 within 2 years from the beginning of its initial contract period; and

(ii) At least 250 Medicare enrollees by the beginning of its fourth contract period.

(d) *Standard: Composition of enrollment*—(1) *Requirement.* Except as specified in paragraphs (d)(2) and (e) of this section, not more than 50 percent of an HMO's or CMP's enrollment may be Medicare beneficiaries.

(2) *Waiver of composition of enrollment standard.* CMS may waive compliance with the requirements of paragraph (d)(1) of this section if the HMO or CMP has made and is making reasonable efforts to enroll individuals who are not Medicare beneficiaries and it meets one of the following requirements:

(i) The HMO or CMP serves a geographic area in which Medicare beneficiaries and Medicaid beneficiaries constitute more than 50 percent of the population. (CMS does not grant a waiver that would permit the percentage of Medicare and Medicaid enrollees to exceed the percentage of Medicare beneficiaries and Medicaid beneficiaries in the population of the geographic area.)

(ii) The HMO or CMP is owned and operated by a government entity. The waiver may be for a period up to three years after the date the HMO or CMP first enters into a contract under this subpart, and may not be extended.

(iii) The HMO or CMP requests waiver of the composition rule because it is in the public interest. The organization provides documentation that supports one of the following:

(A) The organization serves a medically underserved rural or urban area.

(B) The organization demonstrates a long-term business and community service commitment to the area.

(C) The organization believes that a waiver is necessary to promote managed care choices in an area with limited or no managed care choices.

(3) *Waiver granted on or before October 21, 1986.* An HMO or CMP (or a successor HMO or CMP) that as of October 21, 1986, had been granted an exception, waiver, or modification of the requirements of paragraph (d)(1) of this section, but that does not meet the requirements of paragraph (d)(2) of this section, must make (and throughout the period of the exception, waiver, or modification continue to make) reasonable efforts to meet scheduled enrollment goals, consistent with a schedule of compliance approved by CMS.

(i) If CMS determines that the HMO or CMP has complied, or made significant progress toward compliance, with the approved schedule, and that an extension is in the best interest of the Medicare program, CMS may extend the waiver of modification.

(ii) If CMS determines that the HMO or CMP has not complied with the approved schedule, CMS may apply the sanctions described in paragraphs (d)(6) and (d)(7) of this section.

(4) *Basis for application of sanctions.* CMS may, as an alternative to contract termination, apply the sanctions specified in paragraph (d)(6) of this section if CMS determines that the HMO or CMP is not complying with the requirements in paragraphs (d)(1), (d)(2), or (d)(3) of this section, as applicable.

(5) *Notice of sanction.* Before applying the sanctions specified in paragraph (d)(6) of this section, CMS sends a written notice to the HMO or CMP stating the proposed action and its basis. CMS gives the HMO or CMP 15 days after the date of the notice to provide evidence establishing the HMO's or CMP's compliance with the requirements in paragraph (d)(1), (d)(2), or (d)(3) of this section, as applicable.

(6) *Sanctions.* If, following review of the HMO's or CMP's timely response to CMS's notice, CMS determines that an HMO or CMP does not comply with the requirements of paragraphs (d)(1), (d)(2), or (d)(3) of this section, CMS may apply either of the following sanctions:

(i) Require the HMO or CMP to stop accepting new enrollment applications after a date specified by CMS.

(ii) Deny payment for individuals who are formally added or ''accreted'' to CMS's records as Medicare enrollees after a date specified by CMS.

(7) *Termination by CMS.* In addition to the sanctions described in paragraph (d)(6) of this section. CMS may decline to renew an HMO's or CMP's contract in accordance with § 417.492(b), or terminate its contract in accordance with § 417.494(b) if CMS determines that the HMO or CMP no longer substantially meets the requirements of paragraphs (d)(1), (d)(2), or (d)(3) of this section.

(8) *Termination of composition standard.* The 50 percent composition of Medicare beneficiaries terminates for all managed care plans on December 31, 1998.

(e) *Standard: Open enrollment.* (1) Except as specified in paragraph (e)(2) of this section, an HMO or CMP must enroll Medicare beneficiaries on a first-come, first-served basis to the limit of its capacity and provide annual open enrollment periods of at least 30 days duration for Medicare beneficiaries.

(2) CMS may waive the requirement of paragraph (e)(1) of this section if

compliance would prevent compliance with the limitation on enrollment of Medicare beneficiaries and Medicaid beneficiaries (paragraph (d) of this section) or result in an enrollment substantially nonrepresentative of the population of the HMO's or CMP's geographic area. The enrollment would be ''substantially nonrepresentative'' if the proportion of a subgroup to the total enrollment exceeded, by 10 percent or more, its proportion of the population in the HMO's or CMP's geographic area, as shown by census data or other data acceptable to CMS. For purposes of this paragraph, a subgroup means a class of Medicare enrollees as defined in §417.582.

[50 FR 1346, Jan. 10, 1985, as amended at 56 FR 46570, Sept. 13, 1991; 58 FR 38082, July 15, 1993; 60 FR 45676, Sept. 1, 1995; 63 FR 35066, June 26, 1998]

§417.414 Qualifying condition: Range of services.

(a) *Condition.* The HMO or CMP must demonstrate that it is capable of delivering to Medicare enrollees the range of services required in accordance with this section.

(b) *Standard: Range of services furnished by eligible HMOs or CMPs*—(1) *Basic requirement.* Except as specified in paragraph (b)(3) of this section, an HMO or CMP must furnish to its Medicare enrollees (directly or through arrangements with others) all the Medicare services to which those enrollees are entitled to the extent that they are available to Medicare beneficiaries who reside in the HMO's or CMP's geographic area but are not enrolled in the HMO or CMP.

(2) *Criteria for availability.* The services are considered available if—

(i) The sources are located within the HMO's or CMP's geographic area; or

(ii) It is common practice to refer patients to sources outside that geographic area.

(3) *Exception for hospice care.* An HMO or CMP is not required to furnish hospice care as described in part 418 of this chapter. However, HMOs or CMPs must inform their Medicare enrollees about the availability of hospice care if—

(i) A hospice participating in Medicare is located within the HMO's or CMP's geographic area; or

(ii) It is common practice to refer patients to hospices outside the geographic area.

(c) *Standard: Financial responsibility for services furnished outside the HMO or CMP.* (1) An HMO or CMP must assume financial responsibility and provide reasonable reimbursement for emergency services and urgently needed services (as defined in §417.401) that are obtained by its Medicare enrollees from providers and suppliers outside the HMO or CMP even in the absence of the HMO's or CMP's prior approval.

(2) An HMO or CMP must assume financial responsibility for services that the Medicare enrollee attempted to obtain from the HMO or CMP, but that the HMO or CMP failed to furnish or unreasonably denied, and that are found, upon appeal by the enrollee under subpart Q of this part, to be services that the enrollee was entitled to have furnished to him or her by the HMO or CMP.

[50 FR 1346, Jan. 10, 1985, as amended at 58 FR 38078, July 15, 1993; 60 FR 45677, Sept. 1, 1995]

§417.416 Qualifying condition: Furnishing of services.

(a) *Condition.* The HMO or CMP must furnish the required services to its Medicare enrollees through providers and suppliers that meet applicable Medicare statutory definitions and implementing regulations. The HMO or CMP must also ensure that the required services, additional services, and any other supplemental services for which the Medicare enrollee has contracted are available and accessible and are furnished in a manner that ensures continuity.

(b) *Standard: Conformance with conditions of participation, conditions for coverage, and conditions for certification.* (1) Hospitals, SNFs, HHAs, CORFs, and providers of outpatient physical therapy or speech-language pathology services must meet the applicable conditions of participation in Medicare, as set forth elsewhere in this chapter.

(2) Suppliers must meet the conditions for coverage or conditions for certification of their services, as set forth elsewhere in this chapter.

(3) If more than one type of practitioner is qualified to furnish a particular service, the HMO or CMP may select the type of practitioner to be used.

(c) *Standard: Physician supervision.* The HMO or CMP must provide for supervision by a physician of other health care professionals who are directly involved in the provision of health care as generally authorized under section 1861 of the Act. Except as specified in paragraph (d) of this section, with respect to medical services furnished in an HMO's or CMP's clinic or the office of a physician with whom the HMO or CMP has a service agreement, the HMO or CMP must ensure that—

(1) Services furnished by paramedical, ancillary, and other nonphysician personnel are furnished under the direct supervision of a physician;

(2) A physician is present to perform medical (as opposed to administrative) services whenever the clinics or offices are open; and

(3) Each patient is under the care of a physician.

(d) *Exceptions to physician supervision requirement.* The following services may be furnished without the direct personal supervision of a physician:

(1) Services of physician assistants and nurse practitioners (as defined in §491.2 of this chapter), and the services and supplies incident to their services. The conditions for payment, as set forth in §§405.2414 and 405.2415 of this chapter for services furnished by rural health clinics and Federally qualified health centers, respectively, also apply when those services are furnished by an HMO or CMP.

(2) When furnished by an HMO or CMP, services of clinical psychologists who meet the qualifications specified in §410.71(d) of this chapter, and the services and supplies incident to their professional services.

(3) When an HMO or CMP contracts on—

(i) A risk basis, the services of a clinical social worker (as defined at §410.73 of this chapter) and the services and supplies incident to their professional services; or

(ii) A cost basis, the services of a clinical social worker (as defined in §410.73 of this chapter). Services incident to the professional services of a clinical social worker furnished by an HMO or CMP contracting on a cost basis are not covered by Medicare and payment will not be made for these services.

(e) *Standard: Accessibility and continuity.* (1) The HMO or CMP must ensure that the required services and any other services for which Medicare enrollees have contracted are accessible, with reasonable promptness, to the enrollees with respect to geographic location, hours of operation, and provision of after hours service. Medically necessary emergency services must be available twenty-four hours a day, seven days a week.

(2) The HMO or CMP must maintain a health (including medical) record-keeping system through which pertinent information relating to the health care of its Medicare enrollees is accumulated and is readily available to appropriate professionals.

(3) The HMO or CMP must meet network adequacy standards specified in §422.116 of this chapter.

[50 FR 1346, Jan. 10, 1985, as amended at 58 FR 38082, July 15, 1993; 60 FR 45677, Sept. 1, 1995; 63 FR 20130, Apr. 23, 1998; 85 FR 33901, June 2, 2020]

§ 417.418 Qualifying condition: Quality assurance program.

(a) *Condition.* The HMO or CMP must make arrangements for a quality assurance program that meets the requirements of this section.

(b) *Standard.* An HMO or CMP must have an ongoing quality assurance program that meets the requirements set forth in §417.106(a).

[58 FR 38072, July 15, 1993]

Subpart K—Enrollment, Entitlement, and Disenrollment under Medicare Contract

SOURCE: 50 FR 1346, Jan. 10, 1985, unless otherwise noted.

§ 417.420 Basic rules on enrollment and entitlement.

(a) *Enrollment.* Eligible individuals who are entitled to benefits under both Part A and Part B of Medicare or only

Part B may elect to receive those benefits through an HMO or CMP that has in effect a contract with CMS under subpart L of this part.

(b) *Entitlement.* If a Medicare beneficiary enrolls with an HMO or CMP, CMS pays the HMO or CMP on his or her behalf for the services to which he or she is entitled.

(c) *Beneficiary liability.* (1) The HMO or CMP may require payment, in the form of premiums or otherwise, from individuals for services not covered under Medicare, as well as deductible and coinsurance amounts attributable to Medicare covered services.

(2) As described in §417.448, Medicare enrollees of risk HMOs or CMPs are liable for services that they obtain from sources other than the HMO or CMP, unless the services are—

(i) Emergency or urgently needed; or

(ii) Determined, on appeal under subpart Q of this part, to be services that should have been furnished by the HMO or CMP.

[50 FR 1346, Jan. 10, 1985, as amended at 58 FR 38078, July 15, 1993; 60 FR 45677, Sept. 1, 1995; 80 FR 7958, Feb. 12, 2015]

§417.422 Eligibility to enroll in an HMO or CMP.

Except as specified in §§417.423 and 417.424, an HMO or CMP must enroll, either for an indefinite period or for a specified period of at least 12 months, any individual who meets all of the following:

(a) Is entitled to Medicare benefits under Parts A and B or under Part B only.

(b) Lives within the geographic area served by the HMO or CMP.

(c) Is not enrolled in any other HMO or CMP that has entered into a contract under subpart L of this part.

(d) During an enrollment period of the HMO or CMP, completes the HMO's or CMP's application form or another CMS-approved election mechanism and gives whatever information is required for enrollment.

(e) Agrees to abide by the HMO's or CMP's rules after they are disclosed to him or her in connection with the enrollment process.

(f) Is not denied enrollment by the HMO or CMP under a selection policy, if any, that has been approved by CMS under §417.424(b).

(g) Is not denied enrollment by the HMO or CMP on the basis of any of the administrative criteria concerning denial of enrollment in §417.424(a).

(h) Is a United States citizen or an individual who is lawfully present in the United States as determined in 8 CFR 1.3.

[50 FR 1346, Jan. 10, 1985, as amended at 58 FR 38078, July 15, 1993; 60 FR 45677, Sept. 1, 1995; 77 FR 22166, Apr. 12, 2012; 80 FR 7958, Feb. 12, 2015]

§417.423 Special rules: ESRD and hospice patients.

(a) *ESRD patients.* (1) A Medicare beneficiary who has been medically determined to have end-stage renal disease is not eligible to enroll in an HMO or CMP.

(2) However, if a beneficiary is already enrolled in an HMO or CMP when he or she is determined to have end-stage renal disease, the HMO or CMP—

(i) Must reenroll the beneficiary as required by §417.434; and

(ii) May not disenroll the beneficiary except as provided in §417.460.

(b) *Hospice patients.* A Medicare beneficiary who elects hospice care under §418.24 of this chapter is not eligible to enroll in an HMO or CMP as long as the hospice election remains in effect.

[60 FR 45677, Sept. 1, 1995]

§417.424 Denial of enrollment.

(a) *Basis for denial.* An HMO or CMP may deny enrollment to an individual who meets the criteria of §417.422 if acceptance would—

(1) Cause the number of enrollees who are Medicare or Medicaid beneficiaries to exceed 50 percent of the HMO's or CMP's total enrollment;

(2) Prevent the HMO or CMP from complying with any of the other contract qualifying conditions set forth in subpart J of this part;

(3) Require the HMO or CMP to exceed its enrollment capacity; or

(4) Cause the enrollment to become substantially nonrepresentative of the general population in the HMO's or CMP's geographic area.

(b) *Selection policies.* (1) Denial under paragraph (a)(4) of this section must be in accordance with written selection

policies approved by CMS. (2) Enrollment of individuals will not be considered to make the enrollment of the HMO or CMP substantially nonrepresentative of the general population in the HMO's or CMP's geographic area unless, as a result of the enrollment, the proportion of the subgroup of enrollees to which the enrollee belongs as compared to the HMO's or CMP's total enrollment exceeds by at least ten percent the subgroup's proportion of the general population in the geographic area of the HMO or CMP. (A subgroup is a class of Medicare enrollees of an HMO or CMP that CMS constructs on the basis of actuarial factors.)

[50 FR 1346, Jan. 10, 1985; 50 FR 20570, May 17, 1985, as amended at 58 FR 38078, July 15, 1993; 60 FR 45677, Sept. 1, 1995]

§ 417.426 Open enrollment requirements.

(a) *Basic requirements.* (1) HMOs or CMPs must provide open enrollment for Medicare beneficiaries for at least 30 consecutive days during each contract year.

(2) During open enrollment, the HMO or CMP must enroll eligible Medicare beneficiaries in the order in which their applications are received and until its enrollment capacity is reached.

(3) The HMO or CMP may accept applications from Medicare beneficiaries after it has reached capacity if it places those individuals on a waiting list and enrolls them in chronological order as vacancies occur.

(4) An HMO or CMP with a risk contract must accept applications from eligible Medicare beneficiaries during the month of November 1998.

(b) *Capacity to accept new enrollees.* (1) If an HMO or CMP chooses to limit enrollments because of its capacity, it must notify CMS at least 90 days before the beginning of its open enrollment period and, at that time, provide CMS with its reasons for limiting enrollment.

(2) CMS evaluates the HMO's or CMP's submittal under paragraph (b)(1) of this section.

(3) The HMO or CMP must promptly notify CMS if there is any change in its enrollment capacity.

(c) *Reserved vacancies.* (1) Subject to CMS's approval, an HMO or CMP may set aside a reasonable number of vacancies for an anticipated new group contract or for anticipated new enrollees under an existing group contract that will have its enrollment period after the Medicare open enrollment period during the contract year.

(2) Any set aside vacancies that are not filled within a reasonable time after the beginning of the group contract enrollment period must be made available to Medicare beneficiaries and other nongroup applicants under the requirements of this subpart.

[50 FR 1346, Jan. 10, 1985, as amended at 58 FR 38079, July 15, 1993; 60 FR 45677, Sept. 1, 1995; 63 FR 35066, June 26, 1998]

§ 417.427 Extending MA and Part D program disclosure requirements to section 1876 cost contract plans.

(a) The procedures and requirements relating to disclosure in § 422.111 and § 423.128 apply to Medicare contracts with HMOs and CMPs under section 1876 of the Act.

(b) In applying the provisions of §§ 422.111 and 423.128, references to part 422 and part 423 of this chapter must be read as references to this part, and references to MA organizations and Part D sponsors as references to HMOs and CMPs.

[77 FR 22166, Apr. 12, 2012]

§ 417.428 Marketing activities.

(a) With the exception of § 422.2276 of this chapter, the procedures and requirements relating to marketing requirements set forth in subpart V of part 422 of this chapter also apply to Medicare contracts with HMOs and CMPs under section 1876 of the Act.

(b) In applying those provisions, references to part 422 of this chapter must be read as references to this part, and references to MA organizations as references to HMOs and CMPs.

[75 FR 19802, Apr. 15, 2010]

§ 417.430 Application procedures.

(a) *Application forms and other enrollment mechanisms.* (1) The application form must comply with CMS instructions regarding content and format and be approved by CMS as described in

§422.2262 of this chapter. The application must be completed by an HMO or CMP eligible (or soon to become eligible) individual and include authorization for disclosure between HHS and its designees and the HMO or CMP.

(2) The HMO or CMP must file and retain application forms for the period specified in CMS instructions.

(b) *Handling of applications.* An HMO or CMP must have an effective system for receiving, controlling, and processing applications from Medicare beneficiaries. The system must meet the following conditions and requirements:

(1) Each application is dated as of the day it is received.

(2) Applications are processed in chronological order by date of receipt.

(3) The HMO or CMP gives the beneficiary prompt notice of acceptance or denial in a format specified by CMS.

(4) The notice of acceptance. If the HMO or CMP is currently enrolled to capacity, explains the procedures that will be followed when vacancies occur.

(5) The notice of denial explains the reason for denial.

(6) The HMO or CMP transmits the information necessary for CMS to add the beneficiary to its records of the HMO's or CMP's Medicare enrollees—

(i) Within 30 days from the date of application or from the date a vacancy occurs for an applicant who was accepted (for future enrollment) while there were no vacancies; or

(ii) Within an additional period of time approved by CMS on a showing by the HMO or CMP that it needs more time.

(7) The HMO or CMP promptly notifies the beneficiary of the effective month of his or her enrollment as a Medicare enrollee, when it receives that information from CMS.

(8) If the HMO or CMP accepts applications while it is enrolled to capacity, its procedures ensure that vacancies are filled in chronological order by date of application of beneficiaries who are still eligible to enroll, unless that would result in failure to comply with any of the qualifying conditions set forth in §417.413.

[50 FR 1346, Jan. 10, 1985, as amended at 58 FR 38082, July 15, 1993; 60 FR 45677, Sept. 1, 1995; 76 FR 21560, Apr. 15, 2011; 83 FR 16721, Apr. 16, 2018]

§417.432 Conversion of enrollment.

(a) *Basic rule.* An HMO or CMP must accept as a Medicare enrollee any individual who is enrolled in the HMO or CMP for the month immediately before the month in which he or she is entitled to both Medicare Parts A and B or Part B only.

(b) *Effective date of conversion.* Unless the individual chooses to disenroll from the HMO or CMP the individual's conversion to a Medicare enrollee is effective the month in which he or she is entitled to both Medicare Parts A and B or Part B only.

(c) *Prohibition against disenrollment.* An HMO or CMP may not disenroll an individual who is converting under the provisions of paragraph (a) of this section unless one of the conditions specified in §417.460 is met.

(d) *Application form.* The individual who is converting must complete an application form or another CMS-approved election mechanism as described in §417.430(a).

(e) *Expedited submittal of information to CMS.* The HMO or CMP must notify CMS, within the following time frames, of the enrollee's authorization for disclosure and exchange of information and the information necessary for CMS to include the enrollee in its records as a Medicare enrollee of the HMO or CMP:

(1) At least 30, but no earlier than 90, days before the enrollee—

(i) Attains age 65; or

(ii) Reaches his or her 25th month of entitlement to social security disability benefits under title II of the Act or railroad retirement disability benefits under section 7(d) of the Railroad Retirement Act of 1974.

(2) Within 30 days after the enrollee initiates a course of renal dialysis, or on or before the day he or she enters a

hospital in anticipation of a kidney transplant.

[50 FR 1346, Jan. 10, 1985, as amended at 56 FR 46570, Sept. 13, 1991; 58 FR 38082, July 15, 1993; 60 FR 45677, Sept. 1, 1995; 77 FR 22166, Apr. 12, 2012]

§ 417.434 Reenrollment.

If an HMO or CMP requires periodic reenrollment, it must reenroll Medicare enrollees unless there is a basis for disenrollment as set forth in § 417.460.

[50 FR 1346, Jan. 10, 1985, as amended at 58 FR 38082, July 15, 1993]

§ 417.436 Rules for enrollees.

(a) *Maintaining rules.* An HMO or CMP must maintain written rules that deal with, but need not be limited to the following:

(1) All benefits provided under the contract, as described in § 417.440.

(2) How and where to obtain services from or through the HMO or CMP.

(3) The restrictions on coverage for services furnished from sources outside a risk HMO or CMP, other than emergency services and urgently needed services (as defined in § 417.401).

(4) The obligation of the HMO or CMP to assume financial responsibility and provide reasonable reimbursement for emergency services and urgently needed services as required by § 417.414(c).

(5) Any services other than the emergency or urgently needed services that the HMO or CMP chooses to provide as permitted by this part, from sources outside the HMO or CMP. A cost HMO or CMP must disclose that the enrollee may receive services through any Medicare providers and suppliers.

(6) Premium information, including the amount (or if the amount cannot be included, the telephone number of the source from which this information may be obtained) and the procedures for paying premiums and other charges for which enrollees may be liable.

(7) Grievance and appeal procedures.

(8) Disenrollment rights.

(9) The obligation of an enrollee who is leaving the HMO's or CMP's geographic area for more than 90 days to notify the HMO or CMP of the move or extended absence and the HMO's or CMP's policies concerning retention of enrollees who leave the geographic area for more than 90 days, as described in § 417.460(a)(2).

(10) The expiration date of the Medicare contract with CMS and notice that both CMS and the HMO or CMP are authorized by law to terminate or refuse to renew the contract, and that termination or nonrenewal of the contract may result in termination of the individual's enrollment in the HMO or CMP.

(11) Advance directives as specified in paragraph (d) of this section.

(12) Any other matters that CMS may prescribe.

(b) *Availability of rules.* The HMO or CMP must furnish a copy of the rules to each Medicare enrollee at the time of enrollment and at least annually thereafter.

(c) *Changes in rules.* If an HMO or CMP changes its rules, it must submit the changes to CMS in accordance with § 417.428(a)(3), and notify its Medicare enrollees of the changes at least 30 days before the effective date of the changes.

(d) *Advance directives.* (1) An HMO or CMP must maintain written policies and procedures concerning advance directives, as defined in § 489.100 of this chapter, with respect to all adult individuals receiving medical care by or through the HMO or CMP and are required to:

(i) Provide written information to those individuals concerning—

(A) Their rights under the law of the State in which the organization furnishes services (whether statutory or recognized by the courts of the State) to make decisions concerning such medical care, including the right to accept or refuse medical or surgical treatment and the right to formulate, at the individual's option, advance directives. Providers are permitted to contract with other entities to furnish this information but are still legally responsible for ensuring that the requirements of this section are met. Such information must reflect changes in State law as soon as possible, but no later than 90 days after the effective date of the State law; and

(B) The HMO's or CMP's written policies respecting the implementation of

those rights, including a clear and precise statement of limitation if the HMO or CMP cannot implement an advance directive as a matter of conscience. At a minimum, this statement should:

(*1*) Clarify any differences between institution-wide conscience objections and those that may be raised by individual physicians;

(*2*) Identify the state legal authority permitting such objection; and

(*3*) Describe the range of medical conditions or procedures affected by the conscience objection.

(ii) Provide the information specified in paragraphs (d)(1)(i) of this section to each enrollee at the time of initial enrollment. If an enrollee is incapacitated at the time of initial enrollment and is unable to receive information (due to the incapacitating condition or a mental disorder) or articulate whether or not he or she has executed an advance directive, the HMO or CMP may give advance directive information to the enrollee's family or surrogate in the same manner that it issues other materials about policies and procedures to the family of the incapacitated enrollee or to a surrogate or other concerned persons in accordance with State law. The HMO or CMP is not relieved of its obligation to provide this information to the enrollee once he or she is no longer incapacitated or unable to receive such information. Follow-up procedures must be in place to ensure that the information is given to the individual directly at the appropriate time.

(iii) Document in the individual's medical record whether or not the individual has executed an advance directive;

(iv) Not condition the provision of care or otherwise discriminate against an individual based on whether or not the individual has executed an advance directive;

(v) Ensure compliance with requirements of State law (whether statutory or recognized by the courts of the State) regarding advance directives;

(vi) Provide for education of staff concerning its policies and procedures on advance directives; and

(vii) Provide for community education regarding advance directives that may include material required in paragraph (d)(1)(i)(A) of this section, either directly or in concert with other providers or entities. Separate community education materials may be developed and used, at the discretion of the HMO or CMP. The same written materials are not required for all settings, but the material should define what constitutes an advance directive, emphasizing that an advance directive is designed to enhance an incapacitated individual's control over medical treatment, and describe applicable State law concerning advance directives. An HMO or CMP must be able to document its community education efforts.

(2) The HMO or CMP—(i) Is not required to provide care that conflicts with an advance directive.

(ii) Is not required to implement an advance directive if, as a matter of conscience, the HMO or CMP cannot implement an advance directive and State law allows any health care provider or any agent of such provider to conscientiously object.

(3) The HMO or CMP must inform individuals that complaints concerning non-compliance with the advance directive requirements may be filed with the State survey and certification agency.

[58 FR 38072, July 15, 1993, as amended at 59 FR 49843, Sept. 30, 1994; 60 FR 33292, June 27, 1995]

§417.440 Entitlement to health care services from an HMO or CMP.

(a) *Basic rules.* (1) Subject to the conditions and limitations set forth in this subpart, a Medicare enrollee of an HMO or CMP is entitled to receive health care services and supplies directly from, or through arrangements made by, the HMO or CMP as specified in this section and §§417.442–417.446.

(2) A Medicare enrollee is also entitled to receive timely and reasonable payment directly (or have payment made on his or her behalf) for services he or she obtained from a provider or supplier outside the HMO or CMP if those services are—

(i) Emergency services or urgently needed services as defined §417.401;

(ii) Services denied by the HMO or CMP and found (upon appeal under subpart Q of this part) to be services the

enrollee was entitled to have furnished by the HMO or CMP.

(b) *Scope of services*—(1) *Part A and Part B services.* Except as specified in paragraphs (c), (d), and (e) of this section, a Medicare enrollee is entitled to receive from an HMO or CMP all the Medicare-covered services that are available to individuals residing in the HMO's or CMP's geographic area, as follows:

(i) Medicare Part A and Part B services if the enrollee is entitled to benefits under both programs.

(ii) Medicare Part B services if the enrollee is entitled only under that program.

(2) *Supplemental services elected by an enrollee.* (i) Except as provided under paragraph (b)(2)(ii) of this section, a Medicare enrollee of an HMO or CMP may elect to pay for optional services that are offered by the HMO or CMP in addition to the covered Part A and Part B services.

(ii) An HMO or CMP may elect to provide qualified prescription drug coverage (as defined at § 423.104 of this chapter) as an optional supplemental service in accordance with the applicable requirements under part 423 of this chapter, including § 423.104(f)(4) of this chapter.

(iii) The HMO or CMP may not set health status standards for those enrollees whom it accepts for these optional supplemental services.

(3) *Supplemental services imposed by a risk HMO or CMP.* (i) Subject to CMS's approval, a risk HMO or CMP may require Medicare enrollees to accept and pay for services in addition to those covered by Medicare. (ii) If the HMO or CMP elects this option, it must impose the requirement on all Medicare enrollees, without regard to health status. (iii) CMS approves supplemental benefits of this type if CMS determines that imposition of the requirements will not discourage other Medicare beneficiaries from enrolling in the risk HMO or CMP.

(4) *Additional benefits from risk HMOs or CMPs required by statute.* Subject to the conditions stated in § 417.442, a new Medicare enrollee or a current nonrisk Medicare enrollee who converts to risk reimbursement under § 417.444 is eligible to receive, in addition to the covered Part A and Part B benefits for which he or she is eligible, benefits consisting of one or both of the following:

(i) A reduction in the HMO's or CMP's premium rate or in other charges for services furnished to Medicare enrollees.

(ii) Provision of health benefits or services beyond the required Part A and Part B coverage.

(5) *Special supplemental benefits.* Under conditions described in § 417.444(c), current nonrisk Medicare enrollees who are not converted to the risk portion of the contract, may enroll in a special supplemental plan, if offered by the HMO or CMP, for some or all of the additional benefits described in paragraph (b)(4) of this section.

(c) *Limitation on hospice care*—(1) *Extent of limitation*—(i) *Basic rule.* Except as provided in paragraph (c)(1)(ii) of this section, a Medicare enrollee who elects to receive hospice care under § 418.24 of this chapter waives the right to receive from the HMO or CMP any Medicare services (including services equivalent to hospice care) that are related to the terminal condition for which the enrollee elected hospice care, or to a related condition.

(ii) *Exception.* An enrollee who elects hospice care retains the right to services furnished by his or her attending physician if that physician—

(A) Is an employee or contractor of the HMO or CMP; and

(B) Is not an employee of the designated hospice and does not receive compensation from the hospice for those services.

(2) *Effective date of limitation.* The limitation in paragraph (c)(1) of this section begins on the effective date of the beneficiary's election of hospice care and remains in effect until the earlier of the following:

(i) The effective date of the enrollee's revocation of the election of hospice care as described in § 418.28 of this chapter.

(ii) The date the enrollee exhausts his or her hospice benefits.

(3) *Payment to HMO or CMP.* For the period that the Medicare enrollee's election of hospice care is in effect, CMS pays a cost HMO or CMP only as described in § 417.585.

(d) *Limitation on provision of inpatient hospital services.* If a beneficiary's effective date of coverage, as specified in §417.450, in a risk HMO or CMP occurs during an inpatient stay in a hospital paid for under part 412 of this chapter, the HMO or CMP—

(1) Is not responsible for the provision of any of the inpatient hospital services under Part A during the stay and is not required to pay for those services;

(2) Must assume responsibility for payment for or provision of inpatient hospital services under Part A on the day after the day of discharge from the inpatient stay; and

(3) Is responsible for the full scope of services under paragraph (b) of this section, other than inpatient hospital services under Part A, beginning on the effective date of enrollment.

(e) *Extension of provision of inpatient hospital services.* If an enrollee's effective date of disenrollment, as defined by §417.460, occurs during an inpatient stay in a hospital paid for under part 412 of this chapter and the stay is provided or arranged for by the HMO or CMP, or the HMO or CMP is financially responsible for the hospitalization under paragraph (a)(2) of this section, the HMO or CMP—

(1) Is financially responsible for payment of the inpatient services under Part A through the date the beneficiary is discharged from the inpatient stay; and

(2) Is not responsible for the provision of services, furnished on or after the effective date of disenrollment, other than inpatient hospital services under Part A.

(f) *Notice of noncoverage of inpatient hospital care.* (1) If an enrollee is an inpatient of a hospital, entitlement to inpatient hospital care continues until he or she receives notice of noncoverage of that care.

(2) Before giving notice of noncoverage, the HMO or CMP must obtain the concurrence of its affiliated physician responsible for the hospital care of the enrollee, or other physician as authorized by the HMO or CMP.

(3) The HMO or CMP must give the enrollee written notice that includes the following:

(i) The reason why inpatient hospital care is no longer needed.

(ii) The effective date of the enrollee's liability for continued inpatient care.

(iii) The enrollee's appeal rights.

(4) If the HMO or CMP delegates to the hospital the determination of noncoverage of inpatient care, the hospital obtains the concurrence of the HMO- or CMP-affiliated physician responsible for the hospital care of the enrollee, or other physician as authorized by the HMO or CMP, and sends notice, following the procedures set forth in §412.42(c)(3) of this chapter.

[50 FR 1346, Jan. 10, 1985; 50 FR 20570, May 17, 1985, as amended at 52 FR 8901, Mar. 20, 1987; 58 FR 38079, July 15, 1993; 59 FR 59941, Nov. 21, 1994; 60 FR 45678, Sept. 1, 1995; 70 FR 4525, Jan. 28, 2005]

§417.442 Risk HMO's and CMP's: Conditions for provision of additional benefits.

(a) *General rule.* Except as provided in paragraph (b) of this section, a risk HMO or CMP must, during any contract period, provide to its Medicare enrollees the additional benefits described in §417.440(b)(4) if its ACRs (calculated in accordance with §417.594) are less than the average per capita rates that CMS pays for the Medicare enrollees during the contract period.

(b) *Exceptions*—(1) *Reduced payment election.* An HMO or CMP is not obligated to furnish additional services under paragraph (a) of this section if it has requested a reduction in its monthly payment from CMS under §417.592(e), and it—

(i) Elects to receive reduced payment so that there is no difference between the average of its per capita rates of payment and its ACR; or

(ii) Elects to receive partially reduced payment and furnish Medicare enrollees with additional benefits described in §417.440 (b)(4) so that the combined value of benefits and reduced payment is equivalent to the difference between the average of its per capita rates of payment and its ACR.

(2) *Benefit stabilization fund.* An HMO or CMP may elect to have a part of the value of the additional benefits it must

provide under paragraph (a) of this section withheld in a benefit stabilization fund as described in § 417.596.

[50 FR 1346, Jan. 10, 1985; 50 FR 20570, May 17, 1985; 58 FR 38082, July 15, 1993; 60 FR 45678, Sept. 1, 1995]

§ 417.444 Special rules for certain enrollees of risk HMOs and CMPs.

(a) *Applicability.* This section applies to any Medicare enrollee of a risk HMO or CMP who meets the following conditions:

(1) On February 1, 1985, was enrolled—

(i) In an HMO or CMP that had in effect a cost contract entered into under section 1876 of the Act in accordance with regulations in effect before February 1, 1985; or

(ii) In an HCPP that was being reimbursed on a reasonable cost basis under section 1833(a)(1)(A) of the Act.

(2) Has continued enrollment in the same entity without interruption or disenrolled after February 1, 1985, and later reenrolled in the same entity.

(b) *Retention of nonrisk status*—(1) A ''nonrisk'' enrollee is a Medicare beneficiary who meets the conditions of paragraph (a) of this section and is enrolled in an entity that enters into a risk contract as an HMO or CMP. A ''nonrisk'' enrollee may retain nonrisk status indefinitely unless CMS determines under paragraph (c)(1) of this section, that the enrollee's status must be changed, or the enrollee requests the change, as provided in paragraph (c)(2) of this section.

(2) A nonrisk enrollee of a risk HMO or CMP is not entitled to additional benefits under § 417.442.

(c) *Conversion to risk status*—(1) *Conversion based on CMS determination.* If CMS determines that, for administrative reasons or because there are fewer than 75 current nonrisk Medicare enrollees remaining in the HMO or CMP, all of its nonrisk Medicare enrollees must be covered under the risk provisions of the contract, the conversion process is as follows:

(i) CMS notifies each affected enrollee of the decision at least 90 days prior to the effective date.

(ii) The nonrisk Medicare enrollees complete and sign forms stating that they understand and accept the new rules and benefits that will be applicable to them.

(iii) The HMO or CMP notifies each affected enrollee, in writing, at least 30 days in advance, of the date upon which his or her coverage under the risk portion of the contract takes effect.

(2) *Conversion based on enrollee's request.* A nonrisk Medicare enrollee requests, using a form identical or similar to the form described in paragraph (c)(1) of this section, that he or she be covered under the risk portion of the contract.

(d) *Notification.* An HMO or CMP converting from a cost contract to a risk contract must, within 60 days of signing the risk contract, inform nonrisk enrollees of their right to remain nonrisk Medicare enrollees or to convert to risk enrollment at any time in accordance with paragraph (c)(2) of this section.

[58 FR 38073, July 15, 1993]

§ 417.446 [Reserved]

§ 417.448 Restriction on payments for services received by Medicare enrollees of risk HMOs or CMPs.

(a) *Basic rule.* Except for emergency and urgently needed services as defined in § 417.401, risk HMOs or CMPs are not required to make payments to or on behalf of certain Medicare enrollees, for any services received by the enrollees that are not provided—

(1) Directly by the HMO or CMP; or

(2) Through arrangements made by the HMO or CMP.

(b) *Application.* The restriction on payments for services imposed by paragraph (a) of this section applies to services received by—

(1) New Medicare enrollees;

(2) Nonrisk Medicare enrollees who convert to risk reimbursement; and

(3) Nonrisk Medicare enrollees who elect special supplemental benefit plans.

(c) *End of restriction.* The restriction of payments imposed by paragraph (a) of this section ends when a Medicare enrollee leaves the HMO's or CMP's geographic area for an extended period as defined in § 471.460(a)(2) and the HMO or

CMP and the enrollee make arrangements for enrollment to continue as provided in §417.460(a)(2)(iv).

(d) *Timing.* The effective date for the end of the restriction on payments, as discussed in paragraph (c) of this section is the first day of the first month following the month in which the enrollee notifies the HMO or CMP as required in §417.436(a)(9), that he or she has left the HMO's or CMP's geographic area for an extended period.

[51 FR 28573, Aug. 8, 1986, as amended at 56 FR 46571, Sept. 13, 1991; 58 FR 38079, July 15, 1993]

§417.450 Effective date of coverage.

(a) *Basic rules.* Except as specified in paragraph (b) of this section, and notwithstanding the provisions of §417.440(d).

(1) CMS's liability for payments to an HMO or CMP on behalf of a Medicare beneficiary begins on the first day of the month in which he or she is—

(i) Entitled to Medicare benefits; and

(ii) Enrolled in an HMO or CMP; and

(2) The effective month of coverage may not be earlier than the first month after, nor later than the third month after the month in which CMS receives the information necessary to include the beneficiary as a Medicare enrollee of the HMO or CMP in CMS records.

(b) *Exceptions.* (1) CMS may approve a later month if it is requested by the HMO or CMP and the beneficiary.

(2) If an individual becomes an HMO or CMP enrollee before becoming entitled to Medicare Part B benefits, the effective month of coverage is the first month for which he or she becomes entitled to Medicare Part B benefits.

(c) *Notice of effective date of coverage.* For each beneficiary added to CMS's records as an enrollee of an HMO or CMP, CMS gives the HMO or CMP prompt written notice of the month with which CMS's liability begins.

[50 FR 1346, Jan. 10, 1985, as amended at 52 FR 8901, Mar. 20, 1987; 58 FR 38079, July 15, 1993; 60 FR 45678, Sept. 1, 1995]

§417.452 Liability of Medicare enrollees.

(a) *Deductibles and coinsurance.* (1) A Medicare enrollee of an HMO or CMP is responsible for applicable Medicare deductible and coinsurance amounts, unless the HMO's or CMP's charges for these amounts are reduced under the additional benefits provision of §417.442.

(2) The deductible and coinsurance amounts may be paid by or on behalf of the enrollee in the form of a premium, membership fee, charge per unit, or other similar charge.

(3) The sum of the amounts the HMO or CMP charges its Medicare enrollees for Medicare deductibles and coinsurance may not exceed, on the average, the actuarial value of the deductible and coinsurance the Medicare enrollees otherwise would have been liable for had they not enrolled in the HMO or CMP or in another HMO or CMP.

(b) *Services not covered under Medicare.* Unless the services are provided as additional benefits under §417.442, a Medicare enrollee of an HMO or CMP is liable for payment for—

(1) All services that are not covered under Medicare Part A or Part B; or

(2) If entitled only to Medicare Part B benefits, all services that are not covered under Medicare Part B.

(c) *Services for which Medicare is not primary payer.* A Medicare enrollee of an HMO or CMP is liable for payments made to the enrollee for all covered services for which Medicare is not the primary payer as provided in §417.528.

(d) *Optional supplemental benefits plan.* (1) The HMO or CMP may offer its Medicare enrollees a supplemental benefit plan to cover deductible and coinsurance amounts, or services not covered under Medicare, or both.

(2) If a supplemental benefit plan premium includes charges for both noncovered services and the deductible and coinsurance amounts applicable to covered services, the portion of the premium that is for deductibles and coinsurance must be computed separately and must be disclosed to the beneficiary during the enrollment process and before he or she elects coverage options.

(3) The sum of the amounts an HMO or CMP charges its Medicare enrollees for services that are not covered under Part A or Part B may not exceed the ACR for these services.

(e) *Coverage of Part A services for Part B-only Medicare enrollees.* If an HMO or

CMP furnishes coverage of Medicare Part A services to a Medicare enrollee entitled to Part B only, the HMO's or CMP's premium (or other payment method) for these services may not exceed the ACR for these services. In addition, if a risk HMO or CMP furnishes these services and supplemental services, which are the same as the additional benefits furnished Medicare enrollees of the HMO or CMP who are entitled to benefits under both Parts A and B, the HMO's or CMP's combined premium for both these groups of services that the Part B enrollee must pay may not exceed 95 percent of the weighted average AAPCC for Part A services (or the Medicare payment for Part A services, if it is less) for the Medicare enrollee of the HMO or CMP.

[50 FR 1346, Jan. 10, 1985, as amended at 58 FR 38079, July 15, 1993; 60 FR 45678, Sept. 1, 1995]

§ 417.454 Charges to Medicare enrollees.

(a) *Limits on charges.* The HMO or CMP must agree to charge its Medicare enrollees only for the—

(1) Deductible and coinsurance amounts applicable to furnished covered services;

(2) Charges for noncovered services or services for which the enrollee is liable as described in § 417.452; and

(3) Services for which Medicare is not the primary payor as provided in § 417.528.

(b) *Limit on charges for inpatient hospital care.* If a Medicare enrollee who is an inpatient of a hospital requests immediate QIO review (as provided in § 417.605) of any determination by the hospital furnishing services or the HMO or CMP that the inpatient hospital services will no longer be covered, the HMO or CMP may not charge the enrollee for any inpatient care costs incured before noon of the first working day after the QIO issues its review decision.

(c) *Reporting requirements.* A risk HMO or CMP must report, within 90 days after the end of the contract period, all premiums, enrollment fees, and other charges collected from its Medicare enrollees during that period.

(d) *Limit on charges for specified preventive services.* An HMO may not charge deductibles, copayments, or coinsurance for in-network Medicare-covered preventive services (as defined in § 410.152(l)).

(e) *Services for which cost sharing may not exceed cost sharing under original Medicare.* On an annual basis, CMS will evaluate whether there are service categories for which HMOs' cost sharing may not exceed that required under original Medicare and specify in regulation which services are subject to that cost sharing limit. The following services are subject to this limit on cost sharing:

(1) Chemotherapy administration services to include chemotherapy drugs and radiation therapy integral to the treatment regimen.

(2) Renal dialysis services as defined at section 1881(b)(14)(B) of the Act.

(3) Skilled nursing care defined as services provided during a covered stay in a skilled nursing facility during the period for which cost sharing would apply under Original Medicare.

(4) A COVID–19 vaccine and its administration described in section 1861(s)(10)(A) of the Act.

[50 FR 1346, Jan. 10, 1985, as amended at 58 FR 38082, July 15, 1993; 59 FR 59941, Nov. 21, 1994; 60 FR 45678, Sept. 1, 1995; 76 FR 21561, Apr. 15, 2011; 85 FR 71197, Nov. 6, 2020; 88 FR 22328, Apr. 12, 2023]

§ 417.456 Refunds to Medicare enrollees.

(a) *Definitions.* As used in this section—

Amounts incorrectly collected means amounts collected that are in excess of those specified in § 417.452. It includes amounts collected when the enrollee was believed not entitled to Medicare benefits if the enrollee is later determined to have been entitled to Medicare benefits and CMS is liable for payments as specified in § 417.450.

Other amounts due means amounts due a Medicare enrollee for services obtained outside the HMO or CMP if they were—

(1) Emergency services;

(2) Urgently needed services for which the HMO or CMP has assumed financial responsibility; or

(3) On appeal under subpart Q of this part, found to be services the enrollee

was entitled to have furnished by the HMO or CMP.

(b) *Basic commitment.* An HMO or CMP must agree to refund all amounts incorrectly collected from its Medicare enrollees, or from others on behalf of the enrollees, and any other amounts due the enrollees or others on their behalf.

(c) *Refund by lump sum payment.* An HMO or CMP must make refunds to its current and former Medicare enrollees, or to others who have made payments on behalf of enrollees, by lump sum payment for the following:

(1) Incorrectly collected amounts that were not collected as premiums.

(2) Other amounts due.

(3) All amounts due, if the HMO or CMP is going out of business.

(d) *Refund by premium adjustment or lump sum payment or both.* An HMO or CMP may make refund by adjustment of future premiums, by lump sum payment, or by a combination of both methods, for amounts that were incorrectly collected in the form of premiums or through a combination of premium payments and other charges.

(e) *Refund when enrollee has died or cannot be located.* If an enrollee has died or cannot be located after reasonable effort by the HMO or CMP, the HMO or CMP must make the refund in accordance with State law.

(f) *Reduction by CMS.* If the HMO or CMP does not make refund in accordance with paragraphs (b) through (d) of this section by the end of the contract period following the contract period during which an amount was determined to be due an enrollee, CMS reduces its payment to the HMO or CMP by the amounts incorrectly collected or otherwise due, and arranges for those amounts to be paid to the Medicare enrollee.

[50 FR 1346, Jan. 10, 1985, as amended at 58 FR 38079, July 15, 1993; 60 FR 45678, Sept. 1, 1995]

§417.458 Recoupment of uncollected deductible and coinsurance amounts.

An HMO or CMP agrees not to recoup deductible and coinsurance amounts for which Medicare enrollees were liable in a previous contract period except in the following circumstances:

(a) The HMO or CMP failed to collect the deductible and coinsurance amounts during the contract period in which they were due because of—

(1) Underestimation of the actuarial value of the deductible and coinsurance amounts; or

(2) A billing error.

(b) The HMO or CMP has identified the amounts and obtained advance CMS approval of the recoupment and the method and timing of recoupment.

(c) The HMO or CMP collects these amounts no later than the end of the contract period following the contract period during which they were found to be due.

[50 FR 1346, Jan. 10, 1985, as amended at 58 FR 38082, July 15, 1993; 60 FR 45678, Sept. 1, 1995]

§417.460 Disenrollment of beneficiaries by an HMO or CMP.

(a) *General rule.* Except as provided in paragraphs (b) through (i) of this section, an HMO or CMP may not—

(1) Disenroll a Medicare beneficiary; or

(2) Orally or in writing, or by any action or inaction, request or encourage a Medicare enrollee to disenroll.

(b) *Bases for disenrollment: Overview*—(1) *Optional disenrollment.* Generally, an HMO or CMP may disenroll a Medicare enrollee if he or she—

(i) Fails to pay the required premiums or other charges;

(ii) Commits fraud or permits abuse of his or her enrollment card; or

(iii) Behaves in a manner that seriously impairs the HMO's or CMP's ability to furnish health care services to the particular enrollee or to other enrollees.

(2) *Required disenrollment.* Generally, an HMO or CMP must disenroll a Medicare enrollee if he or she—

(i) Moves out of the HMO's or CMP's geographic service area or is incarcerated;

(ii) Fails to convert to the risk provisions of the HMO's or CMP's Medicare contract;

(iii) Loses entitlement to Medicare Part B benefits;

(iv) Is not lawfully present in the United States; or

(v) Dies.

(3) *Related provisions.* Specific requirements, limitations, and exceptions are set forth in paragraphs (c) through (j) of this section.

(c) *Failure to pay premiums or other charges*—(1) *Basic rule.* Except as specified in paragraph (c)(2) of this section, an HMO or CMP may disenroll a Medicare enrollee who fails to pay premiums or other charges imposed by the HMO or CMP for deductible and coinsurance amounts for which the enrollee is liable, if the HMO or CMP—

(i) Can demonstrate to CMS that it made reasonable efforts to collect the unpaid amount;

(ii) Gives the enrollee written notice of disenrollment, including an explanation of the enrollee's right to a hearing under the HMO's or CMP's grievance procedures; and

(iii) Sends the notice of disenrollment to the enrollee before it notifies CMS.

(2) *Exception.* If the enrollee fails to pay the premium for optional supplemental benefits (that is, a package of benefits that an enrollee is not required to accept), but pays the basic premium and other charges, the HMO or CMP may discontinue the optional benefits but may not disenroll the beneficiary.

(3) *Good cause and reinstatement.* When an individual is disenrolled for failure to pay premiums or other charges imposed by the HMO or CMP for deductible and coinsurance amounts for which the enrollee is liable, CMS (or a third party to which CMS has assigned this responsibility, such as an HMO or CMP) may reinstate enrollment in the plan, without interruption of coverage, if the individual does all of the following:

(i) Submits a request for reinstatement for good cause within 60 calendar days of the disenrollment effective date.

(ii) Has not previously requested reinstatement for good cause during the same 60-day period following the involuntary disenrollment.

(iii) Shows good cause for failure to pay.

(iv) Pays all overdue premiums or other charges within 3 calendar months after the disenrollment date.

(v) Establishes by a credible statement that failure to pay premiums or other charges was due to circumstances for which the individual had no control, or which the individual could not reasonably have been expected to foresee.

(4) *Exception for reinstatement.* A beneficiary's enrollment in the plan will not be reinstated if the only basis for such reinstatement is a change in the individual's circumstances subsequent to the involuntary disenrollment for non-payment of premiums or other charges.

(d) *Enrollee commits fraud or permits abuse of the enrollment card*—(1) *Basis for disenrollment.* An HMO or CMP may disenroll a Medicare beneficiary if the beneficiary—

(i) Knowingly provides, on the application form, fraudulent information that materially affects the beneficiary's eligibility to enroll in the HMO or CMP; or

(ii) Intentionally permits others to use his or her enrollment card to obtain services from the HMO or CMP.

(2) *Notice requirement.* If disenrollment is for either of the reasons specified in paragraph (d)(1) of this section, the HMO or CMP must give the beneficiary a written notice of termination of enrollment.

(i) The notice must be mailed to the enrollee before submission of the disenrollment notice to CMS.

(ii) The notice must include an explanation of the enrollee's right to have the disenrollment heard under the grievance procedures established in accordance with § 417.436.

(3) *Report to the Inspector General.* The HMO or CMP must report to the Office of the Inspector General of the Department any disenrollment based on fraud or abuse by the enrollee.

(e) *Disenrollment for cause*—(1) *Basis for disenrollment.* An HMO or CMP may disenroll a Medicare enrollee for cause if the enrollee's behavior is disruptive, unruly, abusive, or uncooperative to the extent that his or her continuing enrollment in the HMO or CMP seriously impairs the HMO's or CMP's ability to furnish services to either the particular enrollee or other enrollees.

(2) *Effort to resolve the problem.* (i) The HMO or CMP must make a serious effort to resolve the problem presented by the enrollee, including the use (or attempted use) of internal grievance procedures, and including providing reasonable accommodations, as determined by CMS, for individuals with mental or cognitive conditions, including mental illness and developmental disabilities.

(ii) The HMO or CMP must inform the individual of the right to use the organization's grievance procedures, through the notices described in paragraph (e)(7) of this section.

(3) *Consideration of extenuating circumstances.* The HMO or CMP must ascertain that the enrollee's behavior is not related to the use of medical services or to mental illness.

(4) *Documentation.* The HMO or CMP must document the problems, efforts, and medical conditions as described in paragraphs (e)(1) through (3) of this section. Dated copies of the notices required in paragraph (d)(2)(iv) of this section must also be submitted to CMS.

(5) *CMS review of an HMO's or CMP's proposed disenrollment for cause.* (i) CMS decides on the basis of review of the documentation submitted by the HMO or CMP, whether disenrollment requirements have been met.

(ii) CMS makes this decision within 20 working days after receipt of the documentation material, and notifies the HMO or CMP within 5 working days after making its decision.

(6) *Effective date of disenrollment.* If CMS permits an HMO or CMP to disenroll an enrollee for cause, the disenrollment takes effect on the first day of the calendar month after the month in which the HMO or CMP gives the enrollee a written notice of disenrollment that meets the requirements set forth in paragraphs (d)(2)(i) and (d)(2)(ii) of this section.

(7) *Other required notices.* The HMO or CMP must provide the individual two notices before submitting the request for disenrollment to CMS.

(i) The first notice, the advance notice, informs the member that continued disruptive behavior could lead to involuntary disenrollment and provides the individual an opportunity to cease the behavior in order to avoid the disenrollment action.

(A) If the disruptive behavior ceases after the enrollee receives the advance notice and then later resumes, the HMO or CMP must begin the process again.

(B) The HMO or CMP must wait at least 30 days after sending the advance notice before sending the second notice, during which 30-days period the individual has to provide an opportunity for the individual to cease their behavior.

(ii) The second notice, the notice of intent to request CMS permission to disenroll the member, notifies the enrollee that the HMO or CMP requests CMS permission to involuntarily disenroll the enrollee. This notice must be provided before submission of the request to CMS.

(f) *Enrollee moves out of the HMO's or CMP's geographic area*—(1) *Basic rules*—(i) *Disenrollment.* Except as provided in paragraph (f)(2) of this section, an HMO or CMP must disenroll a Medicare enrollee who moves out of its geographic area if the HMO or CMP establishes, on the basis of a written statement from the enrollee, or other evidence acceptable to CMS, that the enrollee has permanently moved out of its geographic area.

(A) *Incarceration.* The HMO or CMP must disenroll an individual if the HMO or CMP establishes, on the basis of evidence acceptable to CMS, that the individual is incarcerated and does not reside in the geographic service area of the HMO or CMP per §417.1.

(B) *Notification by CMS of incarceration.* When CMS notifies an HMO or CMP of disenrollment due to the individual being incarcerated and not residing in the geographic service area of the HMO or CMP, as per §417.1, the disenrollment is effective the first of the month following the start of incarceration, unless otherwise specified by CMS.

(C) *Exception.* The exception in paragraph (f)(2) of this section does not apply to individuals who are incarcerated.

(ii) *Notice requirement.* The HMO or CMP must comply with the notice requirements set forth in paragraph (d)(2) of this section.

(iii) *Effect on geographic area.* Failure to disenroll an enrollee who has moved out of the HMO's or CMP's geographic area does not expand that area to encompass the location of the enrollee's new residence.

(2) *Exception.* An HMO or CMP may retain a Medicare enrollee who is absent from its geographic area for an extended period, but who remains within the United States as defined in § 400.200 of this chapter if the enrollee agrees. For purposes of this exception, the following provisions apply:

(i) An absence for an extended period means an uninterrupted absence from the HMO's or CMP's geographic area for more than 90 days but less than 1 year.

(ii) The HMO or CMP and the enrollee may mutually agree upon restrictions for obtaining services while the enrollee is absent for an extended period from the HMO's or CMP's geographic area. However, restrictions may not be imposed on the scope of services described in § 417.440.

(iii) HMOs and CMPs that choose to exercise this exception must make the option available to all Medicare enrollees who are absent for an extended period from their geographic areas. However, HMOs and CMPs may limit this option to enrollees who go to a geographic area served by an affiliated HMO or CMP.

(iv) As used in this paragraph, ''affiliated HMO or CMP'' means an HMO or CMP that—

(A) Is under common ownership or control of the HMO or CMP that seeks to retain the absent enrollees; or

(B) Has in effect an agreement to furnish services to enrollees who are on an extended absence from the geographic area of the HMO or CMP that seeks to retain them.

(v) When the enrollee returns to the HMO's or CMP's geographic area (even temporarily), the restrictions of § 417.448(a) (which limit payment for services not provided or arranged for by the HMO or CMP) apply again immediately.

(vi) If the enrollee fails to return to the HMO's or CMP's geographic area within 1 year from the date he or she left that area, the HMO or CMP must disenroll the beneficiary on the first day of the month following the anniversary of the date the enrollee left that area in accordance with paragraph (f)(1) of this section.

(g) *Failure to convert to risk provisions of Medicare contract*—(1) *Basis for disenrollment.* A risk HMO or CMP must disenroll a nonrisk Medicare enrollee who refuses to convert to the risk provisions of the Medicare contract after CMS determines that all of the HMO's or CMP's nonrisk Medicare enrollees must convert.

(2) *Advance notice requirement.* At least 30 days before it gives CMS notice of disenrollment, the HMO or CMP must give the enrollee written notice of the fact that failure to convert will result in disenrollment.

(h) *Loss of entitlement to Medicare benefits*—(1) *Loss of entitlement to Part A benefits.* If an enrollee loses entitlement to benefits under Part A of Medicare but remains entitled to benefits under Part B, the enrollee automatically continues as a Medicare enrollee of the HMO or CMP and is entitled to receive and have payment made for Part B services, beginning with the month immediately following the last month of his or her entitlement to Part A benefits.

(2) *Loss of entitlement to Part B benefits.* If a Medicare enrollee loses entitlement to Part B benefits, the HMO or CMP must disenroll him or her as a Medicare enrollee effective with the month following the last month of entitlement to Part B benefits. However, the HMO or CMP may continue to enroll the individual under its regular plan if the individual so chooses.

(i) *Death of the enrollee.* Disenrollment is effective with the month following the month of death.

(j) *Enrollee is not lawfully present in the United States.* Disenrollment is effective the first day of the month following notice by CMS that the individual is ineligible in accordance with § 417.422(h).

[60 FR 45678, Sept. 1, 1995, as amended at 77 FR 22166, Apr. 12, 2012; 79 FR 29955, May 23, 2014; 80 FR 7958, Feb. 12, 2015; 89 FR 30812, Apr. 23, 2024]

§ 417.461 Disenrollment by the enrollee.

(a) *Request for disenrollment.* (1) A Medicare enrollee who wishes to disenroll may at any time give the HMO or CMP a signed, dated request in the form and manner prescribed by CMS.

(2) The enrollee may request a certain disenrollment date but it may be no earlier than the first day of the month following the month in which the HMO or CMP receives the request.

(b) *Responsibilities of the HMO or CMP.* The HMO or CMP must—

(1) Submit a disenrollment notice to CMS promptly;

(2) Provide the enrollee with a copy of the request for disenrollment; and

(3) In the case of a risk HMO or CMP, also provide the enrollee with a statement explaining that he or she—

(i) Remains enrolled until the effective date of disenrollment; and

(ii) Until that date, is subject to the restrictions of § 417.448(a) under which neither the HMO or CMP nor CMS pays for services not provided or arranged for by the HMO or CMP.

(c) *Effect of failure to submit disenrollment notice to CMS promptly.* If the HMO or CMP fails to submit timely the correct and complete notice required in paragraph (b)(1) of this section, the HMO or CMP must reimburse CMS for any capitation payments received after the month in which payments would have ceased if the requirement had been met timely.

[60 FR 45679, Sept. 1, 1995]

§ 417.464 End of CMS's liability for payment: Disenrollment of beneficiaries and termination or default of contract.

(a) *Effect of disenrollment: General rule.* (1) CMS's liability for monthly capitation payments to the HMO or CMP generally ends as of the first day of the month following the month in which disenrollment is effective, as shown on CMS's records.

(2) Disenrollment is effective no earlier than the month immediately after, and no later than the third month after, the month in which CMS receives the disenrollment notice in acceptable form.

(b) *Effect of disenrollment: Special rules*—(1) *Fraud or abuse by the enrollee.* If disenrollment is on the basis of fraud committed or abuse permitted by the enrollee, CMS's liability ends as of the first day of the month in which disenrollment is effective.

(2) *Loss of entitlement to Part B benefits.* If disenrollment is on the basis of loss of entitlement to Part B benefits, CMS's liability ends as of the first day of the month following the last month of Part B entitlement.

(3) *Death of enrollee.* If the enrollee dies, CMS's liability ends as of the first day of the month following the month of death.

(4) *Disenrollment at enrollee's request.* If disenrollment is in response to the enrollee's request, CMS's liability ends as of the first day of the month following the month of termination requested by the enrollee.

(c) *Effect of termination or default of contract*—(1) *Termination of contract.* If the contract between CMS and the HMO or CMP is terminated by mutual consent or by unilateral action of either party, CMS's liability for payments ends as of the first day of the month after the last month for which the contract is in effect.

(2) *Default of contract.* If the HMO or CMP defaults on the contract before the end of the contract year because of bankruptcy or other reasons, CMS—

(i) Determines the month in which its liability for payments ends; and

(ii) Notifies the HMO or CMP and all affected Medicare enrollees as soon as practicable.

[60 FR 45680, Sept. 1, 1995]

Subpart L—Medicare Contract Requirements

SOURCE: 50 FR 1346, Jan. 10, 1985, unless otherwise noted.

§ 417.470 Basis and scope.

(a) *Basis.* This subpart implements those portions of section 1857(e)(2) of the Act pertaining to cost sharing in enrollment-related costs and section 1876(c), (g), (h), and (i) of the Act that pertain to the contract between CMS and an HMO or CMP for participation in the Medicare program.

(b) *Scope.* This subpart sets forth—

(1) Specific contract requirements; and

(2) Procedures for renewal, nonrenewal, or termination of a contract.

[50 FR 1346, Jan. 10, 1985, as amended at 58 FR 38079, July 15, 1993; 62 FR 63673, Dec. 2, 1997]

§ 417.472 Basic contract requirements.

(a) *Submittal of contract.* An HMO or CMP that wishes to contract with CMS to furnish services to Medicare beneficiaries must submit a signed contract that meets the requirements of this subpart and any other requirements established by CMS.

(b) *Agreement to comply with regulations and instructions.* The contract must provide that the HMO or CMP agrees to comply with all the applicable requirements and conditions set forth in this subpart and in general instructions issued by CMS.

(c) *Other contract provisions.* In addition to the requirements set forth in §§ 417.474 through 417.488, the contract must contain any other terms and conditions that CMS requires to implement section 1876 of the Act.

(d) *Exemption from Federal procurement regulations.* The Federal Acquisition Regulations and HHS Acquisition Regulations contained in title 48 of the Code of Federal Regulations do not apply to Medicare contracts under section 1876 of the Act.

(e) *Compliance with civil rights laws.* The HMO or CMP must comply with title VI of the Civil Rights Act of 1964 (regulations at 45 CFR part 80), section 504 of the Rehabilitation Act of 1973 (regulations at 45 CFR part 84), and the Age Discrimination Act of 1975 (regulations at 45 CFR part 91).

(f) *Requirements for advance directives.* The HMO or CMP must meet all the requirements for advance directives at § 417.436(d).

(g) *Authority to waive conflicting contract requirements.* Under section 1876(i)(5) of the Act, CMS is authorized to administer the terms of this subpart without regard to provisions of law or other regulations relating to the making, performance, amendment, or modification of contracts of the United States if it determines that those provisions are inconsistent with the efficient and effective administration of the Medicare program.

(h) *Collection of fees from risk HMOs and CMPs.* (1) The rules set forth in § 422.10 of this chapter for M + C plans also apply to collection of fees from risk HMOs and CMPs.

(2) In applying the part 422 rules, references to ''M + C organizations'' or ''M + C plans'' must be read as references to ''risk HMOs and CMPs''.

(i) *HMOs and CMPs.* The HMO or CMP must comply with the requirements at § 422.152(b)(5) and (6) of this chapter.

(j) *Coordinated care and cost contracts.* Subject to paragraph (i) of this section, all coordinated care contracts (including local and regional PPOs, contracts with exclusively SNP benefit packages, private fee-for-service contracts, and MSA contracts), and all cost contracts under section 1876 of the Act, with 600 or more enrollees in July of the prior year, must contract with approved Medicare Consumer Assessment of Healthcare Providers and Systems (CAHPS) survey vendors to conduct the Medicare CAHPS satisfaction survey of Medicare plan enrollees in accordance with CMS specifications and submit the survey data to CMS.

(k) All cost contracts under section 1876 of the Act must agree to be rated under the quality rating system specified at subpart D of part 422, and for cost plans that provide the Part D prescription benefit, under the quality rating system specified at part 423 subpart D, of this chapter. Cost contacts are not required to submit data on or be rated on specific measures determined by CMS to be inapplicable to their contract or for which data are not available, including hospital readmission and call center measures.

(l) *Resolution of complaints in the complaints tracking module.* The HMO or CMP must comply with requirements of §§ 422.125 and 422.504(a)(15) of this chapter to, through the CMS complaints tracking module as defined in § 422.125(a) of this chapter, address and resolve complaints received by CMS against the HMO or CMP within the required timeframes. References to the MA organization or MA plan in those

regulations shall be read as references to the HMO or CMP.

[50 FR 1346, Jan. 10, 1985; 50 FR 20570, May 17, 1985, as amended at 57 FR 8202, Mar. 6, 1992; 58 FR 38079, July 15, 1993; 60 FR 45680, Sept. 1, 1995; 63 FR 35067, June 26, 1998; 75 FR 19802, Apr. 15, 2010; 83 FR 16721, Apr. 16, 2018; 85 FR 19289, Apr. 6, 2020; 89 FR 30812, Apr. 23, 2024]

§417.474 Effective date and term of contract.

(a) *Effective date.* The contract must specify its effective date, which may not be earlier than the date it is signed by both CMS and the HMO or CMP.

(b) *Term.* The contract must specify the duration of its term as follows:

(1) For the initial term, at least 12 months, but no more than 23 months.

(2) For any subsequent term, 12 months.

[60 FR 45680, Sept. 1, 1995]

§417.476 Waived conditions.

If CMS waives any of the qualifying conditions required under subpart J of this part, the contract must specify the following information for each waived condition:

(a) The specific terms of the waiver.

(b) The expiration date of the waiver.

(c) Any other information required by CMS.

[60 FR 45680, Sept. 1, 1995]

§417.478 Requirements of other laws and regulations.

The contract must provide that the HMO or CMP agrees to comply with—

(a) The requirements for QIO review of services furnished to Medicare enrollees as set forth in subchapter D of this chapter;

(b) Sections 1318(a) and (c) of the PHS Act, which pertain to disclosure of certain financial information;

(c) Section 1301(c)(8) of the PHS Act, which relates to liability arrangements to protect enrollees of the HMO or CMP; and

(d) The reporting requirements in §417.126(a), which pertain to the monitoring of an HMO's or CMP's continued compliance.

(e)(1) The prohibitions, procedures and requirements relating to payment to individuals and entities on the preclusion list, defined in §422.2 of this chapter, apply to HMOs and CMPs that contract with CMS under section 1876 of the Act.

(2) In applying the provisions of §§422.2, 422.222, and 422.224 of this chapter under paragraph (e)(1) of this section, references to part 422 of this chapter must be read as references to this part, and references to MA organizations as references to HMOs and CMPs.

[50 FR 1346, Jan. 10, 1985; 50 FR 20570, May 17, 1985, as amended at 56 FR 8853, Mar. 1, 1991; 58 FR 38079, 38082, July 15, 1993; 80 FR 80556, Nov. 15, 2016; 83 FR 16721, Apr. 16, 2018]

§417.479 Requirements for physician incentive plans.

(a) The contract must specify that an HMO or CMP may operate a physician incentive plan only if—

(1) No specific payment is made directly or indirectly under the plan to a physician or physician group as an inducement to reduce or limit medically necessary services furnished to an individual enrollee; and

(2) The stop-loss protection, enrollee survey, and disclosure requirements of this section are met.

(b) *Applicability.* The requirements in this section apply to physician incentive plans between HMOs and CMP and individual physicians or physician groups with which they contract to provide medical services to enrollees. The requirements in this section also apply to subcontracting arrangements as specified in §417.479(i). These requirements apply only to physician incentive plans that base compensation (in whole or in part) on the use or cost of services furnished to Medicare beneficiaries or Medicaid beneficiaries.

(c) *Definitions.* For purposes of this section:

Bonus means a payment an HMO or CMP makes to a physician or physician group beyond any salary, fee-for-service payments, capitation, or returned withhold.

Capitation means a set dollar payment per patient per unit of time (usually per month) that an organization pays a physician or physician group to cover a specified set of services and administrative costs without regard to the actual number of services provided. The services covered may include the

physician's own services, referral services, or all medical services.

Payments means any amounts the HMO or CMP pays physicians or physician groups for services they furnish directly, plus amounts paid for administration and amounts paid (in whole or in part) based on use and costs of referral services (such as withhold amounts, bonuses based on referral levels, and any other compensation to the physician or physician group to influence the use of referral services). Bonuses and other compensation that are not based on referral levels (such as bonuses based solely on quality of care furnished, patient satisfaction, and participation on committees) are not considered payments for purposes of this section.

Physician group means a partnership, association, corporation, individual practice association, or other group that distributes income from the practice among members. An individual practice association is a physician group only if it is composed of individual physicians and has no subcontracts with physician groups.

Physician incentive plan means any compensation arrangement between an HMO or CMP and a physician or physician group that may directly or indirectly have the effect of reducing or limiting services furnished to Medicare beneficiaries or Medicaid beneficiaries enrolled in the HMO or CMP.

Referral services means any specialty, inpatient, outpatient, or laboratory services that a physician or physician group orders or arranges, but does not furnish directly.

Risk threshold means the maximum risk, if the risk is based on referral services, to which a physician or physician group may be exposed under a physician incentive plan without being at substantial financial risk.

Withhold means a percentage of payments or set dollar amounts that an HMO or CMP deducts from a physician's service fee, capitation, or salary payment, and that may or may not be returned to the physician, depending on specific predetermined factors.

(d) *Prohibited physician payments.* No specific payment of any kind may be made directly or indirectly under the incentive plan to a physician or physician group as an inducement to reduce or limit covered medically necessary services covered under the HMO's or CMP's contract furnished to an individual enrollee. Indirect payments include offerings of monetary value (such as stock options or waivers of debt) measured in the present or future.

(e) *General rule: Determination of substantial financial risk.* Substantial financial risk occurs when the incentive arrangements place the physician or physician group at risk for amounts beyond the risk threshold, if the risk is based on the use or costs of referral services. Amounts at risk based solely on factors other than a physician's or physician group's referral levels do not contribute to the determination of substantial financial risk. The risk threshold is 25 percent.

(f) *Arrangements that cause substantial financial risk.* For purposes of this paragraph, *potential payments* means the maximum anticipated total payments (based on the most recent year's utilization and experience and any current or anticipated factors that may affect payment amounts) that could be received if use or costs of referral services were low enough. The following physician incentive plans cause substantial financial risk if risk is based (in whole or in part) on use or costs of referral services and the patient panel size is not greater than 25,000 patients:

(1) Withholds greater than 25 percent of potential payments.

(2) Withholds less than 25 percent of potential payments if the physician or physician group is potentially liable for amounts exceeding 25 percent of potential payments.

(3) Bonuses that are greater than 33 percent of potential payments minus the bonus.

(4) Withholds plus bonuses if the withholds plus bonuses equal more than 25 percent of potential payments. The threshold bonus percentage for a particular withhold percentage may be calculated using the formula—

Withhold = 0.75 (Bonus %) + 25%.

(5) Capitation, arrangements, if—

(i) The difference between the maximum potential payments and the minimum potential payments is more than

25 percent of the maximum potential payments; or

(ii) The maximum and minimum potential payments are not clearly explained in the physician's or physician group's contract.

(6) Any other incentive arrangements that have the potential to hold a physician or physician group liable for more than 25 percent of potential payments.

(g) *Requirements for physician incentive plans that place physicians at substantial financial risk.* HMOs and CMPs that operate incentive plans that place physicians or physician groups at substantial financial risk must do the following:

(1) Conduct enrollee surveys. These surveys must—

(i) Include either all current Medicare/Medicaid enrollees in the HMO or CMP and those who have disenrolled (other than because of loss of eligibility in Medicaid or relocation outside the HMO's or CMP's service area) in the past 12 months, or a sample of these same enrollees and disenrollees;

(ii) Be designed, implemented, and analyzed in accordance with commonly accepted principles of survey design and statistical analysis;

(iii) Address enrollees/disenrollees satisfaction with the quality of the services provided and their degree of access to the services; and

(iv) Be conducted no later than 1 year after the effective date of the Medicare contract and at least annually thereafter.

(2) Ensure that all physicians and physician groups at substantial financial risk have either aggregate or per-patient stop-loss protection in accordance with the following requirements:

(i) If aggregate stop-loss protection is provided, it must cover 90 percent of the costs of referral services (beyond allocated amounts) that exceed 25 percent of potential payments.

(ii) If the stop-loss protection provided is based on a per-patient limit, the stop-loss limit per patient must be determined based on the size of the patient panel and may be a single combined limit or consist of separate limits for professional services and institutional services. In determining patient panel size, the patients may be pooled in accordance with paragraph (h)(2) of this section. Stop-loss protection must cover 90 percent of the costs of referral services that exceed the per patient limit. The per-patient stop-loss limit is as follows:

Panel size	Single combined limit	Separate institutional limit	Separate professional limit
1–1000	$6,000	$10,000	$3,000
1,001–5000	30,000	40,000	10,000
5,001–8,000	40,000	60,000	15,000
8,001–10,000	75,000	100,000	20,000
10,001–25,000	150,000	200,000	25,000
>25,000	none	none	none

(h) *Disclosure and other requirements for organizations with physician incentive plans*—(1) *Disclosure to CMS.* Each health maintenance organization or competitive medical plan must provide to CMS information concerning its physician incentive plans as requested.

(2) *Pooling of patients.* Pooling of patients is permitted only if—

(i) It is otherwise consistent with the relevant contracts governing the compensation arrangements for the physician or physician group;

(ii) The physician or physician group is at risk for referral services with respect to each of the categories of patients being pooled;

(iii) The terms of the compensation arrangements permit the physician or physician group to spread the risk across the categories of patients being pooled;

(iv) The distribution of payments to physicians from the risk pool is not calculated separately by patient category; and

(v) The terms of the risk borne by the physicians or physician group are comparable for all categories of patients being pooled.

(3) *Disclosure to Medicare beneficiaries.* Each health maintenance organization or competitive medical plan must provide the following information to any Medicare beneficiary who requests it:

(i) Whether the prepaid plan uses a physician incentive plan that affects the use of referral services.

(ii) The type of incentive arrangement.

(iii) Whether stop-loss protection is provided.

(iv) If the prepaid plan was required to conduct a survey, a summary of the survey results.

(i) *Requirements related to subcontracting arrangements*—(1) *Physician groups.* An HMO or CMP that contracts with a physician group that places the individual physician members at substantial financial risk for services they do not furnish must do the following:

(i) Disclose to CMS any incentive plan between the physician group and its individual physicians that bases compensation to the physician on the use or cost of services furnished to Medicare beneficiaries or Medicaid beneficiaries. The disclosure must include the information specified in paragraphs (h)(1)(i) through (h)(1)(vii) of this section and be made at the times specified in paragraph (h)(2) of this section.

(ii) Provide adequate stop-loss protection to the individual physicians.

(iii) Conduct enrollee surveys as specified in paragraph (g)(1) of this section.

(2) *Intermediate entities.* An HMO or CMP that contracts with an entity (other than a physician group) for the provision of services to Medicare beneficiaries must do the following:

(i) Disclose to CMS any incentive plan between the entity and a physician or physician group that bases compensation to the physician or physician group on the use or cost of services furnished to Medicare beneficiaries or Medicaid beneficiaries. The disclosure must include the information required to be disclosed under paragraphs (h)(1)(i) through (h)(1)(vii) of this section and be made at the times specified in paragraph (h)(2) of this section.

(ii) If the physician incentive plan puts a physician or physician group at substantial financial risk for the cost of services the physician or physician group does not furnish—

(A) Meet the stop-loss protection requirements of this subpart; and

(B) Conduct enrollee surveys as specified in paragraph (g)(1) of this section.

(3) For purposes of paragraph (i)(2) of this section, an entity includes, but is not limited to, an individual practice association that contracts with one or more physician groups and a physician hospital organization.

(j) *Sanctions against the HMO or CMP.* CMS may apply intermediate sanctions, or the Office of Inspector General may apply civil money penalties described at § 417.500, if CMS determines that an HMO or CMP fails to comply with the requirements of this section.

[61 FR 13446, Mar. 27, 1996; 61 FR 46385, Sept. 3, 1996, as amended at 61 FR 69049, Dec. 31, 1996; 68 FR 50855, Aug. 22, 2003]

§ 417.480 Maintenance of records: Cost HMOs and CMPs.

A reasonable cost contract must provide that the HMO or CMP agrees to maintain books, records, documents, and other evidence of accounting procedures and practices that—

(a) Are sufficient to—

(1) Ensure an audit trail; and

(2) Properly reflect all direct and indirect costs claimed to have been incurred under the contract; and

(b) Include at least records of the following:

(1) Ownership, HMO or CMP, and operation of the HMO's or CMP's financial, medical, and other recordkeeping systems.

(2) Financial statements for the current contract period and three prior periods.

(3) Federal income tax or information returns for the current contract period and three prior periods.

(4) Asset acquisition, lease, sale, or other action.

(5) Agreements, contracts, and subcontracts.

(6) Franchise, marketing, and management agreements.

(7) Schedules of charges for the HMO's or CMP's fee-for-service patients.

(8) Matters pertaining to costs of operations.

(9) Amounts of income received by source and payment.

(10) Cash flow statements.

(11) Any financial reports filed with other Federal programs or State authorities.

[50 FR 1346, Jan. 10, 1985, as amended at 58 FR 38082, July 15, 1993; 60 FR 45680, Sept. 1, 1995]

§ 417.481 Maintenance of records: Risk HMOs and CMPs.

A risk contract must provide that the HMO or CMP agrees to maintain

and make available to CMS upon request, books, records, documents, and other evidence of acounting procedures and practices that—

(a) Are sufficient to—

(1) Establish component rates of the ACR for determining additional and supplementary benefits; and

(2) Determine the rates utilized in setting premiums for State insurance agency purposes; and

(b) Include at least any records or financial reports filed with other Federal agencies or State authorities.

[50 FR 1346, Jan. 10, 1985, as amended at 58 FR 38082, July 15, 1993; 60 FR 45680, Sept. 1, 1995]

§417.482 Access to facilities and records.

The contract must provide that the HMO or CMP agrees to the following:

(a) HHS may evaluate, through inspection or other means, the quality, appropriateness, and timeliness of services furnished under the contract to its Medicare enrollees.

(b) HHS may evaluate, through inspection or other means, the facilities of the HMO or CMP when there is reasonable evidence of some need for that inspection.

(c) HHS, the Comptroller General, or their designees may audit or inspect any books and records of the HMO or CMP or its transferee that pertain to any aspect of services performed, reconciliation of benefit liabilities, and determination of amounts payable under the contract.

(d) HHS may evaluate, through inspection or other means, the enrollment and disenrollment records for the current contract period and three prior periods, when there is reasonable evidence of some need for that inspection.

(e) In the case of a reasonable cost HMO or CMP to make available for the purposes specified in paragraphs (a), (b), (c), and (d) of this section, its premises, physical facilities, and equipment, its records relating to its Medicare enrollees, the records specified in §417.480 and any additional relevant information that CMS may require.

(f) That the right to inspect, evaluate, and audit, will extend through three years from the date of the final settlement for any contract period unless—

(1) CMS determines there is a special need to retain a particular record or group of records for a longer period and notifies the HMO or CMP at least 30 days before the normal disposition date;

(2) There has been a termination, dispute, fraud, or similar fault by the HMO or CMP, in which case the retention may be extended to three years from the date of any resulting final settlement; or

(3) CMS determines that there is a reasonable possibility of fraud, in which case it may reopen a final settlement at any time.

[50 FR 1346, Jan. 10, 1985, as amended at 58 FR 38082, July 15, 1993]

§417.484 Requirement applicable to related entities.

(a) *Definition.* As used in this section, *related entity* means any entity that is related to the HMO or CMP by common ownership or control and—

(1) Performs some of the HMO's or CMP's management functions under contract or delegation;

(2) Furnishes services to Medicare enrollees under an oral or written agreement; or

(3) Leases real property or sells materials to the HMO or CMP at a cost of more than $2,500 during a contract period.

(b) *Requirement.* The contract must provide that the HMO or CMP agrees to require all related entities to agree that—

(1) HHS, the Comptroller General, or their designees have the right to inspect, evaluate, and audit any pertinent books, documents, papers, and records of the subcontractor involving transactions related to the subcontract; and

(2) The right under paragraph (b)(1) of this section to information for any particular contract period will exist for a period equivalent to that specified in §417.482(f).

(3) That payments must not be made to individuals and entities included on

the preclusion list, defined in § 422.2 of this chapter.

[50 FR 1346, Jan. 10, 1985, as amended at 58 FR 38082, July 15, 1993; 81 FR 80556, Nov. 15, 2016; 83 FR 16721, Apr. 16, 2018]

§ 417.486 Disclosure of information and confidentiality.

The contract must provide that the HMO or CMP agrees to the following:

(a) To submit to CMS—

(1) All financial information required under subpart O of this part and for final settlement;

(2) Any other information necessary for the administration or evaluation of the Medicare program; and

(3) Risk adjustment data as specified in § 422.310 of this chapter for the purposes of determining an individual's health status. In applying this paragraph (a)(3), references to Medicare Advantage (MA) organizations in § 422.310 must be read to mean HMOs and CMPs.

(b) To comply with the requirements set forth in part 420, subpart C, of this chapter pertaining to the disclosure of ownership and control information.

(c) To comply with the requirements of the Privacy Act, as implemented by 45 CFR part 5b and subpart B of part 401 of this chapter, with respect to any system of records developed in performing carrier or intermediary functions under §§ 417.532 and 417.533.

(d) To meet the confidentiality requirements of § 482.24(b)(3) of this chapter for medical records and for all other enrollee information that is—

(1) Contained in its records or obtained from CMS or other sources; and

(2) Not covered under paragraph (c) of this section.

[50 FR 1346, Jan. 10, 1985, as amended at 58 FR 38082, July 15, 1993; 60 FR 45680, Sept. 1, 1995; 90 FR 15909, Apr. 15, 2025]

§ 417.488 Notice of termination and of available alternatives: Risk contract.

A risk contract must provide that the HMO or CMP agrees to give notice as follows if the contract is terminated:

(a) At least 60 days before the effective date of termination, to give its Medicare enrollees a written notice that—

(1) Specifies the termination date; and

(2) Describes the alternatives available for obtaining Medicare services after termination.

(b) To pay the cost of the written notices.

[60 FR 45680, Sept. 1, 1995]

§ 417.490 Renewal of contract.

A contract with an HMO or CMP is renewed automatically for the next 12-month period unless CMS or the HMO or CMP decides not to renew, in accordance with § 417.492.

[50 FR 1346, Jan. 10, 1985, as amended at 58 FR 38082, July 15, 1993]

§ 417.492 Nonrenewal of contract.

(a) *Nonrenewal by the HMO or CMP.* (1) If an HMO or CMP does not intend to renew its contract, it must—

(i) Give written notice to CMS at least 90 days before the end of the current contract period; and

(ii) Notify each Medicare enrollee by mail at least 60 days before the end of the contract period.

(2) CMS may accept a nonrenewal notice submitted less than 90 days before the end of a contract period if—

(i) The HMO or CMP notifies its Medicare enrollees and the public in accordance with paragraph (a)(1) of this section; and

(ii) Acceptance would not otherwise jeopardize the effective and efficient administration of the Medicare program.

(b) *Nonrenewal by CMS*—(1) *Notice of nonrenewal.* If CMS decides not to renew a contract, it gives written notice of nonrenewal as follows:

(i) To the HMO or CMP at least 90 days before the end of the contract period.

(ii) To the HMO's or CMP's Medicare enrollees at least 60 days before the end of the contract period.

(2) *Notice of appeal rights.* CMS gives the HMO or CMP written notice of its

right to appeal the nonrenewal decision, in accordance with part 422 subpart N of this chapter, if CMS's decision was based on any of the reasons specified in §417.494(b).

[50 FR 1346, Jan. 10, 1985, as amended at 58 FR 38079, July 15, 1993; 60 FR 45681, Sept. 1, 1995; 75 FR 19803, Apr. 15, 2010; 77 FR 22166, Apr. 12, 2012]

§417.494 Modification or termination of contract.

(a) *Modification or termination by mutual consent.* (1) CMS and an HMO or CMP may modify or terminate a contract at any time by written mutual consent.

(2) If the contract is modified, the HMO or CMP must notify its Medicare enrollees of any changes that CMS determines are appropriate for notification.

(3) If the contract is terminated, the HMO or CMP must notify its Medicare enrollees, and CMS notifies the general public, at least 30 days before the termination date.

(b) *Termination by CMS.* (1) CMS may terminate a contract for any of the following reasons:

(i) The HMO or CMP has failed substantially to carry out the terms of the contract.

(ii) The HMO or CMP is carrying out the contract in a manner that is inconsistent with the effective and efficient implementation of section 1876 of the Act.

(iii) The HMO or CMP has failed substantially to comply with the composition of enrollment requirements specified in §417.413(d).

(iv) CMS determines that the HMO or CMP no longer meets the requirements of section 1876 of the Act and this subpart for being an HMO or CMP.

(2) If CMS decides to terminate a contract, it sends a written notice informing the HMO or CMP of its right to appeal the termination in accordance with part 422 subpart N of this chapter.

(3) An HMO or CMP with a risk contract must notify its Medicare enrollees of the termination as described in §417.488.

(4) CMS notifies the HMO's or CMP's Medicare enrollees and the general public of the termination at least 30 days before the effective date of termination.

(c) *Termination by the HMO or CMP.* The HMO or CMP may terminate the contract if CMS has failed substantially to carry out the terms of the contract.

(1) The HMO or CMP must notify CMS at least 90 days before the effective date of the termination and must include in its notice the reasons for the termination.

(2) The HMO or CMP must notify its Medicare enrollees of the termination at least 60 days before the termination date. Risk HMOs or CMPs must also provide a written description of alternatives available for obtaining Medicare services after termination of the contract. The HMO or CMP is responsible for the cost of these notices.

(3) The HMO or CMP must notify the general public of the termination at least 30 days before the termination date.

(4) The contract is terminated effective 60 days after the HMO or CMP mails the notice to Medicare enrollees as required in paragraph (c)(2) of this section.

(5) CMS's liability for payment ends as of the first day of the month after the last month for which the contract is in effect.

[50 FR 1346, Jan. 10, 1985, as amended at 52 FR 22322, June 11, 1987; 56 FR 46571, Sept. 13, 1991; 58 FR 38079, 38082, July 15, 1993; 60 FR 45681, Sept. 1, 1995; 75 FR 19803, Apr. 15, 2010]

§417.496 Cost plan crosswalk.

(a) *General rules*—(1) *Definition.* Crosswalk means the movement of enrollees from one plan (or plan benefit package (PBP)) to another plan (or PBP) under a cost plan contract between the CMP or HMO and CMS. To crosswalk enrollees from one PBP to another is to change the enrollment from the first PBP to the second.

(2) *Prohibition.* (i) Crosswalks are prohibited between different contracts.

(ii) Crosswalks are prohibited between different plan IDs unless the crosswalk to a different plan ID meets the requirements in paragraph (c)(1)(i) of this section.

(3) *Compliance with renewal/nonrenewal rules.* The cost plan must comply with renewal and nonrenewal rules

in §§ 417.490 and 417.492 in order to complete plan crosswalks.

(b) *Allowable crosswalk types.* All cost plans may perform a crosswalk in the following circumstances:

(1) *Renewal.* A plan in the following contract year that links to a current contract year plan and retains the entire service area from the current contract year. The following contract year plan must retain the same plan ID as the current contract year plan.

(2) *Consolidated renewal.* A plan in the following contract year that combines 2 or more PBPs. The plan ID for the following contract year must retain one of the current contract year plan IDs.

(3) *Renewal with a service area expansion (SAE).* A plan in the following contract year plan that links to a current contract year plan and retains all of its plan service area from the current contract year, but also adds one or more new counties. The following year contract plan must retain the same plan ID as the current contract year plan.

(4) *Renewal with a service area reduction (SAR).* A plan in the following contract year that links to a current contract year plan and only retains a portion of its plan service area. The following contract year plan must retain the same plan ID as the current contract year plan. The crosswalk is limited to the enrollees in the remaining service area.

(c) *Exception.* (1) In order to perform a crosswalk that is not specified in paragraph (b) of this section, a cost organization must request an exception. CMS reviews requests and may permit a crosswalk exception in the following circumstance:

(i) Except as specified in paragraph (c)(1)(ii) of this section, terminating cost plans offering optional benefits may transfer enrollees from one of the PBPs under its contract to another PBP under its contract, including new PBPs that have no optional benefits or optional benefits different than those in the terminating PBP.

(ii) A terminating cost plan cannot move an enrollee from a PBP that does not include Part D to a PBP that does include Part D.

(iii) If the terminated supplemental benefit includes Part D and the new PBP does not, enrollees must receive written notification about the following:

(A) That they are losing Part D coverage;

(B) The options for obtaining Part D; and

(C) The implications of not getting Part D through some other means.

(2) [Reserved]

[86 FR 6093, Jan. 19, 2021]

§ 417.500 Intermediate sanctions for and civil monetary penalties against HMOs and CMPs.

(a) Except as provided in paragraph (c) of this section, the rights, procedures, and requirements related to intermediate sanctions and civil money penalties set forth in part 422 subparts O and T of this chapter also apply to Medicare contracts with HMOs or CMPs under sections 1876 of the Act.

(b) In applying paragraph (a) of this section, references to part 422 of this chapter must be read as references to this part and references to MA organizations must be read as references to HMOs or CMPs.

(c) In applying paragraph (a) of this section, the amounts of civil money penalties that can be imposed are governed by section 1876(i)(6)(B) and (C) of the Act, not by the provisions in part 422 of this chapter.

[75 FR 19803, Apr. 15, 2010]

Subpart M—Change of Ownership and Leasing of Facilities: Effect on Medicare Contract

§ 417.520 Effect on HMO and CMP contracts.

(a) The provisions set forth in subpart L of part 422 of this chapter also apply to Medicare contracts with HMOs and CMPs under section 1876 of the Act.

(b) In applying these provisions, references to ''M + C organizations'' must be read as references to ''HMOs and CMPs''.

(c) In § 422.550, reference to ''subpart K of this part'' must be read as reference to ''subpart L of part 417 of this chapter''.

(d) In §422.553, reference to ''subpart K of this part'' must be read as reference to ''subpart J of part 417 of this chapter''.

[63 FR 35067, June 26, 1998]

Subpart N—Medicare Payment to HMOs and CMPs: General Rules

§417.524 Payment to HMOs or CMPs: General.

(a) *Basic rule.* The payments that CMS makes to an HMO or CMP under this subpart and subparts O and P of this part for furnishing covered Medicare services are in place of any payment that CMS would otherwise make to a beneficiary or the HMO or CMP under sections 1814(b) and 1833(a) of the Act.

(b) *Basis of payment.* (1) CMS pays the HMOs or CMPs on either a reasonable cost basis or a risk basis depending on the type of contract the HMO or CMP has with CMS.

(2) In certain cases a risk HMO or CMP also receives payments on a reasonable cost basis for certain Medicare enrollees who retain nonrisk status, as provided in §417.444, after the HMO or CMP enters into a risk contract.

[60 FR 46229, Sept. 6, 1995]

§417.526 Payment for covered services.

Subpart O of this part set forth the principles that CMS follows in determining Medicare payment to an HMO or CMP that has a reasonable cost contract. Subpart P of this part describes the per capita method of Medicare payment to HMOs or CMPs that contract on a risk basis.

[50 FR 1346, Jan. 10, 1985; 50 FR 20570, May 17, 1985, as amended at 58 FR 38080, July 15, 1993; 60 FR 46229, Sept. 6, 1995]

§417.528 Payment when Medicare is not primary payer.

(a) *Limits on payments and charges.* (1) CMS may not pay for services to the extent that Medicare is not the primary payer under section 1862(b) of the Act and part 411 of this chapter.

(2) The circumstances under which an HMO or CMP may charge, or authorize a provider to charge, for covered Medicare services for which Medicare is not the primary payer are stated in paragraphs (b) and (c) of this section.

(b) *Charge to other insurers or the enrollee.* If a Medicare enrollee receives from an HMO or CMP covered services that are also covered under State or Federal worker's compensation, automobile medical, or any no-fault insurance, or any liability insurance policy or plan, including a self-insured plan, the HMO or CMP may charge, or authorize a provider that furnished the service to charge—

(1) The insurance carrier, employer, or other entity that is liable to pay for these services; or

(2) The Medicare enrollee, to the extent that he or she has been paid by the carrier, employer, or other entity.

(c) *Charge to group health plans (GHPs) or large group health plans (LGHPs).* An HMO or CMP may charge a GHP or LGHP for covered services it furnished to a Medicare enrollee and may charge the Medicare enrollee to the extent that he or she has been paid by the GHP or LGHP for these covered services if—

(1) The Medicare enrollee is covered under the plan; and

(2) Under section 1862(b) of the Act, CMS is precluded from paying for the covered services .

(d) *Responsibilities of HMO or CMP.* An HMO or CMP must—

(1) Identify payers that are primary to Medicare under section 1862(b) of the Act;

(2) Determine the amounts payable by these payers; and

(3) Coordinate the benefits of its Medicare enrollees with these payers.

[50 FR 1346, Jan. 10, 1985, as amended at 58 FR 38080, July 15, 1993; 60 FR 46229, Sept. 6, 1995]

Subpart O—Medicare Payment: Cost Basis

SOURCE: 50 FR 1346, Jan. 10, 1985, unless otherwise noted.

§417.530 Basis and scope.

This subpart sets forth the principles that CMS follows to determine the amount it pays for services furnished by a cost HMO or CMP to its Medicare enrollees. These principles are based on sections 1861(v) and 1876 of the Act and

are, for the most part, the same as those set forth—

(a) In part 412 of this chapter, for paying the costs of inpatient hospital services which, for cost HMOs and CMPs, are considered ''reasonable'' only if they do not exceed the amounts allowed under the prospective payment system; and

(b) In part 413 of this chapter, for the costs of all other covered services.

[60 FR 46230, Sept. 6, 1995]

§ 417.531 Hospice care services.

(a) If a Medicare enrollee of an HMO or CMP with a reasonable cost contract makes an election under § 418.24 of this chapter to receive hospice care services, payment for these services is made to the hospice that furnishes the services in accordance with part 418 of this chapter.

(b) While the enrollee's hospice election is in effect, CMS pays the HMO or CMP on a reasonable cost basis for only the following covered Medicare services furnished to the Medicare enrollee:

(1) Services of the enrollee's attending physician if the physician is an employee or contractor of the HMO or CMP and is not employed by or under contract to the enrollee's hospice.

(2) Services not related to the treatment of the terminal condition for which hospice care was elected or a condition related to the terminal condition.

[50 FR 1346, Jan. 10, 1985, as amended at 58 FR 38082, July 15, 1993; 60 FR 46230, Sept. 6, 1995]

§ 417.532 General considerations.

(a) *Conditions and criteria for payment.* (1) The costs incurred by the HMO or CMP to furnish services covered by Medicare are reimbursable if they are—

(i) Proper and necessary;

(ii) Reasonable in amount; and

(iii) Except as provided in § 417.550, appropriately apportioned among the HMO's or CMP's Medicare enrollees, other enrollees, and nonenrolled patients.

(2) In determining fair and equitable payment for the HMOs or CMPs, CMS generally applies the cost payment principles set forth in § 413.5 of this chapter.

(3) In judging whether costs are reasonable, CMS applies the weighted average of the AAPCCs of each class of the HMO's or CMP's Medicare enrollees (as defined in § 417.582) for the HMO's or CMP's geographic area as an absolute limitation on the total amount payable.

(b) *Method and amount of payment to the HMO or CMP.* (1) CMS makes interim per capita payments each month for each Medicare enrollee, equivalent to the interim per capita cost rate determined in accordance with § 417.570.

(2) CMS adjusts the interim per capita rate as necessary during the contract period and makes final adjustments at the end of the contract period.

(3) In determining the amount due the HMO or CMP, CMS deducts from the reasonable cost actually incurred by the HMO or CMP for covered services furnished to its Medicare enrollees, an amount equal to the actuarial value of the applicable Medicare Part A and Part B deductible and coinsurance amounts that would have applied to the covered services for which payment is being made if these enrollees had not enrolled in the HMO or CMP or another HMO or CMP.

(c) *Election by HMO or CMP.* An HMO or CMP must elect, on an individual provider basis, one of the following methods for payment for hospital and SNF services it furnishes to Medicare enrollees:

(1) Direct payment by CMS.

(2) Direct payment by the HMO or CMP.

(d) *Notice of election.* The election must be made in writing before the beginning of the contract period and is binding for that period.

(e) *Payment by HMO or CMP.* If the HMO or CMP elects to pay providers directly, as provided in paragraph (c) of this section, it must—

(1) Determine the eligibility of its Medicare enrollees to receive covered services through the HMO or CMP;

(2) Make proper coverage decisions and appropriate payments, in accordance with §§ 421.100 and 421.200 of this chapter, for the services furnished to its Medicare enrollees;

(3) Ensure that providers maintain and furnish appropriate documentation of physician certification and recertification, to the extent required under subpart B of part 424 of this chapter; and

(4) Carry out any other procedures required by CMS.

(f) *Review of HMO's or CMP's bill processing capabilities.* If the HMO or CMP elects to pay providers directly, CMS determines whether the HMO or CMP has the experience and capability to carry out the responsibilities specified in paragraph (e) of this section in an efficient and effective manner.

(g) *Direct payment by CMS.* (1) If the HMO or CMP elects to have CMS pay for provider services, CMS pays each provider on a reasonable cost basis or under the PPS system, whichever is appropriate for the particular provider under part 412 or part 413 of this chapter.

(2) In computing the Medicare payment to the HMO or CMP, CMS deducts these payments and any other payments made by the Medicare intermediary or carrier on behalf of the HMO or CMP (such as payment for emergency or urgently needed services under §417.558).

(h) *Payment for services furnished to Medicare beneficiaries not enrolled in the HMO or CMP.* CMS pays the HMO or CMP for services it furnishes to Medicare beneficiaries who are not its enrollees through the HMO's or CMP's Medicare intermediary or carrier, as appropriate.

[50 FR 1346, Jan. 10, 1985; 50 FR 20570, May 17, 1985, as amended at 53 FR 6648, Mar. 2, 1988; 58 FR 38082, July 15, 1993; 60 FR 46230, Sept. 6, 1995]

§417.533 Part B carrier responsibilities.

In paying for Part B services furnished to its enrollees by suppliers, the HMO or CMP must—

(a) Determine the eligibility of individuals to receive those services through the HMO or CMP;

(b) Make proper coverage decisions and appropriate payment as authorized under §421.200 of this chapter for the services for which its Medicare enrollees are eligible; and

(c) Carry out any other procedures that CMS may require.

[50 FR 1346, Jan. 10, 1985, as amended at 58 FR 38082, July 15, 1993; 60 FR 46230, Sept. 6, 1995]

§417.534 Allowable costs.

(a) *Definition—Allowable costs* means the direct and indirect costs, including normal standby costs incurred by the HMO or CMP, that are proper and necessary for efficient delivery of needed health care services. They include the costs of furnishing services to the HMO's or CMP's Medicare enrollees, other enrollees, and nonenrolled patients, which are typical ''provider'' costs, and costs (such as marketing, enrollment, membership, and operation of the HMO or CMP) that are peculiar to health care prepayment organizations.

(b) *Basic rules.* (1) The allowability of an HMO's or CMP's costs for furnishing services is generally determined in accordance with principles applicable to provider costs, as set forth in §417.536.

(2) The allowability of other costs is determined in accordance with principles set forth in §§417.538 through 417.550.

(3) Costs for covered services for which Medicare is not the primary payor, as described in §417.528, are not allowable.

(c) *Medicare Part D program costs.* To the extent that an HMO or CMP provides qualified prescription drug coverage to enrollees under Part D, no costs related to the offering or provision of Part D benefits are reimbursed under this part. These costs are reimbursed solely under the applicable provisions of part 423 of this chapter.

[50 FR 1346, Jan. 10, 1985, as amended at 58 FR 38082, July 15, 1993; 70 FR 4525, Jan. 28, 2005]

§417.536 Cost payment principles.

(a) *Applicability.* Unless otherwise specified in this subpart, the principles set forth in parts 412 and 413 of this chapter are applicable to the costs incurred by an HMO or CMP or by providers and other facilities owned or operated by the HMO or CMP or related to it by common ownership or control. The most common examples of these costs are set forth in this section.

(b) *Depreciation.* An appropriate allowance for depreciation on buildings and equipment is an allowable cost, in accordance with §§ 413.134, 413.144, and 413.149 of this chapter.

(c) *Interest expense.* Necessary and proper interest on both current and capital indebtedness is an allowable cost, in accordance with § 413.153 of this chapter.

(d) *Cost of educational activities.* An appropriate part of the net cost of approved educational activities of a provider or other health care facility owned or operated by an HMO or CMP is an allowable cost in accordance with § 413.85 of this chapter.

(e) *Compensation of owners.* An appropriate amount of compensation for services of owners is an allowable cost, if the services are actually performed and are necessary, as specified in § 413.102 of this chapter.

(f) *Bad debts.* (1) Bad debts attributable to Medicare deductible and coinsurance amounts are allowable only if the requirements of § 413.89 of this chapter are met, subject to the limitations described under § 413.89(h) and the exceptions for services described under § 413.89(i).

(2) If all or part of the deductible and coinsurance amounts is payable through a monthly premium or other periodic payment, the amount allowed as a bad debt may not exceed three times the monthly rate for the actuarial value of the deductible and coinsurance amounts, or its equivalent, if the periodic payment is on other than a monthly basis.

(3) Any bad debt related to a service furnished to a Medicare enrollee of the HMO or CMP, and claimed on a cost report submitted for payment by a provider or other facility reimbursed on a cost basis, may not be claimed as a bad debt by the HMO or CMP.

(g) *Charity and courtesy allowances.* As specified in § 413.89 of this chapter, charity and courtesy allowances are deductions from revenue and may not be included as allowable costs.

(h) *Research costs.* As specified in § 413.90 of this chapter, costs incurred for research purposes, over and above patient care, are not allowable costs.

(i) *Value of services of nonpaid workers.* The value of services of nonpaid workers of an organization is not an allowable cost, except as provided in § 413.94 of this chapter.

(j) *Purchase discounts and allowances and refund of expenses.* Discounts and allowances that an HMO or CMP receives on purchases of goods and services and refunds of previous expense payments must be deducted from the costs to which they relate, in accordance with § 413.98 of this chapter.

(k) *Cost to related entities.* (1) The costs of services, facilities, or supplies furnished to an HMO or CMP by a related entity are allowable at the cost to the related entity in accordance with § 413.17 of this chapter.

(2) An entity is not considered related to the HMO or CMP merely because—

(i) It has a risk or incentive agreement under which the HMO or CMP reimburses or compensates the entity for services it furnishes to the HMOs' or CMPs' enrollees; or

(ii) Substantially all the services the entity furnishes are furnished to the HMO's or CMP's enrollees.

(3) However, an entity described in paragraph (k)(2) of this section and an HMO or CMP are considered related if either of them is in a position to exercise significant management or ownership influence or control over the other.

(l) *Return on equity capital of proprietary providers owned by the HMO or CMP.* An allowance for a reasonable return on equity capital invested and used in providing services is allowable in addition to the reasonable cost of services furnished by a proprietary provider owned by the HMO or CMP. The amount of the allowance is determined in accordance with § 413.157 of this chapter.

(m) *Limitations on payment.* Medicare payment for covered services furnished by entities owned by or operated by, or related to, an HMO or CMP paid on a reasonable cost basis is subject to certain provisions of parts 412 and 413 of this chapter that pertain to reasonable cost and reasonable charge. Those provisions include, but are not necessarily limited to, the following:

(1) For ESRD treatment, the limitations authorized under § 413.170 of this chapter.

(2) For services of physical, occupational, and speech therapists and other therapists and nonphysician health specialists, the limitations set forth in § 413.106 of this chapter.

(3) For drugs, the allowable cost as determined under §§ 405.517 and 410.29 of this chapter.

(4) The overall cost limits established in accordance with § 413.30 of this chapter.

(5) The limitation to the lesser of reasonable cost or customary charges, as set forth in § 413.13 of this chapter.

[50 FR 1346, Jan. 10, 1985; 50 FR 20570, May 17, 1985, as amended at 51 FR 34832, Sept. 30, 1986; 51 FR 37398, Oct. 22, 1986; 58 FR 38080, July 15, 1993; 60 FR 46230, Sept. 6, 1995; 77 FR 67531, Nov. 9, 2012; 85 FR 59025, Sept. 18, 2020]

§ 417.538 Enrollment and marketing costs.

(a) *Principle.* Costs incurred by an HMO or CMP in performing the enrollment and marketing activities described in subpart k of this part are allowable.

(b) *Included costs.* Allowable enrollment and marketing costs are those necessary and proper costs incurred in offering the HMO's or CMP's plan to potential enrollees in accordance with this part. Those costs include selling, advertising, promotional, and other marketing costs and may not exceed an amount that would be incurred by a prudent and cost-conscious management.

(c) *Application.* Enrollment and marketing costs are allowable, whether incurred directly by HMO or CMP staff or under contract with marketing specialists or other outside consultants.

(d) *Limitation on payment.* The relatively higher costs that an HMO or CMP is likely to incur in initially offering its plan to Medicare beneficiaries are taken into account in determining whether enrollment and marketing costs are reasonable in amount. However, if those costs exceed amounts that would be paid by prudent management, the excess is not allowable.

[50 FR 1346, Jan. 10, 1985, as amended at 58 FR 38082, July 15, 1993; 60 FR 46230, Sept. 6, 1995]

§ 417.540 Enrollment costs.

(a) *Principle.* Enrollment costs are allowable if incurred in maintaining and servicing subscriber contracts for prepayment enrollees.

(b) *Kind of costs included.* Enrollment costs include, but are not limited to, reasonable costs incurred in connection with maintaining statistical, financial, and other data on enrollees.

[50 FR 1346, Jan. 10, 1985, as amended at 58 FR 38082, July 15, 1993]

§ 417.542 Reinsurance costs.

Reinsurance costs are not allowable.

§ 417.544 Physicians' services furnished directly by the HMO or CMP.

(a) *Principles.* (1) Compensation paid by an HMO or CMP to physicians is an allowable cost to the extent that it is commensurate with the compensation paid for similar services performed by similar physicians practicing in the same or a similar locality.

(2) Physician compensation may take various forms, but the aggregate compensation allowable must be reasonable in relation to the services personally furnished.

(3) If aggregate physician compensation costs exceed what is normally incurred, the excess is not a reasonable cost.

(b) *Application.* (1) In determining the allowability of the costs of physicians' services, the cost of personal services (for example, expenses attributable to salaries, wages, incentive payments, fringe benefits) must be distinguished from the cost of nonpersonal services (for example, expenses attributable to facilities, equipment, support personnel, supplies).

(2) To be allowable, compensation must be reasonable in relation to the personal services furnished.

[50 FR 1346, Jan. 10, 1985, as amended at 58 FR 38082, July 15, 1993; 60 FR 46230, Sept. 6, 1995]

§ 417.546 Physicians' services and other Part B supplier services furnished under arrangements.

General principle. The amount paid by an HMO or CMP for physicians' services and other Part B supplier services

furnished under arrangements is an allowable cost to the extent it is reasonable. Costs are considered reasonable if they—

(a) Do not exceed those that a prudent and cost-conscious buyer would incur to purchase those services; and

(b) Are comparable to costs incurred for similar services furnished by similar physicians or other suppliers in the same or a similar geographic area.

[50 FR 1346, Jan. 10, 1985, as amended at 58 FR 38082, July 15, 1993; 60 FR 34887, July 5, 1995; 60 FR 45372, Aug. 31, 1995]

§ 417.548 Provider services through arrangements.

(a) *Principle.* The cost incurred by an HMO or CMP for covered services furnished under arrangement with a provider is allowable to the extent that it would be allowable and payable under parts 412 and 413 of this chapter, unless the HMO or CMP petitions CMS and demonstrates to HFCA's satisfaction that payment in excess of the amount authorized under parts 412 and 413 of this chapter is justified on the basis of advantages gained by the HMO or CMP.

(b) *Application.* An advantage gained must represent a real and tangible benefit received by the HMO or CMP for the excess cost incurred, and any excess payment is subject to other applicable requirements of parts 405, 412 and 413 of this chapter, including tests of reasonableness.

(c) *Example.* In the case of an arrangement an HMO or CMP has with a provider that is located outside the HMO's or CMP's geographic area and that is not related to the HMO or CMP by common ownership or control, payment of the provider's charges to the HMO or CMP (rather than the payment amounts determined under part 412 or part 413 of this chapter) may be justified in exchange for the advantages of not having to incur the administrative costs of determining the provider's reasonable cost and of making a more timely final settlement with the HMO or CMP. However, repayment of the provider's charges would be acceptable only if—

(1) The provider furnishes services to the HMO's or CMP's enrollees infrequently;

(2) The charges represent an insignificant portion of total Medicare reimbursement to the HMO or CMP; and

(3) The charges do not exceed the customary charges by the provider to its other patients for similar services.

[50 FR 1346, Jan. 10, 1985, as amended at 51 FR 34832, Sept. 30, 1986; 58 FR 38080, July 15, 1993; 60 FR 46230, Sept. 6, 1995]

§ 417.550 Special Medicare program requirements.

(a) *Principle.* CMS pays the full reasonable cost incurred by an HMO or CMP for activities that are solely for Medicare purposes and unique to Medicare contracts under section 1876 of the Act.

(b) *Application.* CMS pays the full reasonable cost of the following activities:

(1) Reporting increases and decreases in the number of Medicare enrollees.

(2) Obtaining independent certification of the HMO's or CMP's cost report to the extent that it is for Medicare purposes.

(3) Reporting special data that CMS requires solely for program planning and evaluation.

(c) *Prior approval requirement.* The costs specified in paragraph (b) of this section must be separately budgeted and approved by CMS before the contract period begins.

(d) *Limit on full payment.* Full payment is limited to the costs specified in paragraph (b) of this section. All other administrative costs must be apportioned in accordance with § 417.552.

[60 FR 46230, Sept. 6, 1995]

§ 417.552 Cost apportionment: General provisions.

(a) *Basic rule.* The HMO or CMP must apportion its total allowable direct and indirect costs among its Medicare enrollees, its other enrollees, and its nonenrolled patients—

(1) In accordance with this subpart; and

(2) Using methods approved by CMS.

(b) *Purpose of apportionment.* The purpose of apportionment is to ensure that—

(1) The cost of services furnished to Medicare enrollees is not borne by other enrollees and nonenrolled patients; and

(2) The cost of the services furnished to other enrollees and nonenrolled patients is not borne by Medicare.

[50 FR 1346, Jan. 10, 1985, as amended at 58 FR 38082, July 15, 1993; 60 FR 46230, Sept. 6, 1995]

§417.554 Apportionment: Provider services furnished directly by the HMO or CMP.

The Medicare share of the cost of covered services furnished to Medicare enrollees by providers that are owned or operated by the HMO or CMP or are related to the HMO or CMP by common ownership or control must be determined in accordance with the apportionment methods set forth in part 412, §§413.24, 413.55, and 415.55 of this chapter.

[51 FR 28574, Aug. 8, 1986, as amended at 51 FR 34832, Sept. 30, 1986; 58 FR 38082, July 15, 1993; 60 FR 46231, Sept. 6, 1995; 60 FR 63189, Dec. 8, 1995]

§417.556 Apportionment: Provider services furnished by the HMO or CMP through arrangements with others.

The Medicare share of the cost of covered services furnished to Medicare enrollees through arrangements with providers other than those specified in §417.554 must be determined as follows:

(a) The Medicare share must be based on the cost the HMO or CMP pays the provider under their arrangement, to the extent that cost is reasonable and within the limits established by §§417.534 through 417.548.

(b) Except as specified in paragraph (c) of this section, apportionment must be on the same approved basis that is used by the provider for Medicare beneficiaries who are not Medicare enrollees of the HMO or CMP, subject to the conditions and limitations set forth in §417.548.

(c) If, because of the special nature or terms of the HMO's or CMP's arrangement with the provider, apportionment on the basis specified in paragraph (b) of this section would result in Medicare's bearing the costs of furnishing services to individuals other than the HMO's or CMP's Medicare enrollees, apportionment must be on another basis that is approved by CMS and that will ensure that Medicare does not pay any of the cost of furnishing services to individuals who are not Medicare enrollees of the HMO or CMP.

(d) If the HMO or CMP elects to have providers reimbursed by the HMO's or CMP's Medicare intermediary, the Medicare share is the amount the intermediary paid the provider.

[50 FR 1346, Jan. 10, 1985, as amended at 58 FR 38082, July 15, 1993]

§417.558 Emergency, urgently needed, and out-of-area services for which the HMO or CMP accepts responsibility.

(a) *Source of payment.* Either CMS or the HMO or CMP may pay a provider for emergency or urgently needed services or other covered out-of-area services for which the HMO or CMP accepts responsibility.

(b) *Limits on payment.* If the HMO or CMP pays, the payment amount may not exceed the amount that is allowable under part 412 or part 413 of this chapter.

(c) *Exception to limit on payment.* Payment in excess of the limit imposed by paragraph (b) of this section is allowable only if the HMO or CMP demonstrates to CMS's satisfaction that it is justified on the basis of advantages gained by the HMO or CMP, as set forth in §417.548.

[60 FR 46231, Sept. 6, 1995]

§417.560 Apportionment: Part B physician and supplier services.

(a) *Medical services furnished directly by the HMO or CMP.* The total allowable cost of Part B physician and supplier services furnished by employees or partners of the HMO or CMP or by a related entity of the HMO or CMP must be apportioned on the basis of the ratio of covered Part B services furnished to Medicare enrollees to total services furnished to all the HMO's or CMP's enrollees and nonenrolled patients. The HMO or CMP must use a method for reporting costs that is approved by CMS. CMS bases its approval on a finding that the method—

(1) Results in an accurate and equitable allocation of allowable costs; and

(2) Is justifiable from an administrative and cost efficiency standpoint.

(b) *Medical services furnished under arrangements made by the HMO or CMP.*

When the HMO or CMP pays for Part B physician and supplier services on some basis other than fee-for-service, the reasonable cost the HMO or CMP pays under its financial arrangement with the physician or supplier must be apportioned between Medicare enrollees and others based on the ratio of covered services furnished to Medicare enrollees to the total services furnished to all enrollees and nonenrolled patients. If apportionment on this basis would result in Medicare bearing the cost of furnishing services to individuals who are not Medicare enrollees, the Medicare share must be determined on another basis (approved by CMS) to ensure that Medicare pays only for services furnished to Medicare enrollees.

(c) *Medical services furnished under an arrangement that provides for the HMO or CMP to pay on a fee-for-service basis.* The Medicare share of the cost of Part B physician and supplier services furnished to Medicare enrollees under arrangements, and paid for by the HMO or CMP on a fee-for-service basis, is determined by multiplying the total amount for all such services by the ratio of charges for covered services furnished to Medicare enrollees to the total charges for all such services.

(d) *Emergency services, urgently needed services, and other covered medical services for which the HMO or CMP assumes financial responsibility.* The Medicare share of the cost of Part B emergency or urgently needed services or other Part B services that are not furnished by a provider and for which the HMO or CMP accepts financial responsibility is determined in accordance with paragraphs (b) and (c) of this section.

[50 FR 1346, Jan. 10, 1985, as amended at 58 FR 38082, July 15, 1993; 60 FR 34888, July 5, 1995]

§ 417.564 Apportionment and allocation of administrative and general costs.

(a) *Costs not directly associated with providing medical care.* Enrollment, marketing, and other administrative and general costs that benefit the total enrollment of the HMO or CMP and are not directly associated with furnishing medical care must be apportioned on the basis of a ratio of Medicare enrollees to the total HMO or CMP enrollment.

(b) *Costs significantly related to providing medical services.* (1) The following administrative and general costs, which bear a significant relationship to the services furnished, are not apportioned to Medicare directly; they must be allocated or distributed to the HMO or CMP components and then apportioned to Medicare in accordance with §§ 417.552 through 417.560:

(i) Facility costs.

(ii) Interest expense.

(iii) Medical record costs.

(iv) Centralized purchasing costs.

(v) Accounting and data processing costs.

(vi) Other administrative and general costs that are not included in paragraph (a) of this section.

(2) The allocation or distribution process must be as follows:

(i) If a separate entity or department of an HMO or CMP performs administrative functions the benefit of which can be quantitatively measured (such as centralized purchasing and data processing), the total allowable costs of this entity or department must be allocated or distributed to the components of the HMO or CMP in reasonable proportion to the benefits received by these components.

(ii) If a separate entity or department of an HMO or CMP performs administrative functions the benefit of which cannot be quantitatively measured (such as facility costs), the total allowable costs of this entity or department must be allocated or distributed to the components of the HMO or CMP on the basis of a ratio of total incurred and distributed costs per component to the total incurred and distributed costs for all components.

(iii) For the costs incurred under paragraphs (b)(1)(i) through (iv) of this section that include personnel costs, the organization must be able to identify the person hours expended for each administrative task and the rate of pay for those persons performing the tasks. Administrative tasks performed and rate of pay for the persons performing those tasks must match in terms of the skill level needed to accomplish those tasks. This information must be made available to CMS upon request.

(c) *Costs excluded from administrative costs.* In accordance with section 1861(v) of the Act, the following costs must be excluded from administrative costs:

(1) Donations.
(2) Fines and penalties.
(3) Political and lobbying activities.
(4) Charity or courtesy allowances.
(5) Spousal education.
(6) Entertainment.
(7) Return on equity.

[60 FR 46231, Sept. 6, 1995, as amended at 75 FR 19803, Apr. 15, 2010]

§417.566 Other methods of allocation and apportionment.

(a) *Justification.* A method of apportionment or allocation of costs, other than the methods prescribed in this subpart may be used if it results in a more accurate and equitable apportionment of allowable costs and is justifiable from an administrative and cost standpoint.

(b) *Required approval.* (1) An HMO or CMP that desires to use an alternative method must submit a written request for CMS approval at least 90 days before the beginning of the period for which the different method is to be used.

(2) If CMS approves use of a different method, the HMO or CMP may not revert to another method without first obtaining CMS's approval.

[50 FR 1346, Jan. 10, 1985, as amended at 58 FR 38082, July 15, 1993]

§417.568 Adequate financial records, statistical data, and cost finding.

(a) *Maintenance of records.* (1) An HMO or CMP must maintain sufficient financial records and statistical data for proper determination of costs payable by CMS for covered services the HMO or CMP furnished to its Medicare enrollees either directly or under arrangements with others. These include accurate and sufficient detail of incurred costs and enrollment data.

(2) Unless otherwise provided for in this subpart, the HMO or CMP must follow standardized definitions and accounting, statistics, and reporting practices that are widely accepted in the health care industry.

(b) *Provision of data.* (1) The HMO or CMP must provide adequate cost and statistical data, based on its financial and statistical records, that can be verified by qualified auditors.

(2) The cost data must be based on an approved method of cost finding and, except as provided in paragraph (b)(3) of this section, on the accrual method of accounting.

(3) For governmental institutions that use a cash basis of accounting, cost data developed on this basis is acceptable. However, only depreciation on capital assets, rather than the expenditure for the capital asset, is allowable.

(c) *Provider services furnished directly by the HMO or CMP.* If the HMO or CMP furnishes provider services directly, the provider is subject to the cost-finding and cost-reporting requirements set forth in parts 412 and 413 of this chapter. The provider must use an approved cost-finding method described in §413.24 of this chapter to determine the actual cost of these covered services.

(d) *Supplier services furnished directly by the HMO or CMP.* If the HMO or CMP furnishes Part B physician and supplier services directly, it must furnish statistics that indicate the frequency and type of service provided, in the form and detail prescribed by CMS.

(e) *Part B physician and supplier services furnished through arrangement.* If the HMO or CMP furnishes Part B physician and supplier services under arrangements with others, it must furnish to CMS statistical, financial, and other information with respect to those services in the form and detail prescribed by CMS.

[50 FR 1346, Jan. 10, 1985, as amended at 58 FR 38082, July 15, 1993; 60 FR 46231, Sept. 6, 1995]

§417.570 Interim per capita payments.

(a) *Principle of payment.* (1) CMS makes monthly advance payments equivalent to the HMO's or CMP's interim per capita rate for each beneficiary who is registered in CMS records as a Medicare enrollee of the HMO or CMP.

(2) Additional lump-sum payments may be made at other times during the contract period, at CMS's discretion, to adjust the total amounts paid during the contract period to the level of incurred costs.

(b) *Determination of rate.* The interim per capita rate of payment is equal to the estimated per capita cost of providing covered services to the HMO's or CMP's Medicare enrollees, based upon the types and components of costs that are reimbursable under this part. The interim per capita rate is determined annually by CMS on the basis of the HMO's or CMP's annual operating and enrollment forecast (as set forth in § 417.572) and may be revised during the contract period as explained in paragraphs (c) and (d) of this section.

(c) *Adjustments of payments.* In order to maintain the interim payments at the level of current reasonable costs, CMS will adjust the interim per capita rate, to the extent necessary, on the basis of adequate data supplied by the HMO or CMP in its interim estimated cost and enrollment reports or on other evidence showing that the rate based on actual costs is more or less than the current rate. Adjustments may also be made if there is—

(1) A change in the number of Medicare enrollees that affects the per capita rate;

(2) A material variation from the costs estimated when the annual operating budget was prepared; or

(3) A significant change in the use of covered services by the HMO's or CMP's Medicare enrollees.

(d) *Reduction of interim payments.* If the HMO or CMP does not submit, on time, the reports and other data required to determine the proper amount of payment, CMS may reduce interim payments to the extent appropriate, or may take any other action authorized under this part. An interim payment reduction remains in effect until CMS can make a reasonable estimate of per capita costs.

[50 FR 1346, Jan. 10, 1985, as amended at 58 FR 38082, July 15, 1993]

§ 417.572 Budget and enrollment forecast and interim reports.

(a) *Annual submittal.* The HMO or CMP must submit an annual operating budget and enrollment forecast, in the form and detail required by CMS, at least 90 days before the beginning of each contract period. The forecast must be based on financial and statistical data and records that can be verified if CMS requires a detailed review of supporting records. The data and records include, but are not limited to, all ledgers, books, records, and original evidence of costs, and statistical data used in the determination of reasonable cost.

(b) *Effect of failure to submit on time.* If the HMO or CMP does not submit the budget and enrollment forecast on time, CMS may—

(1) Establish an interim per capita rate of payment on the basis of the best available data and adjust payments on the basis of that rate until the required reports are submitted and a new interim per capita rate can be established; or

(2) If there is not enough data on which to base an interim per capita rate, inform the HMO or CMP that interim payments will not be made until the required reports are submitted.

(c) *Interim cost reports.* (1) An HMO or CMP must submit interim cost reports on a quarterly basis in the form and detail prescribed by CMS. These interim cost reports must be submitted no later than 60 days after the close of each quarter of the contract period.

(2) CMS may reduce the frequency of the reports required under paragraph (c)(1) of this section if CMS determines that, on the basis of the HMO's or CMP's reporting experience, there is good cause to do so.

[50 FR 1346, Jan. 10, 1985, as amended at 58 FR 38082, July 15, 1993]

§ 417.574 Interim settlement.

(a) *Determination.* Within 30 days following the receipt of the HMO's or CMP's final interim cost and enrollment reports, CMS will make an interim determination of the estimated amount payable to the HMO or CMP for the reasonable cost of covered services furnished to its Medicare enrollees during the contract period. CMS will base the determination on the interim cost report and enrollment data submitted by the HMO or CMP, and any other relevant data CMS finds appropriate. For this purpose, CMS will accept costs as reported, subject to later review or audit, unless there are obvious errors or inconsistencies.

(b) *Payment.* Any difference between the total amount of interim payments

and the amount found payable on the basis of the interim determination under paragraph (a) of this section, must be paid by the HMO or CMP or will be paid by CMS, whichever is appropriate, no later than 30 days after CMS's determination.

[50 FR 1346, Jan. 10, 1985, as amended at 58 FR 38082, July 15, 1993]

§417.576 Final settlement.

(a) *General rule.* Final settlement and payment of amounts due the HMO or CMP or the appropriate Medicare trust funds are made following the HMO's or CMP's submission and CMS's review of an independently certified cost report and supporting documents as described in paragraph (b) of this section.

(b) *Certified cost report as basis for final settlement*—(1) *Timing of cost report.* The HMO or CMP must submit to CMS an independently certified cost report and supporting documents, in the form and detail required by CMS, no later than 180 days after the end of each contract period, unless CMS extends the period for good cause shown by the HMO or CMP.

(2) *Content of cost report.* The cost report and supporting documents must include the following:

(i) The per capita costs incurred in furnishing covered services to its Medicare enrollees, determined in accordance with subpart O of this part and including—

(A) The costs incurred by entities related to the HMO or CMP by common ownership or control; and

(B) For reports for cost-reporting periods that begin on or after January 1, 1996, the costs of hospital and SNF services paid by Medicare's intermediaries under the option provided by §417.532(d).

(ii) The HMO's or CMP's methods of apportioning cost among Medicare enrollees, and nonenrolled patients, in accordance with the payment procedures specified in this subpart (as, applicable, in parts 412 and 413 of this chapter); and

(iii) Any other information required by CMS.

(3) *Failure to report required financial information.* If the HMO or CMP fails to submit the required cost report and supporting documents within 180 days (or an extended period approved by CMS under paragraph (b)(1) of this section), CMS may—

(i) Consider the failure to report as evidence of likely overpayment; and

(ii) Initiate recovery of amounts previously paid, or reduce interim payments, or both.

(c) *Final determination and adjustment.* (1) After receipt of acceptable reports as specified in paragraph (b) of this section, CMS determines the total payment due the HMO or CMP for furnishing covered services to its Medicare enrollees (which is subject to the audit provisions of this subpart) and makes a retroactive adjustment to bring interim payments into agreement with the payable amount due the HMO or CMP.

(2) A final settlement may be made with the HMO or CMP even though a provider that is not owned or operated by the HMO or CMP or related to the HMO or CMP by common ownership or control and that provides services to the HMO's or CMP's Medicare enrollees has not had a final settlement with CMS under parts 412 and 413 of this chapter for services furnished by the provider to Medicare beneficiaries who are not enrolled in the HMO or CMP. In this situation—

(i) CMS must be satisfied that the costs of covered services furnished to the HMO's or CMP's Medicare enrollees, as shown in the reports specified in paragraph (b) of this section, are reasonable and that the interest of the Medicare program would best be served by not delaying final settlement with the HMO or CMP until there is a final settlement with the provider for services furnished to Medicare beneficiaries not enrolled in the HMO or CMP; and

(ii) Prompt settlement with the HMO or CMP would be in the best interest of the Medicare program if, for instance, the provider's costs represent an insignificant portion of total payment due to the HMO or CMP; or if CMS is satisfied that the provider's costs, as shown in the reports specified in paragraph (b) of this section, will not be modified, to any significant extent, by the final settlement with the provider under parts 412 and 413 of this chapter.

(d) *Notice of amount of payment.* The notice of amount of Medicare payment—

(1) Explains CMS's determination regarding total Medicare payment due the HMO or CMP for the contract period covered by the financial information specified in paragraph (b) of this section;

(2) Relates this determination to the HMO's or CMP's claimed total payable cost for that period;

(3) Explains the amounts and reasons, by appropriate reference to law, regulations, and Medicare program policy and procedures, if the determined amounts differ from the HMO's or CMP's claim; and

(4) Informs the HMO or CMP of its right to a hearing in accordance with the requirements specified in § 405.1801(b)(2) of this chapter

(e) *Basis for retroactive adjustment.* (1) CMS's determination (as contained in the notice of amount of Medicare payment) constitutes the basis for making retroactive adjustments to any Medicare payment made to the HMO or CMP during the period to which the determination applies.

(2) Further payments to the HMO or CMP may be withheld or offset in order to recover, or to aid in the recovery of, any overpayment identified in the determination as having been made to the HMO or CMP, even if the HMO or CMP requests a hearing in accordance with the requirements specified in § 405.1801(b)(2) of this chapter.

(3) Any withholding continues until the earliest of the following occurs:

(i) The overpayment is liquidated.

(ii) The HMO or CMP enters into an agreement with CMS to refund the overpaid amount.

(iii) CMS, on the basis of subsequently acquired information, determines that there was no overpayment.

(iv) The decision of a hearing specified in paragraph (d)(4) of this section is that there was no overpayment.

[50 FR 1346, Jan. 10, 1985, as amended at 51 FR 34833, Sept. 30, 1986; 58 FR 38082, July 15, 1993; 60 FR 34888, July 5, 1995; 60 FR 46231, Sept. 6, 1995; 73 FR 30267, May 23, 2008]

Subpart P—Medicare Payment: Risk Basis

SOURCE: 50 FR 1346, Jan. 10, 1985, unless otherwise noted.

§ 417.580 Basis and scope.

(a) *Basis.* This subpart implements those portions of section 1876 (a), (e), and (g) of the Act that pertain to the amount CMS pays an organization for its Medicare enrollees who are enrolled on a risk basis.

(b) *Scope.* This subpart sets forth—

(1) Method of payment;

(2) Procedures for determining the HMO's or CMP's payment rate; and

(3) Procedures for determining the additional benefits (and their value) the HMO or CMP must provide to its Medicare enrollees.

[50 FR 1346, Jan. 10, 1985; 50 FR 20570, May 17, 1985, as amended at 58 FR 38080, July 15, 1993; 60 FR 46231, Sept. 6, 1995]

§ 417.582 Definitions.

As used in this subpart—

AAPCC stands for adjusted average per capita cost.

ACR stands for adjusted community rate.

Actuarial factors means factors such as the age, sex, and disability level distribution of the population and any other relevant factors that CMS determines have a significant effect on the level of utilization and cost of health services.

APCRP stands for average of per capita rates of payment.

Class of Medicare enrollees means a group of Medicare enrollees of an HMO or CMP that CMS constructs on the basis of actuarial factors.

Similar area means an area similar to the HMO's or CMP's geographic area but free from special characteristics that would distort the determination of the AAPCC.

U.S. per capita incurred cost means the average per capita cost, including intermediary or carrier administrative costs, incurred by Medicare, as determined on an accrual basis, for covered services furnished to Medicare beneficiaries nationwide during the most

recent period for which CMS has complete data.

[50 FR 1346, Jan. 10, 1985; 50 FR 20570, May 17, 1985, as amended at 58 FR 38080, July 15, 1993; 60 FR 46232, Sept. 6, 1995]

§417.584 Payment to HMOs or CMPs with risk contracts.

Except in the circumstances specified in §417.440(d) for inpatient hospital care, and as provided in §417.585 for hospice care, CMS makes payment for covered services only to the HMO or CMP.

(a) *Principle of payment.* CMS makes monthly advance payments equivalent to the HMO's or CMP's per capita rate of payment for each beneficiary who is registered in CMS records as a Medicare enrollee of the HMO or CMP.

(b) *Determination of rate.* (1) The annual per capita rate of payment for each class of Medicare enrollees is equal to 95 percent of the AAPCC (as determined under the provisions of §417.588) for that class of Medicare enrollees.

(2) CMS furnishes each HMO or CMP with its per capita rate of payment for each class of Medicare enrollees not later than 90 days before the beginning of the HMO's or CMP's contract period.

(c) *Adjustments to payments.* If the actual number of Medicare enrollees differs from the estimated number on which the amount of advance monthly payment was based, CMS adjusts subsequent monthly payments to take account of the difference.

(d) *Reduction of payments.* If an HMO or CMP requests a reduction in its monthly payment in accordance with §417.592(b)(2), CMS reduces the amount of payment by the appropriate amount.

(e) *Determination of rate for calendar year 1998.* For calendar year 1998, HMOs or CMPs with risk contracts will be paid in accordance with principles contained in subpart F of part 422 of this chapter.

[50 FR 1346, Jan. 10, 1985; 50 FR 20570, May 17, 1985, as amended at 52 FR 8901, Mar. 20, 1987; 58 FR 38082, July 15, 1993; 60 FR 46232, Sept. 6, 1995; 63 FR 35067, June 26, 1998]

§417.585 Special rules: Hospice care.

(a) No payment is made to an HMO or CMP on behalf of a Medicare enrollee who has elected hospice care under §418.24 of this chapter except for the portion of the payment applicable to the additional benefits described in §417.592. This no-payment rule is effective from the first day of the month following the month of election to receive hospice care, until the first day of the month following the month in which the enrollee resumes normal Medicare coverage.

(b) During the time the election is in effect, the HMO or CMP may bill CMS on a fee-for-service basis (subject to the usual Medicare rules of payment) but only for the following covered Medicare services:

(1) Services of the enrollee's attending physician if the physician is an employee or contractor of the HMO or CMP and is not employed by or under contract to the enrollee's hospice.

(2) Services not related to the treatment of the terminal condition for which the enrollee elected hospice care or a condition related to the terminal condition.

(3) Services furnished after the revocation or expiration of the enrollee's hospice election until the full monthly capitation payments begin again.

(c) Payment for hospice care services furnished to Medicare enrollees of an HMO or CMP is made to the Medicare-participating hospice elected by the enrollee.

[50 FR 1346, Jan. 10, 1985, as amended at 58 FR 38082, July 15, 1993; 60 FR 46232, Sept. 6, 1995]

§417.588 Computation of adjusted average per capita cost (AAPCC).

(a) *Basic data.* In computing the AAPCC, CMS uses the U.S. per capita incurred cost and adjusts it by the factors specified in paragraph (c) of this section to establish an AAPCC for each class of Medicare enrollees.

(b) *Advance notice to the HMO or CMP.* Before the beginning of a contract period, CMS informs the HMO or CMP of the specific adjustment factors it will use in computing the AAPCC.

(c) *Adjustment factors*—(1) *Geographic.* CMS makes an adjustment to reflect the relative level of Medicare expenditures for beneficiaries who reside in the HMO's or CMP's geographic area (or a similar area). This adjustment is based

on reimbursement for Medicare covered services and uses the most accurate and timely data that pertain to the HMO's or CMP's geographic area and that is available to CMS when it makes the determination.

(2) *Enrollment.* CMS makes a further adjustment to remove the cost effect of all area Medicare beneficiaries who are enrolled in the HMO or CMP or another HMO or CMP.

(3) *Age, sex, and disability status.* CMS makes adjustments to reflect the age and sex distribution and the disability status of the HMO's or CMP's enrollees based on Medicare program experience and available data that indicate cost differences that result from those factors.

(4) *Other relevant factors.* If accurate data are available and appropriate, CMS makes adjustments to reflect welfare and institutional status and other relevant factors.

[50 FR 1346, Jan. 10, 1985, as amended at 58 FR 38083, July 15, 1993; 60 FR 46232, Sept. 6, 1995]

§ 417.590 Computation of the average of the per capita rates of payment.

(a) *Computation by the HMO or CMP.* As indicated in § 417.584(b), before an HMO's or CMP's contract period begins, CMS determines a per capita rate of payment for each class of the HMO's or CMP's Medicare enrollees. In order to determine the additional benefits required under § 417.592, weighted averages of those per capita rates must be computed separately for enrollees entitled to Part A and Part B, and for enrollees entitled only to Part B. Except as provided in paragraph (b) of this section, the HMO or CMP must make the computations.

(b) *Computation by CMS.* If the HMO or CMP claims to have insufficient enrollment experience to make the computations required by paragraph (a) of this section, and CMS agrees with the claim, CMS makes the computations, using the best available information, which may include the enrollment experience of other risk HMOs and CMPs.

[58 FR 38075, July 15, 1993]

§ 417.592 Additional benefits requirement.

(a) *General rules.* (1) An HMO or CMP that has an APCRP (as determined under § 417.590) greater than its ACR (as determined under § 417.594) must elect one of the options specified in paragraph (b) of this section.

(2) The dollar value of the elected option must, over the course of a contract period, be at least equal to the difference between the APCRP and the proposed ACR.

(b) *Options*—(1) *Additional benefits.* Provide its Medicare enrollees with additional benefits in accordance with paragraph (c) of this section.

(2) *Payment reduction.* Request CMS to reduce its monthly payments.

(3) *Combination of additional benefits and payment reduction.* Provide fewer than the additional benefits required under paragraph (b)(1) of this section and request CMS to reduce the monthly payments by the remaining difference between the APCRP and the ACR.

(4) *Combination of additional benefits and withholding in a stabilization fund.* Provide fewer than the additional benefits required under paragraph (b)(1) of this section, and request CMS to withhold in a stabilization fund (as provided in § 417.596) the remaining difference between the APCRP and the ACR.

(c) *Special rules: Additional benefits option.* (1) The HMO or CMP must determine additional benefits separately for enrollees entitled to both Part A and Part B benefits and those entitled only to Part B.

(2) The HMO or CMP may elect to provide additional benefits in any of the following forms—

(i) A reduction in the HMO's or CMP's premium or in other charges it imposes in the form of deductibles or coinsurance.

(ii) Health benefits in addition to the required Part A and Part B covered services.

(iii) A combination of reduced charges and additional benefits.

(d) *Notification to CMS.* (1) The HMO or CMP must give CMS notice of its ACR and its weighted APCRP at least 45 days before its contract period begins.

(2) An HMO or CMP that elects the option of providing additional benefits must include in its submittal—

(i) A description of the additional benefits it will provide to its Medicare enrollees; and

(ii) Supporting evidence to show that the selected benefits meet the requirements of paragraph (a)(2) of this section with respect to dollar value equivalence.

[60 FR 46232, Sept. 6, 1995]

§417.594 Computation of adjusted community rate (ACR).

(a) *Basic rule.* Each HMO or CMP must compute its basic rate as follows:

(1) Compute an initial rate in accordance with paragraph (b) of this section.

(2) Adjust and reduce the initial rate in accordance with paragraphs (c) and (d) of this section.

(b) *Computation of initial rates.* (1) The HMO or CMP must compute its initial rate using either of the following systems:

(i) A community rating system as defined in §417.104(b); or

(ii) A system, approved by CMS, under which the HMO or CMP develops an aggregate premium for all its enrollees and weights the aggregate by the size of the various enrolled groups that compose its enrollment.

(For purposes of this section, enrolled groups are defined as employee groups or other bodies of subscribers that enroll in the HMO or CMP through payment of premiums.)

(2) Regardless of which method the HMO or CMP uses—

(i) The initial rate must be equal to the premium it would charge its non-Medicare enrollees for the Medicare-covered services;

(ii) The HMO or CMP must compute the rates separately for enrollees entitled to Medicare Part A and Part B and for those entitled only to Part B; and

(iii) The HMO or CMP must identify and take into account anticipated revenue from health insurance payers for those services for which Medicare is not the primary payer as provided in §417.528.

(3) Except as provided in paragraph (b)(4) of this section, the HMO or CMP must identify in its initial rate calculation, the following components whose rates must be consistent with rates used by the HMO or CMP in calculating premiums for non-Medicare enrollees:

(i) Hospital services (services covered under Medicare Part A and Part B shown separately).

(ii) Physicians' services.

(iii) Other medical services (for example, X-ray and laboratory services).

(iv) Home health services.

(v) Out-of-plan claims for emergency services.

(vi) Skilled nursing care services.

(vii) Ambulance services.

(viii) Other Medicare covered services.

(ix) General and administrative.

(x) Noncovered Medicare services (for example, eyeglasses).

(xi) Services for which Medicare is the secondary payer.

(xii) Enrollee liabilities (for example, deductibles, coinsurance, or copayments) for covered services.

(4) An HMO or CMP that does not usually separate its premium components as described in paragraph (b)(3) of this section may calculate its initial rate with the methods it uses for its other enrolled groups if the HMO or CMP provides CMS with the documentation necessary to support any adjustments the HMO or CMP makes to the initial rate in accordance with paragraph (e) of this section.

(5) The initial rate calculation must not carry forward any losses experienced by the HMO or CMP during prior contract periods. The HMO or CMP must submit supporting documentation to assure CMS that rates do not include past losses but only premiums for the price of additional benefits and services of the upcoming contract period.

(c) *Adjustment of initial rates*—(1) *Purpose of adjustment.* The purpose of adjustment is to reflect the utilization characteristics of Medicare enrollees.

(2) *Adjustment by the HMO or CMP.* The HMO or CMP may adjust the rate for a particular service using more than one of the following factors if they do not duplicate each other:

(i) *Unit of service.* If the HMO or CMP purchases or identifies services on a unit of service basis and the unit of

service is defined the same for all enrollees, the HMO or CMP may make an adjustment in its initial rate to reflect the number of units of services furnished to its Medicare enrollees in comparison to those furnished to other enrollees.

(ii) *Complexity or intensity of services.* The HMO or CMP may make an adjustment to reflect the differences in the complexity or intensity of services furnished to its Medicare enrollees if the calculation of its initial rate includes the elements of this adjustment.

(3) *Support documentation.* All adjustments made by the HMO or CMP must be accompanied by adequate supporting data. If an HMO or CMP does not have sufficient enrollment experience to develop this data, it may, during its initial contract period, use documented statistics from a nationally recognized statistical source.

(4) *Adjustment by CMS.* If the HMO or CMP does not have adequate data to adjust the initial rate calculated under paragraph (b) of this section to reflect the utilization characteristics of its Medicare enrollees, CMS will, at the HMO's or CMP's request, adjust the initial rate. CMS adjusts the rate on the basis of differences in the utilization characteristics of—

(i) Medicare and non-Medicare enrollees in other HMOs or CMPs; or

(ii) Medicare beneficiaries (in the HMO's or CMP's area, or State, or the United States) who are eligible to enroll in an HMO or CMP and other individuals in that same area, or State, or the United States.

(d) *Reduction of adjusted rates.* The HMO or CMP or CMS further reduces the adjusted rates by the actuarial value of applicable Medicare deductibles and coinsurance.

(e) *CMS review*—(1) *Submission of data.* The HMO or CMP must submit its ACR and the methodology used to compute it for CMS review and approval, and must include adequate supporting data.

(2) *Appeals procedures.* (i) If CMS determines that an HMO's or CMP's ACR computation is not acceptable, the HMO or CMP may, within 30 days after receipt of notice of the determination, file with CMS a request for a hearing.

(ii) The request must state why the HMO or CMP believes the determination is incorrect, and include any supporting evidence the HMO or CMP considers pertinent.

(iii) A hearing officer designated by CMS conducts the hearing in accordance with the hearing procedures set forth in §§ 405.1819 through 405.1833 of this chapter.

[50 FR 1346, Jan. 10, 1985, as amended at 58 FR 38080, July 15, 1993; 60 FR 46232, Sept. 6, 1995]

§ 417.596 Establishment of a benefit stabilization fund.

(a) *General.* If an HMO or CMP is required to provide its Medicare enrollees with additional benefits as described in § 417.592, the organization may request that CMS withhold a part of its monthly per capita payment in a benefit stabilization fund. The fund will be used to prevent excessive fluctuation in the provision of those additional benefits in subsequent contract periods.

(b) *Notification to CMS.* An HMO's or CMP's request to have monies withheld in a benefit stabilization fund must be made when the HMO or CMP notifies CMS under § 417.592(d) of its ACR and its APCRP in preparation for its next contract period.

(c) *Limitations on the amounts withheld*—(1) *Limit per contract period.* Except as provided in paragraph (c)(3) of this section, CMS does not withhold in a benefit stabilization fund more than 15 percent of the difference between an HMO's or CMP's ACR and its ACPRP for a given contract period.

(2) *Cumulative limit.* If CMS has established a benefit stabilization fund for an HMO or CMP, it does not approve a request for withholding made by that HMO or CMP for a subsequent contract period that would cause the total value of the benefit stabilization fund to exceed 25 percent of the difference between the HMO's or CMP's ACR and the average of its per capita rates of payment for that subsequent contract period.

(3) *Exception.* CMS may grant an exception to the limit described in paragraph (c)(1) of this section if an HMO or CMP can demonstrate to CMS's satisfaction that the value of the additional

benefits it provides to its Medicare enrollees fluctuates substantially in excess of 15 percent from one contract period to another.

(d) *Financial management of benefit stabilization funds.* (1) The amounts withheld by CMS to establish and maintain a benefit stabilization fund are in the custody of the Federal Health Insurance Trust Fund and the Federal Supplementary Medical Insurance Trust Fund.

(2) The amounts withheld in a benefit stabilization fund are accounted for by CMS in accounts in which interest does not accrue to the HMO or CMP.

[50 FR 1346, Jan. 10, 1985; 50 FR 20570, May 17, 1985, as amended by 56 FR 46571, Sept. 13, 1991; 58 FR 38083, July 15, 1993; 60 FR 46233, Sept. 6, 1995]

§417.597 Withdrawal from a benefit stabilization fund.

(a) *Notification to CMS.* An HMO's or CMP's request to make a withdrawal from its benefit stabilization fund for use during a contract period must be made when the HMO or CMP notifies CMS of its ACR and its ACPRP for that contract period. In making its request, the HMO or CMP must—

(1) Indicate how it intends to use the withdrawn amounts;

(2) Justify the need for the withdrawal in terms of stabilizing the additional benefits it provides to Medicare enrollees;

(3) Document the HMO's or CMP's experience with fluctuations of revenue requirements relative to the additional benefits it provides to Medicare enrollees; and

(4) Document its experience during the contract period previous to the one for which it requests withdrawal to ensure that the HMO or CMP will not be using the withdrawn amounts to refinance losses suffered during that previous contract period.

(b) *Criteria for CMS approval.* CMS approves a request for a withdrawal from a benefit stabilization fund for use during the next contract period only if—

(1) The HMO's or CMP's average of its per capita rates of payment for the next contract period is less than that of the previous contract period;

(2) The HMO's or CMP's ACR for the next contract period is significantly higher than that of the previous contract period; or

(3) The HMO's or CMP's revenue requirements for the next contract period for providing the additional benefits it provided during the previous contract period is significantly higher than the requirements for that previous period and the ACR for the next contract period results in an additional benefits package that is less in total value than that of the previous contract period.

(c) *Basis for denial.* CMS does not approve a request for a withdrawal from a benefit stabilization fund if the withdrawal would allow the HMO or CMP to—

(1) Offer without charge the supplemental services it provides to its Medicare enrollees under the provisions of §417.440 (b)(2) or (b)(3); or

(2) Refinance prior contract period losses or to avoid losses in the upcoming contract period.

(d) *Form of payment.* Payment of monies withdrawn from a benefit stabilization fund is made, in equal parts, as an additional amount to the monthly advance payment made to the HMO or CMP under §417.584 during the period of the contract.

[58 FR 38075, July 15, 1993, as amended at 60 FR 46233, Sept. 6, 1995]

§417.598 Annual enrollment reconciliation.

CMS's payment to an HMO or CMP may be subject to an enrollment reconciliation at least annually. CMS conducts this reconciliation as necessary to ensure that the payments made do not exceed or fall short of the appropriate per capita rate of payment for each Medicare enrollee of the HMO or CMP during the contract period. The HMO or CMP must submit any information or reports required by CMS to conduct the reconciliation.

[50 FR 1346, Jan. 10, 1985, as amended at 58 FR 38080, July 15, 1993; 60 FR 46233, Sept. 6, 1995]

Subpart Q—Beneficiary Appeals

§ 417.600 Basis and scope.

(a) *Statutory basis.* (1) Section 1869 of the Act provides the right to a redetermination, reconsideration, hearing, and judicial review for individuals dissatisfied with a determination regarding their Medicare benefits.

(2) Section 1876 of the Act provides for Medicare payments to HMOs and CMPs that contract with CMS to enroll Medicare beneficiaries and furnish Medicare-covered health care services to them.

(3) Section 234 of the MMA requires section 1876 contractors to operate under the same provisions as MA plans where two plans of the same type enter the cost plan contract's service area.

(b) *Applicability.* (1) The rights, procedures, and requirements relating to beneficiary appeals and grievances set forth in subpart M of part 422 of this chapter also apply to Medicare contracts with HMOs and CMPs under section 1876 of the Act.

(2) In applying those provisions, references to section 1852 of the Act must be read as references to section 1876 of the Act, and references to MA organizations as references to HMOs and CMPs.

[60 FR 46233, Sept. 6, 1995, as amended at 62 FR 23374, Apr. 30, 1997; 70 FR 4713, Jan. 28, 2005]

Subpart R—Medicare Contract Appeals

SOURCE: 50 FR 1346, Jan. 10, 1985, unless otherwise noted.

§ 417.640 Applicability.

(a) The rights, procedures, and requirements relating to contract determinations and appeals set forth in part 422 subpart N of this chapter also apply to Medicare contracts with HMOs or CMPs under section 1876 of the Act.

(b) In applying paragraph (a) of this section, references to part 422 of this chapter must be read as references to this part and references to MA organizations must be read as references to HMOs or CMPs.

[75 FR 19803, Apr. 15, 2010]

Subparts S–T [Reserved]

Subpart U—Health Care Prepayment Plans

SOURCE: 50 FR 1375, Jan. 10, 1985, unless otherwise noted.

§ 417.800 Payment to HCPPs: Definitions and basic rules.

(a) *Definitions.* As used in this subpart, unless the context indicates otherwise—

Covered Part B services means physicians' services, diagnostic X-ray tests, laboratory, other diagnostic tests, and any additional medical and other health services, that the HCPP furnishes to its Medicare enrollees.

Health care prepayment plan (HCPP) means an organization that meets the following conditions:

(1) Effective January 1, 1999, (or on the effective date of the HCPP agreement in the case of a 1998 applicant) either—

(A) Is union or employer sponsored; or

(B) Does not provide, or arrange for the provision of, any inpatient hospital services.

(2) Is responsible for the organization, financing, and delivery of covered Part B services to a defined population on a prepayment basis.

(3) Meets the conditions specified in paragraph (b) of this section.

(4) Elects to be reimbursed on a reasonable cost basis.

Medicare enrollee means a beneficiary under Part B of Medicare who has been identified on CMS records as an enrollee of the HCPP. *Reporting period* means the period specified by CMS for which an HCPP must report its costs and utilization.

(b) *Qualifying conditions.* (1) Except as provided in paragraph (b)(2) of this section, an organization wishing to participate as an HCPP must—

(i) Enter into a written agreement with CMS as specified in § 417.801;

(ii) Furnish physicians' services through its employees or under a formal arrangement with a medical group, independent practice association or individual physicians; and

(iii) Furnish covered Part B services to its Medicare enrollees through institutions, entities, and persons that have qualified under the applicable requirements of title XVIII of the Social Security Act and section 353 of the PHS Act.

(2) An organization that, as of January 31, 1983, was being reimbursed on a reasonable cost basis under section 1833(a)(1)(A) of the Act, and that would not otherwise meet the conditions specified in paragraph (b)(1) of this section, may receive reimbursement on a reasonable cost basis as an HCPP, provided it files an agreement with CMS as required by §417.801.

(c) *Payment of reasonable cost.* (1) Except as otherwise provided in this subpart, CMS pays an HCPP on the basis of the reasonable cost it incurs, as specified in subpart O of this part, for the covered Part B services furnished to its Medicare enrollees.

(2) *Payment for Part B services: Basic rules*—(i) *Cost basis payment.* Except as provided in paragraph (d) of this section, CMS pays an HCPP on the basis of the reasonable costs it incurs, as specified in subpart O of this part, for the covered Part B services furnished to its Medicare enrollees.

(ii) *Deductions.* In determining the amount due an HCPP for covered Part B services furnished to its Medicare enrollees, CMS deducts, from the reasonable cost actually incurred by the HCPP, the following:

(A) The actuarial value of the Part B deductible.

(B) An amount equal to 20 percent of the cost incurred for any service that is subject to the Medicare coinsurance.

(d) *Covered services not reimbursed to an HCPP.* (1) Services reimbursed under Part A are not reimbursable to an HCPP. CMS makes payment for these services directly to the hospital, or other provider of services, on a reasonable cost basis through the provider's Medicare fiscal intermediary (for more details, see parts 412 and 413 of this chapter).

(2) Covered Part B services furnished by a provider of services to an HCPP's Medicare enrollees are not payable to the HCPP. CMS makes payment for these services to the provider on behalf of the Medicare enrollee through the provider's Medicare fiscal intermediary. This requirement does not affect Medicare payment to the HCPP for physicians' services furnished to its Medicare enrollees for which the physicians are compensated by the HCPP.

(e) *Payment for services to nonenrollees.* CMS makes payment to an HCPP for covered Part B services furnished by the HCPP to a Medicare beneficiary who is not enrolled in the HCPP if the beneficiary assigns his rights to payment in accordance with §424.55 of this chapter. Payment is made on a reasonable charge basis through the HCPP's Medicare carrier.

[50 FR 1346, Jan. 10, 1985, as amended at 51 FR 34833, Sept. 30, 1986; 53 FR 6648, Mar. 2, 1988; 57 FR 7135, Feb. 28, 1992; 58 FR 38081, July 15, 1993; 60 FR 34888, July 5, 1995; 63 FR 35067, June 26, 1998; 63 FR 52611, Oct. 1, 1998]

§417.801 Agreements between CMS and health care prepayment plans.

(a) *General requirement.* (1) In order to participate and receive payment under the Medicare program as an HCPP as defined in §417.800, an organization must enter into a written agreement with CMS.

(2) An existing group practice prepayment plan (GPPP) that continues as an HCPP under this subpart U must have entered into a written agreement with CMS within 60 days of January 31, 1983.

(b) *Terms.* The agreement must provide that the HCPP agrees to—

(1) Maintain compliance with the requirements for participation and reimbursement on a reasonable cost basis of HCPPs as specified in §417.800;

(2) Not charge the Medicare enrollee or any other person for items or services for which that enrollee is entitled to have payment made under the provisions of this part, except for any deductible or coinsurance amounts for which the enrollee is liable;

(3) Refund, as promptly as possible, any money incorrectly collected as charges or premiums, or in any other way from Medicare enrollees in the HCPP in accordance with the requirements specified in §417.456;

(4) Not impose any limitations on the acceptance of Medicare enrollees or beneficiaries for care and treatment that it does not impose on all other individuals;

(5) Meet the advance directives requirements specified in § 417.436(d) of this part;

(6) Establish administrative review procedures in accordance with §§ 417.830 through 417.840 for Medicare enrollees who are dissatisfied with denied services or claims; and

(7) Consider any additional requirements that CMS finds necessary or desirable for efficient and effective program administration.

(c) *Duration of agreement.* Except for the term of the initial agreement, the agreement is for a term of one year and may be renewed annually by mutual consent. The term of the initial agreement is set by CMS.

(d) *Termination or nonrenewal of agreement by CMS.* (1) CMS may terminate or not renew an agreement if it determines that—

(i) The HCPP no longer meets the requirements for participation and reimbursement as an HCPP as specified in § 417.800;

(ii) The HCPP is not in substantial compliance with the provisions of the agreement, applicable CMS regulations, or applicable provisions of the Medicare law. This includes, but is not limited to, the following:

(A) Failure to provide for and document adequate access to providers.

(B) Failure to comply with CMS requirements concerning provision of data and maintenance of records.

(C) Failure to comply with financial requirements specified at § 417.806; or

(iii) The HCPP undergoes a change in ownership as specified in subpart M of this part.

(2) CMS will give notice of termination or nonrenewal to the HCPP at least 90 days before the effective date stated in the notice.

(e) *Termination or nonrenewal of agreement by HCPP.* (1) If an HCPP does not wish to renew its agreement at the end of the term, it must give written notice to CMS at least 90 days before the end of the term of the agreement. If an HCPP wishes to terminate its agreement before the end of the term, it must file a written notice with CMS stating the intended effective date of termination.

(2) CMS may approve the termination date proposed by the HCPP, or set a different date no later than 6 months after that date. CMS makes this decision based on a finding that termination on a specific date would not—

(i) Unduly disrupt the furnishing of services to the community serviced by the HCPP; or

(ii) Otherwise interfere with the efficient administration of the Medicare program.

[50 FR 1375, Jan. 10, 1985, as amended at 57 FR 8202, Mar. 6, 1992; 58 FR 38081, July 15, 1993; 59 FR 49843, Sept. 30, 1994; 59 FR 59943, Nov. 21, 1994; 77 FR 22166, Apr. 12, 2012]

§ 417.802 Allowable costs.

(a) *General rule.* The costs that are considered allowable for HCPP reimbursement are the same as those for reasonable cost HMOs and CMPs specified in subpart O of this part, except those in §§ 417.531, 417.532 (a)(3) and (c) through (g), 417.536 (l) and (m), 417.546, 417.548, and 417.550(b)(2).

(b) *Physicians' services and other Part B supplier services furnished under arrangements*—(1) *Principle.* The amount paid by an HCPP for physicians' services and other Part B supplier services furnished under arrangements is an allowable cost to the extent it is reasonable.

(2) *Application: Payment on other than a fee-for-service basis.* If the HCPP pays for physicians' services and other Part B supplier services on other than a fee-for-service basis—

(i) Except as specified in paragraph (b)(2)(ii) of this section, the costs incurred by the HCPP may be considered reasonable if they—

(A) Do not exceed those that a prudent and cost-conscious buyer would incur to purchase those services; and

(B) Are comparable to costs incurred for similar services furnished by similar physicians and other suppliers in the same or a similar locality.

(ii)(A) If a physician group to whom the HCPP makes payment compensates its physicians on a fee-for-service basis, the HCPP's payment to the group may not exceed the reasonable charges for those services, as defined in subpart E of part 405 of this chapter.

(B) Payment in excess of the limits specified in paragraph (b)(2)(ii)(A) of this section is allowable if the group has procedures under which members

of the group accept effective incentives, such as risk-sharing, designed to avoid unnecessary or unduly costly utilization of health services. In such cases, the amount paid by the HCPP is considered reasonable if it meets the conditions specified in paragraph (b)(2)(i) of this section.

(3) *Application: Payment on a fee-for-service basis.* If the HCPP pays for physicians' services and other Part B supplier services on a fee-for-service basis—

(i) Except as specified in paragraph (b)(3)(ii) of this section, the costs incurred by the HCPP are considered reasonable if they do not exceed—

(A) The reasonable charges for those services, as defined in subpart E of part 405 of this chapter; and

(B) The amount that CMS would pay for those services if they were furnished to beneficiaries who are not enrolled in the HCPP and who receive the services from sources other than providers of services or other entities that are reimbursed on a reasonable cost basis.

(ii) Payment to a physician group organized on an individual-practice basis is not subject to the paragraph (b)(3)(i) of this section if the group pays its physicians on a fee-for-service basis and has procedures under which the members of the group accept effective incentives, such as risk-sharing, designed to avoid unnecessary or unduly costly utilization of health services. In these cases, the amount paid by an HCPP is considered reasonable if it meets the conditions specified in paragraph (b)(2)(i) of this section.

[50 FR 1375, Jan. 10, 1985, as amended at 58 FR 38081, July 15, 1993]

§ 417.804 Cost apportionment.

(a) The HCPP follows the cost apportionment principles specified in §§ 417.552 through 417.566, except for provisions on provider costs and provisions on departmental apportionment.

(b) The HCPP may use a method for reporting costs that is approved by CMS. CMS bases its approval on a finding that the method—

(1) Results in an accurate and equitable allocation of allowable costs; and

(2) Is justifiable from an administrative and cost efficiency standpoint.

§ 417.806 Financial records, statistical data, and cost finding.

(a) The principles specified in § 417.568 apply to HCPPs, except those in paragraph (c) of that section.

(b) The HCPP may use a method for reporting costs that is approved by CMS. CMS bases its approval on a finding that the method—

(1) Results in an accurate and equitable allocation of allowable costs; and

(2) Is justifiable from an administrative and cost efficiency standpoint.

(c) An HCPP must permit the Department and the Comptroller General to audit or inspect any books and records of the HCPP and of any related organization that pertain to the determination of amounts payable for covered Part B services furnished its Medicare enrollees. For purposes of this requirement, the principles specified in § 417.486 apply to HCPPs.

[50 FR 1375, Jan. 10, 1985, as amended at 58 FR 38081, July 15, 1993]

§ 417.808 Interim per capita payments.

The HCPP follows the principles specified in §§ 417.570 and 417.572 on interim per capita payments, except for the following:

(a) When applying these principles to HCPPs, the term ''reporting period'' should be used instead of the term ''contract period'' contained in that section.

(b) An HCPP must submit to CMS an annual operating budget and enrollment forecast, in the form and detail specified by CMS, at least 60 days before the beginning of each reporting period. A reporting period must be 12 consecutive months, except that the HCPP's initial reporting period for participating in Medicare may be as short as 6 months or as long as 18 months.

(c) An HCPP must submit to CMS an interim cost report and enrollment data applicable to the first 6-month period of the HCPP's reporting period in the form and detail specified by CMS. The interim cost report must be submitted not later than 45 days after the close of the first 6-month period of the HCPP's reporting period.

(d) In lieu of an interim payment based on the actual monthly enrollment in an HCPP, CMS and the HCPP

may agree to a uniform monthly interim reimbursement rate for a reporting period. This interim rate is based on the HCPP's budget and enrollment forecast, if CMS is satisfied that the rate is consistent with efficiency and economy, and will not result in excessive adjustment at the end of the reporting period.

§ 417.810 Final settlement.

(a) *General requirement.* CMS and an HCPP must make a final settlement, and payment of amounts due either to the HCPP or to CMS, following the submission and review of the HCPP's annual cost report and the supporting documents specified in paragraph (b) of this section.

(b) *Annual cost report as basis for final settlement*—(1) *Form and due date.* An HCPP must submit to CMS a cost report and supporting documents in the form and detail specified by CMS, no later than 120 days following the close of a reporting period.

(2) *Contents.* The report must include—

(i) The HCPP's per capita incurred costs of providing covered Part B services to its Medicare enrollees during the reporting period, including any costs incurred by another organization related to the HCPP by common ownership or control;

(ii) The HCPP's methods of apportioning costs among its Medicare enrollees, enrollees who are not Medicare beneficiaries, and other nonenrollees, including Medicare beneficiaries receiving health care services on a fee-for-service or other basis; and

(iii) Information on enrollment and other data as specified by CMS.

(3) *Extension of time to submit cost report.* CMS may grant an HCPP an extension of time to submit a cost report for good cause shown.

(4) *Failure to report required financial information.* If an HCPP does not submit the required cost report and supporting documents within the time specified in paragraph (b)(1) of this section, and has not requested and received an extension of time for good cause shown, CMS may—

(i) Regard the failure to report this information as evidence of likely overpayment and reduce or suspend interim payments to the HCPP; and

(ii) Determine that amounts previously paid are overpayments, and make appropriate recovery.

(c) *Determination of final settlement.* Following the HCPP's submission of the reports specified in paragraph (b) of this section in acceptable form, CMS makes a determination of the total reimbursement due the HCPP for the reporting period and the difference, if any, between this amount and the total interim payments made to the HCPP. CMS sends to the HCPP a notice of the amount of reimbursement by the Medicare program. This notice—

(1) Explains CMS's determination of total reimbursement due the HCPP for the reporting period; and

(2) Informs the HCPP of its right to have the determination reviewed at a hearing in accordance with the requirements specified in § 405.1801(b)(2) of this chapter.

(d) *Payment of amounts due.* (1) Within 30 days of CMS's determination, CMS or the HCPP, as appropriate, will make payment of any difference between the total amount due and the total interim payments made to the HCPP by CMS.

(2) If the HCPP does not pay CMS within 30 days of CMS's determination of any amounts the HCPP owes CMS, CMS may offset further payments to the HCPP to recover, or to aid in the recovery of, any overpayment identified in its determination.

(3) Any offset of payments CMS makes under paragraph (d)(2) of this section will remain in effect even if the HCPP has requested a hearing in accordance with the requirements specified in § 405.1801(b)(2) of this chapter.

(e) *Tentative settlement.* (1) If a final settlement cannot be made within 90 days after the HCPP submits the report specified in paragraph (b) of this section, CMS will make an interim settlement by estimating the amount payable to the HCPP.

(2) CMS or the HCPP will make payment within 30 days of CMS's determination under the tentative settlement of any estimated amounts due.

(3) The tentative settlement is subject to adjustment at the time of a final settlement.

[50 FR 1375, Jan. 10, 1985, as amended at 58 FR 38081, July 15, 1993; 73 FR 30267, May 23, 2008]

§417.830 Scope of regulations on beneficiary appeals.

Sections 417.832 through 417.840 establish procedures for the presentation and resolution of organization determinations, reconsiderations, hearings, Departmental Appeals Board review, court reviews, and finality of decisions that are applicable to Medicare enrollees of an HCPP.

[59 FR 59943, Nov. 21, 1994, as amended at 61 FR 32348, June 24, 1996]

§417.832 Applicability of requirements and procedures.

(a) The administrative review rights and procedures specified in §§417.834 through 417.840 pertain to disputes involving an organization determination, as defined in §417.838, with which the enrollee is dissatisfied.

(b) Physicians and other individuals who furnish items or services under arrangements with an HCPP have no right of administrative review under §§417.834 through 417.840.

(c) The provisions of part 405 dealing with the representation of parties apply to organization determinations and appeals.

(d) The provisions of part 405 dealing with administrative law judge hearings, Medicare Appeals Council review, and judicial review are applicable, unless otherwise provided.

[59 FR 59943, Nov. 21, 1994, as amended at 70 FR 4713, Jan. 28, 2005]

§417.834 Responsibility for establishing administrative review procedures.

The HCPP is responsible for establishing and maintaining the administrative review procedures that are specified in §§417.830 through 417.840.

[59 FR 59943, Nov. 21, 1994]

§417.836 Written description of administrative review procedures.

Each HCPP is responsible for ensuring that all Medicare enrollees are informed in writing of the administrative review procedures that are available to them.

[59 FR 59943, Nov. 21, 1994]

§417.838 Organization determinations.

(a) *Actions that are organization determinations.* For purposes of §§417.830 through 417.840, an organization determination is a refusal to furnish or arrange for services, or reimburse the party for services provided to the beneficiary, on the grounds that the services are not covered by Medicare.

(b) *Actions that are not organization determinations.* The following are not organization determinations for purposes of §§417.830 through 417.840:

(1) A determination regarding services that were furnished by the HCPP, either directly or under arrangement, for which the enrollee has no further obligation for payment.

(2) A determination regarding services that are not covered under the HCPP's agreement with CMS.

[59 FR 59943, Nov. 21, 1994]

§417.840 Administrative review procedures.

The HCPP must apply §422.568 through §422.626 of this chapter to—

(a) Organization determinations and fast-track appeals that affect its Medicare enrollees; and

(b) Reconsiderations, hearings, Medicare Appeals Council review, and judicial review of the organization determinations and fast-track appeals specified in paragraph (a) of this section.

[75 FR 19803, Apr. 15, 2010]

Subpart V—Administration of Outstanding Loans and Loan Guarantees

§417.910 Applicability.

The regulations in this subpart apply, as appropriate, to public and private entities that have loans or loan guarantees that—

(a) Were awarded to them before October 1986 under section 1304 or section 1305 of the PHS Act; and

(b) Are still outstanding.

[59 FR 49842, Sept. 30, 1994]

§ 417.911 Definitions.

As used in this subpart—

Any 12-month period means the 12-month period beginning on the first day of any month.

Expansion of services means—

(1) The addition of any health service not previously provided by or through the HMO, that requires an increase in the facilities, equipment, or health professionals of the HMO; or

(2) The improvement or upgrading of existing facilities or equipment, or an increase in the number of categories of health professionals, of the HMO so that the HMO could provide directly services that it previously provided through contract or referral or which it could not previously provide with its existing facilities or equipment.

First 60 months of operation or expansion means the 60-month period beginning on the first day of the month during which the HMO first provided services to enrollees, or in the case of significant expansion, first provided services in accordance with its expansion plan.

Health system agency means an entity that has been designated in accordance with section 1515 of the PHS Act; and the term *State health planning and development agency* means an agency that has been designated in accordance with section 1521 of the PHS Act.

Initial costs of operation means any cost incurred in the first 60 months of an operation or expansion that met any of the following requirements:

(1) Under generally accepted accounting principles or under accounting practices prescribed or permitted by State regulatory authority, was not a capital cost.

(2) Was required by State regulatory authority to meet reserves or tangible net equity requirements.

(3) Was for a payment made to reduce balance sheet liabilities existing at the beginning of the 60-month period, but only if—

(i) The payment had been approved in writing by the Secretary; and

(ii) The total of these payments did not exceed 20 percent of the amount of the loan.

(4) Was for a small capital expenditure, but only if—

(i) The cost had been approved in writing by the Secretary; and

(ii) The total of these costs did not exceed $200,000 in any 12-month period, and $400,000 during the first 60 months of operation or expansion.

Nonprofit as applied to a private entity, means a private agency, institution, or organization, no part of the net earnings of which inures, or may lawfully inure, to the benefit of any private shareholder or individual.

Significant expansion means—

(1) A planned substantial increase in the enrollment of the HMO, that requires an increase in the number of health professionals serving enrollees of the HMO or an expansion of the physical capacity of the HMO's total health facilities; or

(2) A planned expansion of the service area beyond the current service area, that would be made possible by the addition of health service delivery facilities and health professionals to serve enrollees at a new site or sites in areas previously without service sites.

Small capital expenditure means expenditures for—

(1) Equipment as defined in 2 CFR 200.1; or

(2) Alterations and renovations required to change the interior arrangements or other physical characteristics of an existing facility or installed equipment, so that it may be more effectively used for its currently designated purpose, or adapted to a changed use.

[58 FR 38076, July 15, 1993, as amended at 59 FR 49842, Sept. 30, 1994; 81 FR 3011, Jan. 20, 2016; 89 FR 80069, Oct. 2, 2024]

§ 417.920 Planning and initial development.

(a) Under section 1304 of the PHS Act, grants and loan guarantees were awarded for projects for planning and initial development of HMOs.

(b) Planning projects included projects for any of the following:

(1) Establishment of an HMO.

(2) Significant expansion of the HMO's enrollment or geographic area.

(c) Initial development projects included projects for any of the following:

(1) Establishment of an HMO.

(2) Significant expansion of the HMO's enrollment or geographic area.

(3) Expansion of the range or amount of services furnished by the HMO.

[58 FR 38076, July 15, 1993]

§ 417.930 Initial costs of operation.

Under section 1305 of the PHS, loans and loan guarantees were awarded for initial costs of operation of HMOs.

[58 FR 38077, July 15, 1993]

§ 417.931 [Reserved]

§ 417.934 Reserve requirement.

(a) *Timing.* Unless the Secretary approved a longer period, an entity that received a loan or loan guarantee under section 1305 of the PHS Act was required to establish a restricted reserve account on the earlier of the following:

(1) When the HMO's revenues and costs of operation reached the breakeven point.

(2) At the end of the 60-month period following the Secretary's endorsement of the loan or loan guarantee.

(b) *Purpose and amount of reserve.* The reserve had to be constituted so as to accumulate, no later than 12 years after endorsement of the loan or loan guarantee, an amount equal to 1 year's principal and interest.

[59 FR 49842, Sept. 30, 1994]

§ 417.937 Loan and loan guarantee provisions.

(a) *Disbursement of loan proceeds.* The principal amount of any loan made or guaranteed by the Secretary under this subpart was disbursed to the entity in accordance with an agreement entered into between the parties to the loan and approved by the Secretary.

(b) *Length and maturity of loans.* The principal amount of each loan or loan guarantee, together with interest thereon, is repayable over a period of 22 years, beginning on the date of endorsement of the loan, or loan guarantee by the Secretary. The Secretary could approve a shorter repayment period if he or she determined that a repayment period of less than 22 years is more appropriate to an entity's total financial plan.

(c) *Repayment.* The principal amount of each loan or loan guarantee, together with interest thereon is repayable in accordance with a repayment schedule that is agreed upon by the parties to the loan or loan guarantee and approved by the Secretary before or at the time of endorsement of the loan. Unless otherwise specifically authorized by the Secretary, each loan made or guaranteed by the Secretary is repayable in substantially level combined installments of principal and interest to be paid at intervals not less frequently than annually, sufficient in amount to amortize the loan through the final year of the life of the loan. Principal repayment during the first 60 months of operation could be deferred with payment of interest only during that period. The Secretary could set rates of interest for each disbursement at a rate comparable to the rate of interest prevailing on the date of disbursement for marketable obligations of the United States of comparable maturities, adjusted to provide for appropriate administrative charges.

[59 FR 49842, Sept. 30, 1994]

§ 417.940 Civil action to enforce compliance with assurances.

The provisions of § 417.163(g) apply to entities that have outstanding loans or loan guarantees administered under this subpart.

[59 FR 49843, Sept. 30, 1994]

PART 418—HOSPICE CARE

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AUTHORITY: 42 U.S.C. 1302 and 1395hh.

SOURCE: 48 FR 56026, Dec. 16, 1983, unless otherwise noted.

Subpart A—General Provision and Definitions

§ 418.1 Statutory basis.

This part implements section 1861(dd) of the Social Security Act (the Act). Section 1861(dd) of the Act specifies services covered as hospice care and the conditions that a hospice program must meet in order to participate in the Medicare program. Section 1861(dd) also specifies limitations on coverage of, and payment for, inpatient hospice care. The following sections of the Act are also pertinent:

(a) Sections 1812(a) (4) and (d) of the Act specify eligibility requirements for the individual and the benefit periods.

(b) Section 1813(a)(4) of the Act specifies coinsurance amounts.

(c) Sections 1814(a)(7) and 1814(i) of the Act contain conditions and limitations on coverage of, and payment for, hospice care.

(d) Sections 1862(a) (1), (6) and (9) of the Act establish limits on hospice coverage.

[48 FR 56026, Dec. 16, 1983, as amended at 57 FR 36017, Aug. 12, 1992; 74 FR 39413, Aug. 6, 2009]

§418.2 Scope of part.

Subpart A of this part sets forth the statutory basis and scope and defines terms used in this part. Subpart B specifies the eligibility and election requirements and the benefit periods. Subparts C and D specify the conditions of participation for hospices. Subpart E is reserved for future use. Subparts F and G specify coverage and payment policy. Subpart H specifies coinsurance amounts applicable to hospice care.

[74 FR 39413, Aug. 6, 2009]

§418.3 Definitions.

For purposes of this part—

Attending physician means a—

(1)(i) Doctor of medicine or osteopathy legally authorized to practice medicine and surgery by the State in which he or she performs that function or action; or

(ii) Nurse practitioner who meets the training, education, and experience requirements as described in §410.75(b) of this chapter; or

(iii) Physician assistant who meets the requirements of §410.74(c) of this chapter.

(2) Is identified by the individual, at the time he or she elects to receive hospice care, as having the most significant role in the determination and delivery of the individual's medical care.

Bereavement counseling means emotional, psychosocial, and spiritual support and services provided before and after the death of the patient to assist with issues related to grief, loss, and adjustment.

BFCC–QIO means Beneficiary and Family Centered Care Quality Improvement Organization.

Cap period means the twelve-month period ending September 30 used in the application of the cap on overall hospice reimbursement specified in §418.309.

Clinical note means a notation of a contact with the patient and/or the family that is written and dated by any person providing services and that describes signs and symptoms, treatments and medications administered, including the patient's reaction and/or response, and any changes in physical, emotional, psychosocial or spiritual condition during a given period of time.

Comprehensive assessment means a thorough evaluation of the patient's physical, psychosocial, emotional and spiritual status related to the terminal illness and related conditions. This includes a thorough evaluation of the caregiver's and family's willingness and capability to care for the patient.

Dietary counseling means education and interventions provided to the patient and family regarding appropriate nutritional intake as the patient's condition progresses. Dietary counseling is provided by qualified individuals, which may include a registered nurse, dietitian or nutritionist, when identified in the patient's plan of care.

Employee means a person who:

(1) Works for the hospice and for whom the hospice is required to issue a W–2 form on his or her behalf;

(2) If the hospice is a subdivision of an agency or organization, an employee of the agency or organization who is assigned to the hospice; or

(3) Is a volunteer under the jurisdiction of the hospice.

Hospice means a public agency or private organization or subdivision of either of these that is primarily engaged in providing hospice care as defined in this section.

Hospice care means a comprehensive set of services described in 1861(dd)(1) of the Act, identified and coordinated by an interdisciplinary group to provide for the physical, psychosocial,

spiritual, and emotional needs of a terminally ill patient and/or family members, as delineated in a specific patient plan of care.

Initial assessment means an evaluation of the patient's physical, psychosocial and emotional status related to the terminal illness and related conditions to determine the patient's immediate care and support needs.

Licensed professional means a person licensed to provide patient care services by the State in which services are delivered.

Multiple location means a Medicare-approved location from which the hospice provides the same full range of hospice care and services that is required of the hospice issued the certification number. A multiple location must meet all of the conditions of participation applicable to hospices.

Palliative care means patient and family-centered care that optimizes quality of life by anticipating, preventing, and treating suffering. Palliative care throughout the continuum of illness involves addressing physical, intellectual, emotional, social, and spiritual needs and to facilitate patient autonomy, access to information, and choice.

Physician means an individual who meets the qualifications and conditions as defined in section 1861(r) of the Act and implemented at §410.20 of this chapter.

Physician designee means a doctor of medicine or osteopathy designated by the hospice who assumes the same responsibilities and obligations as the medical director when the medical director is not available.

Pseudo-patient means a person trained to participate in a role-play situation, or a computer-based mannequin device. A pseudo-patient must be capable of responding to and interacting with the hospice aide trainee, and must demonstrate the general characteristics of the primary patient population served by the hospice in key areas such as age, frailty, functional status, cognitive status and care goals.

Representative means an individual who has the authority under State law (whether by statute or pursuant to an appointment by the courts of the State) to authorize or terminate medical care or to elect or revoke the election of hospice care on behalf of a terminally ill patient who is mentally or physically incapacitated. This may include a legal guardian.

Restraint means—(1) Any manual method, physical or mechanical device, material, or equipment that immobilizes or reduces the ability of a patient to move his or her arms, legs, body, or head freely, not including devices, such as orthopedically prescribed devices, surgical dressings or bandages, protective helmets, or other methods that involve the physical holding of a patient for the purpose of conducting routine physical examinations or tests, or to protect the patient from falling out of bed, or to permit the patient to participate in activities without the risk of physical harm (this does not include a physical escort); or

(2) A drug or medication when it is used as a restriction to manage the patient's behavior or restrict the patient's freedom of movement and is not a standard treatment or dosage for the patient's condition.

Seclusion means the involuntary confinement of a patient alone in a room or an area from which the patient is physically prevented from leaving.

Simulation means a training and assessment technique that mimics the reality of the homecare environment, including environmental distractions and constraints that evoke or replicate substantial aspects of the real world in a fully interactive fashion, in order to teach and assess proficiency in performing skills, and to promote decision making and critical thinking.

Terminally ill means that the individual has a medical prognosis that his or her life expectancy is 6 months or less if the illness runs its normal course.

[48 FR 56026, Dec. 16, 1983, as amended at 52 FR 4499, Feb. 12, 1987; 55 FR 50834, Dec. 11, 1990; 70 FR 45144, Aug. 4, 2005; 72 FR 50227, Aug. 31, 2007; 73 FR 32204, June 5, 2008; 79 FR 50509, Aug. 22, 2014; 83 FR 38654, Aug. 6, 2018; 84 FR 38543, Aug. 6, 2019; 86 FR 42605, Aug. 4, 2021]

Subpart B—Eligibility, Election and Duration of Benefits

§ 418.20 Eligibility requirements.

In order to be eligible to elect hospice care under Medicare, an individual must be—

(a) Entitled to Part A of Medicare; and

(b) Certified as being terminally ill in accordance with § 418.22.

§ 418.21 Duration of hospice care coverage—Election periods.

(a) Subject to the conditions set forth in this part, an individual may elect to receive hospice care during one or more of the following election periods:

(1) An initial 90-day period;

(2) A subsequent 90-day period; or

(3) An unlimited number of subsequent 60-day periods.

(b) The periods of care are available in the order listed and may be elected separately at different times.

[55 FR 50834, Dec. 11, 1990, as amended at 57 FR 36017, Aug. 12, 1992; 70 FR 70546, Nov. 22, 2005]

§ 418.22 Certification of terminal illness.

(a) *Timing of certification*—(1) *General rule.* The hospice must obtain written certification of terminal illness for each of the periods listed in § 418.21, even if a single election continues in effect for an unlimited number of periods, as provided in § 418.24(c).

(2) *Basic requirement.* Except as provided in paragraph (a)(3) of this section, the hospice must obtain the written certification before it submits a claim for payment.

(3) *Exceptions.* (i) If the hospice cannot obtain the written certification within 2 calendar days, after a period begins, it must obtain an oral certification within 2 calendar days and the written certification before it submits a claim for payment.

(ii) Certifications may be completed no more than 15 calendar days prior to the effective date of election.

(iii) Recertifications may be completed no more than 15 calendar days prior to the start of the subsequent benefit period.

(4) *Face-to-face encounter.* (i) As of January 1, 2011, a hospice physician or hospice nurse practitioner must have a face-to-face encounter with each hospice patient whose total stay across all hospices is anticipated to reach the 3rd benefit period. The face-to-face encounter must occur prior to, but no more than 30 calendar days prior to, the 3rd benefit period recertification, and every benefit period recertification thereafter, to gather clinical findings to determine continued eligibility for hospice care.

(ii) During a Public Health Emergency, as defined in § 400.200 of this chapter, or through September 30, 2025, whichever is later, if the face-to-face encounter conducted by a hospice physician or hospice nurse practitioner is for the sole purpose of hospice recertification, such encounter may occur via a telecommunications technology and is considered an administrative expense. *Telecommunications technology* means the use of interactive multimedia communications equipment that includes, at a minimum, the use of audio and video equipment permitting two-way, real-time interactive communication between the patient and the distant site hospice physician or hospice nurse practitioner.

(b) *Content of certification.* Certification will be based on the physician's or medical director's clinical judgment regarding the normal course of the individual's illness. The certification must conform to the following requirements:

(1) The certification must specify that the individual's prognosis is for a life expectancy of 6 months or less if the terminal illness runs its normal course.

(2) Clinical information and other documentation that support the medical prognosis must accompany the certification and must be filed in the medical record with the written certification as set forth in paragraph (d)(2) of this section. Initially, the clinical information may be provided verbally, and must be documented in the medical record and included as part of the hospice's eligibility assessment.

(3) The physician must include a brief narrative explanation of the clinical findings that supports a life expectancy

of 6 months or less as part of the certification and recertification forms, or as an addendum to the certification and recertification forms.

(i) If the narrative is part of the certification or recertification form, then the narrative must be located immediately prior to the physician's signature.

(ii) If the narrative exists as an addendum to the certification or recertification form, in addition to the physician's signature on the certification or recertification form, the physician must also sign immediately following the narrative in the addendum.

(iii) The narrative shall include a statement directly above the physician signature attesting that by signing, the physician confirms that he/she composed the narrative based on his/her review of the patient's medical record or, if applicable, his/her examination of the patient.

(iv) The narrative must reflect the patient's individual clinical circumstances and cannot contain check boxes or standard language used for all patients.

(v) The narrative associated with the 3rd benefit period recertification and every subsequent recertification must include an explanation of why the clinical findings of the face-to-face encounter support a life expectancy of 6 months or less.

(4) The physician or nurse practitioner who performs the face-to-face encounter with the patient described in paragraph (a)(4) of this section must attest in writing that he or she had a face-to-face encounter with the patient, including the date of that visit. The attestation must include the physician's or nurse practitioner's signature and the date it was signed. The attestation could be a separate and distinct section of, or an addendum to, the recertification or a clinical note that indicates the face-to-face encounter occurred, and includes the clinical findings of the face-to-face encounter, the date of the visit, the signature of the physician or nurse practitioner who conducted the face-to-face encounter, and the date of the signature. If the attestation of the nurse practitioner or a non-certifying hospice physician is a separate and distinct section of, or an addendum to, the recertification, the attestation shall state that the clinical findings of that visit were provided to the certifying physician for use in determining continued eligibility for hospice care.

(5) All certifications and recertifications must be signed and dated by the physician(s), and must include the benefit period dates to which the certification or recertification applies.

(c) *Sources of certification.* (1) For the initial 90-day period, the hospice must obtain written certification statements (and oral certification statements if required under paragraph (a)(3) of this section) from—

(i) The medical director of the hospice, the physician designee (as defined in § 418.3), or the physician member of the hospice interdisciplinary group; and

(ii) The individual's attending physician, if the individual has an attending physician. The attending physician must meet the definition of physician specified in § 410.20 of this subchapter.

(2) For subsequent periods, the only requirement is certification by one of the physicians listed in paragraph (c)(1)(i) of this section.

(d) *Maintenance of records.* Hospice staff must—

(1) Make an appropriate entry in the patient's medical record as soon as they receive an oral certification; and

(2) File written certifications in the medical record.

[55 FR 50834, Dec. 11, 1990, as amended at 57 FR 36017, Aug. 12, 1992; 70 FR 45144, Aug. 4, 2005; 70 FR 70547, Nov. 22, 2005; 74 FR 39413, Aug. 6, 2009; 75 FR 70463, Nov. 17, 2010; 76 FR 47331, Aug. 4, 2011; 85 FR 19289, Apr. 6, 2020; 88 FR 51199, Aug. 2, 2023; 89 FR 64272, Aug. 6, 2024; 90 FR 37430, Aug. 5, 2025]

§ 418.24 Election of hospice care.

(a) *Election statement.* An individual who meets the eligibility requirement of § 418.20 may file an election statement with a particular hospice. If the individual is physically or mentally incapacitated, his or her representative (as defined in § 418.3) may file the election statement.

(b) *Content of election statement.* The election statement must include the following:

(1) Identification of the particular hospice and of the attending physician that will provide care to the individual. The individual or representative must acknowledge that the identified attending physician was his or her choice.

(2) The individual's or representative's acknowledgement that he or she has been given a full understanding of the palliative rather than curative nature of hospice care, as it relates to the individual's terminal illness and related conditions.

(3) Acknowledgement that the individual has been provided information on the hospice's coverage responsibility and that certain Medicare services, as set forth in paragraph (g) of this section, are waived by the election. For Hospice elections beginning on or after October 1, 2020, this would include providing the individual with information indicating that services unrelated to the terminal illness and related conditions are exceptional and unusual and hospice should be providing virtually all care needed by the individual who has elected hospice.

(4) The effective date of the election, which may be the first day of hospice care or a later date, but may be no earlier than the date of the election statement.

(5) For Hospice elections beginning on or after October 1, 2020, the Hospice must provide information on individual cost-sharing for hospice services.

(6) For Hospice elections beginning on or after October 1, 2020, the Hospice must provide notification of the individual's (or representative's) right to receive an election statement addendum, as set forth in paragraph (c) of this section, if there are conditions, items, services, and drugs the hospice has determined to be unrelated to the individual's terminal illness and related conditions and would not be covered by the hospice.

(7) For Hospice elections beginning on or after October 1, 2020, the Hospice must provide information on the Beneficiary and Family Centered Care Quality Improvement Organization (BFCC–QIO), including the right to immediate advocacy and BFCC–QIO contact information.

(8) The signature of the individual or representative.

(c) *Content of hospice election statement addendum.* For hospice elections beginning on or after October 1, 2020, in the event that the hospice determines there are conditions, items, services, or drugs that are unrelated to the individual's terminal illness and related conditions, the individual (or representative), non-hospice providers furnishing such items, services, or drugs, or Medicare contractors may request a written list as an addendum to the election statement. The election statement addendum must include the following:

(1) The addendum must be titled ''Patient Notification of Hospice Non-Covered Items, Services, and Drugs.''

(2) Name of the hospice.

(3) Individual's name and hospice medical record identifier.

(4) Identification of the individual's terminal illness and related conditions.

(5) A list of the individual's conditions present on hospice admission (or upon plan of care update) and the associated items, services, and drugs not covered by the hospice because they have been determined by the hospice to be unrelated to the terminal illness and related conditions.

(6) A written clinical explanation, in language the individual (or representative) can understand, as to why the identified conditions, items, services, and drugs are considered unrelated to the individual's terminal illness and related conditions and not needed for pain or symptom management. This clinical explanation must be accompanied by a general statement that the decision as to whether or not conditions, items, services, and drugs are related is made for each patient and that the individual should share this clinical explanation with other health care providers from which they seek items, services, or drugs unrelated to their terminal illness and related conditions.

(7) References to any relevant clinical practice, policy, or coverage guidelines.

(8) Information on the following:

(i) *Purpose of Addendum.* The purpose of the addendum is to notify the individual (or representative), in writing, of those conditions, items, services,

and drugs the hospice will not be covering because the hospice has determined they are unrelated to the individual's terminal illness and related conditions.

(ii) *Right to Immediate Advocacy*. The addendum must include language that immediate advocacy is available through the Medicare Beneficiary and Family Centered Care-Quality Improvement Organization (BFCC–QIO) if the individual (or representative) disagrees with the hospice's determination.

(9) Name and signature of the individual (or representative) and date signed, along with a statement that signing this addendum (or its updates) is only acknowledgement of receipt of the addendum (or its updates) and not the individual's (or representative's) agreement with the hospice's determinations. If the beneficiary (or representative) refuses to sign the addendum, the hospice must document on the addendum the reason the addendum was not signed and the addendum would become part of the patient's medical record. If a non-hospice provider or Medicare contractor requests the addendum, the non-hospice provider or Medicare contractor are not required to sign the addendum.

(10) Date the hospice furnished the addendum.

(d) *Timeframes for the hospice election statement addendum.* (1) If the addendum is requested within the first 5 days of a hospice election (that is, in the first 5 days of the hospice election date), the hospice must provide this information, in writing, to the individual (or representative), non-hospice provider, or Medicare contractor within 5 days from the date of the request.

(2) If the addendum is requested during the course of hospice care (that is, after the first 5 days of the hospice election date), the hospice must provide this information, in writing, within 3 days of the request to the requesting individual (or representative), non-hospice provider, or Medicare contractor.

(3) If there are any changes to the plan of care during the course of hospice care, the hospice must update the addendum and provide these updates, in writing, to the individual (or representative) in order to communicate these changes to the individual (or representative).

(4) If the individual dies, revokes, or is discharged within the required timeframe for furnishing the addendum (as outlined in paragraphs (d)(1) and (2) of this section, and before the hospice has furnished the addendum, the addendum would not be required to be furnished to the individual (or representative). The hospice must note the reason the addendum was not furnished to the patient and the addendum would become part of the patient's medical record if the hospice has completed it at the time of discharge, revocation, or death.

(5) If the beneficiary dies, revokes, or is discharged prior to signing the addendum (as outlined in paragraphs (d)(1) and (2) of this section), the addendum would not be required to be signed in order for the hospice to receive payment. The hospice must note (on the addendum itself) the reason the addendum was not signed and the addendum would become part of the patient's medical record.

(e) *Notice of election*. The hospice chosen by the eligible individual (or his or her representative) must file the Notice of Election (NOE) with its Medicare contractor within 5 calendar days after the effective date of the election statement.

(1) *Consequences of failure to submit a timely notice of election*. When a hospice does not file the required Notice of Election for its Medicare patients within 5 calendar days after the effective date of election, Medicare will not cover and pay for days of hospice care from the effective date of election to the date of filing of the notice of election. These days are a provider liability, and the provider may not bill the beneficiary for them.

(2) *Exception to the consequences for filing the NOE late*. CMS may waive the consequences of failure to submit a timely-filed NOE specified in paragraph (e)(1) of this section. CMS will determine if a circumstance encountered by a hospice is exceptional and qualifies for waiver of the consequence specified in paragraph (e)(1) of this section. A hospice must fully document

and furnish any requested documentation to CMS for a determination of exception. An exceptional circumstance may be due to, but is not limited to, the following:

(i) Fires, floods, earthquakes, or similar unusual events that inflict extensive damage to the hospice's ability to operate.

(ii) A CMS or Medicare contractor systems issue that is beyond the control of the hospice.

(iii) A newly Medicare-certified hospice that is notified of that certification after the Medicare certification date, or which is awaiting its user ID from its Medicare contractor.

(iv) Other situations determined by CMS to be beyond the control of the hospice.

(f) *Duration of election.* An election to receive hospice care will be considered to continue through the initial election period and through the subsequent election periods without a break in care as long as the individual—

(1) Remains in the care of a hospice;

(2) Does not revoke the election; and

(3) Is not discharged from the hospice under the provisions of § 418.26.

(g) *Waiver of other benefits.* For the duration of an election of hospice care, an individual waives all rights to Medicare payments for the following services:

(1) Hospice care provided by a hospice other than the hospice designated by the individual (unless provided under arrangements made by the designated hospice).

(2) Any Medicare services that are related to the treatment of the terminal condition for which hospice care was elected or a related condition or that are equivalent to hospice care except for services—

(i) Provided by the designated hospice:

(ii) Provided by another hospice under arrangements made by the designated hospice; and

(iii) Provided by the individual's attending physician if that physician is not an employee of the designated hospice or receiving compensation from the hospice for those services.

(h) *Re-election of hospice benefits.* If an election has been revoked in accordance with § 418.28, the individual (or his or her representative if the individual is mentally or physically incapacitated) may at any time file an election, in accordance with this section, for any other election period that is still available to the individual.

(i) *Changing the attending physician.* To change the designated attending physician, the individual (or representative) must file a signed statement with the hospice that states that he or she is changing his or her attending physician.

(1) The statement must identify the new attending physician, and include the date the change is to be effective and the date signed by the individual (or representative).

(2) The individual (or representative) must acknowledge that the change in the attending physician is due to his or her choice.

(3) The effective date of the change in attending physician cannot be before the date the statement is signed.

[55 FR 50834, Dec. 11, 1990, as amended at 70 FR 70547, Nov. 22, 2005; 79 FR 50509, Aug. 22, 2014; 84 FR 38544, Aug. 6, 2019; 86 FR 42605, Aug. 4, 2021; 89 FR 64272, Aug. 6, 2024]

§ 418.25 Admission to hospice care.

(a) The hospice admits a patient only on the recommendation of the medical director (or the physician designee, as defined in § 418.3) or the physician member of the hospice interdisciplinary group, in consultation with, or with input from, the patient's attending physician (if any).

(b) In reaching a decision to certify that the patient is terminally ill, the hospice medical director (or the physician designee, as defined in § 418.3) or the physician member of the hospice interdisciplinary group, must consider at least the following information:

(1) Diagnosis of the terminal condition of the patient.

(2) Other health conditions, whether related or unrelated to the terminal condition.

(3) Current clinically relevant information supporting all diagnoses.

[70 FR 70547, Nov. 22, 2005, as amended at 89 FR 64272, Aug. 6, 2024; 90 FR 37431, Aug. 5, 2025]

§ 418.26 Discharge from hospice care.

(a) *Reasons for discharge.* A hospice may discharge a patient if—

(1) The patient moves out of the hospice's service area or transfers to another hospice;

(2) The hospice determines that the patient is no longer terminally ill; or

(3) The hospice determines, under a policy set by the hospice for the purpose of addressing discharge for cause that meets the requirements of paragraphs (a)(3)(i) through (a)(3)(iv) of this section, that the patient's (or other persons in the patient's home) behavior is disruptive, abusive, or uncooperative to the extent that delivery of care to the patient or the ability of the hospice to operate effectively is seriously impaired. The hospice must do the following before it seeks to discharge a patient for cause:

(i) Advise the patient that a discharge for cause is being considered;

(ii) Make a serious effort to resolve the problem(s) presented by the patient's behavior or situation;

(iii) Ascertain that the patient's proposed discharge is not due to the patient's use of necessary hospice services; and

(iv) Document the problem(s) and efforts made to resolve the problem(s) and enter this documentation into its medical records.

(b) *Discharge order.* Prior to discharging a patient for any reason listed in paragraph (a) of this section, the hospice must obtain a written physician's discharge order from the hospice medical director. If a patient has an attending physician involved in his or her care, this physician should be consulted before discharge and his or her review and decision included in the discharge note.

(c) *Effect of discharge.* An individual, upon discharge from the hospice during a particular election period for reasons other than immediate transfer to another hospice—

(1) Is no longer covered under Medicare for hospice care;

(2) Resumes Medicare coverage of the benefits waived under § 418.24(e); and

(3) May at any time elect to receive hospice care if he or she is again eligible to receive the benefit.

(d) *Discharge planning.* (1) The hospice must have in place a discharge planning process that takes into account the prospect that a patient's condition might stabilize or otherwise change such that the patient cannot continue to be certified as terminally ill.

(2) The discharge planning process must include planning for any necessary family counseling, patient education, or other services before the patient is discharged because he or she is no longer terminally ill.

(e) *Filing a notice of termination of election.* When the hospice election is ended due to discharge, the hospice must file a notice of termination/revocation of election with its Medicare contractor within 5 calendar days after the effective date of the discharge, unless it has already filed a final claim for that beneficiary.

[70 FR 70547, Nov. 22, 2005, as amended at 79 FR 50509, Aug. 22, 2014; 84 FR 38544, Aug. 6, 2019]

§ 418.28 Revoking the election of hospice care.

(a) An individual or representative may revoke the individual's election of hospice care at any time during an election period.

(b) To revoke the election of hospice care, the individual or representative must file a statement with the hospice that includes the following information:

(1) A signed statement that the individual or representative revokes the individual's election for Medicare coverage of hospice care for the remainder of that election period.

(2) The date that the revocation is to be effective. (An individual or representative may not designate an effective date earlier than the date that the revocation is made).

(c) An individual, upon revocation of the election of Medicare coverage of hospice care for a particular election period—

(1) Is no longer covered under Medicare for hospice care;

(2) Resumes Medicare coverage of the benefits waived under § 418.24(f)(2); and

(3) May at any time elect to receive hospice coverage for any other hospice election periods that he or she is eligible to receive.

(d) When the hospice election is ended due to revocation, the hospice must file a notice of termination/revocation of election with its Medicare contractor within 5 calendar days after the effective date of the revocation, unless it has already filed a final claim for that beneficiary.

[48 FR 56026, Dec. 16, 1983, as amended at 79 FR 50509, Aug. 22, 2014; 84 FR 38544, Aug. 6, 2019]

§ 418.30 Change of the designated hospice.

(a) An individual or representative may change, once in each election period, the designation of the particular hospice from which hospice care will be received.

(b) The change of the designated hospice is not a revocation of the election for the period in which it is made.

(c) To change the designation of hospice programs, the individual or representative must file, with the hospice from which care has been received and with the newly designated hospice, a statement that includes the following information:

(1) The name of the hospice from which the individual has received care and the name of the hospice from which he or she plans to receive care.

(2) The date the change is to be effective.

Subpart C—Conditions of Participation: Patient Care

SOURCE: 73 FR 32204, June 5, 2008, unless otherwise noted.

§ 418.52 Condition of participation: Patient's rights.

The patient has the right to be informed of his or her rights, and the hospice must protect and promote the exercise of these rights.

(a) *Standard: Notice of rights and responsibilities.* (1) During the initial assessment visit in advance of furnishing care the hospice must provide the patient or representative with verbal (meaning spoken) and written notice of the patient's rights and responsibilities in a language and manner that the patient understands.

(2) The hospice must comply with the requirements of subpart I of part 489 of this chapter regarding advance directives. The hospice must inform and distribute written information to the patient concerning its policies on advance directives, including a description of applicable State law.

(3) The hospice must obtain the patient's or representative's signature confirming that he or she has received a copy of the notice of rights and responsibilities.

(b) *Standard: Exercise of rights and respect for property and person.* (1) The patient has the right:

(i) To exercise his or her rights as a patient of the hospice;

(ii) To have his or her property and person treated with respect;

(iii) To voice grievances regarding treatment or care that is (or fails to be) furnished and the lack of respect for property by anyone who is furnishing services on behalf of the hospice; and

(iv) To not be subjected to discrimination or reprisal for exercising his or her rights.

(2) If a patient has been adjudged incompetent under state law by a court of proper jurisdiction, the rights of the patient are exercised by the person appointed pursuant to state law to act on the patient's behalf.

(3) If a state court has not adjudged a patient incompetent, any legal representative designated by the patient in accordance with state law may exercise the patient's rights to the extent allowed by state law.

(4) The hospice must:

(i) Ensure that all alleged violations involving mistreatment, neglect, or verbal, mental, sexual, and physical abuse, including injuries of unknown source, and misappropriation of patient property by anyone furnishing services on behalf of the hospice, are reported immediately by hospice employees and contracted staff to the hospice administrator;

(ii) Immediately investigate all alleged violations involving anyone furnishing services on behalf of the hospice and immediately take action to prevent further potential violations while the alleged violation is being verified. Investigations and/or documentation of all alleged violations

must be conducted in accordance with established procedures;

(iii) Take appropriate corrective action in accordance with state law if the alleged violation is verified by the hospice administration or an outside body having jurisdiction, such as the State survey agency or local law enforcement agency; and

(iv) Ensure that verified violations are reported to State and local bodies having jurisdiction (including to the State survey and certification agency) within 5 working days of becoming aware of the violation.

(c) *Standard: Rights of the patient.* The patient has a right to the following:

(1) Receive effective pain management and symptom control from the hospice for conditions related to the terminal illness;

(2) Be involved in developing his or her hospice plan of care;

(3) Refuse care or treatment;

(4) Choose his or her attending physician;

(5) Have a confidential clinical record. Access to or release of patient information and clinical records is permitted in accordance with 45 CFR parts 160 and 164.

(6) Be free from mistreatment, neglect, or verbal, mental, sexual, and physical abuse, including injuries of unknown source, and misappropriation of patient property;

(7) Receive information about the services covered under the hospice benefit;

(8) Receive information about the scope of services that the hospice will provide and specific limitations on those services.

§ 418.54 Condition of participation: Initial and comprehensive assessment of the patient.

The hospice must conduct and document in writing a patient-specific comprehensive assessment that identifies the patient's need for hospice care and services, and the patient's need for physical, psychosocial, emotional, and spiritual care. This assessment includes all areas of hospice care related to the palliation and management of the terminal illness and related conditions.

(a) *Standard: Initial assessment.* The hospice registered nurse must complete an initial assessment within 48 hours after the election of hospice care in accordance with § 418.24 is complete (unless the physician, patient, or representative requests that the initial assessment be completed in less than 48 hours.)

(b) *Standard: Timeframe for completion of the comprehensive assessment.* The hospice interdisciplinary group, in consultation with the individual's attending physician (if any), must complete the comprehensive assessment no later than 5 calendar days after the election of hospice care in accordance with § 418.24.

(c) *Standard: Content of the comprehensive assessment.* The comprehensive assessment must identify the physical, psychosocial, emotional, and spiritual needs related to the terminal illness that must be addressed in order to promote the hospice patient's well-being, comfort, and dignity throughout the dying process. The comprehensive assessment must take into consideration the following factors:

(1) The nature and condition causing admission (including the presence or lack of objective data and subjective complaints).

(2) Complications and risk factors that affect care planning.

(3) Functional status, including the patient's ability to understand and participate in his or her own care.

(4) Imminence of death.

(5) Severity of symptoms.

(6) *Drug profile.* A review of all of the patient's prescription and over-the-counter drugs, herbal remedies and other alternative treatments that could affect drug therapy. This includes, but is not limited to, identification of the following:

(i) Effectiveness of drug therapy.

(ii) Drug side effects.

(iii) Actual or potential drug interactions.

(iv) Duplicate drug therapy.

(v) Drug therapy currently associated with laboratory monitoring.

(7) *Bereavement.* An initial bereavement assessment of the needs of the patient's family and other individuals focusing on the social, spiritual, and cultural factors that may impact their

ability to cope with the patient's death. Information gathered from the initial bereavement assessment must be incorporated into the plan of care and considered in the bereavement plan of care.

(8) The need for referrals and further evaluation by appropriate health professionals.

(d) *Standard: Update of the comprehensive assessment.* The update of the comprehensive assessment must be accomplished by the hospice interdisciplinary group (in collaboration with the individual's attending physician, if any) and must consider changes that have taken place since the initial assessment. It must include information on the patient's progress toward desired outcomes, as well as a reassessment of the patient's response to care. The assessment update must be accomplished as frequently as the condition of the patient requires, but no less frequently than every 15 days.

(e) *Standard: Patient outcome measures.* (1) The comprehensive assessment must include data elements that allow for measurement of outcomes. The hospice must measure and document data in the same way for all patients. The data elements must take into consideration aspects of care related to hospice and palliation.

(2) The data elements must be an integral part of the comprehensive assessment and must be documented in a systematic and retrievable way for each patient. The data elements for each patient must be used in individual patient care planning and in the coordination of services, and must be used in the aggregate for the hospice's quality assessment and performance improvement program.

§ 418.56 Condition of participation: Interdisciplinary group, care planning, and coordination of services.

The hospice must designate an interdisciplinary group or groups as specified in paragraph (a) of this section which, in consultation with the patient's attending physician, must prepare a written plan of care for each patient. The plan of care must specify the hospice care and services necessary to meet the patient and family-specific needs identified in the comprehensive assessment as such needs relate to the terminal illness and related conditions.

(a) *Standard: Approach to service delivery.* (1) The hospice must designate an interdisciplinary group or groups composed of individuals who work together to meet the physical, medical, psychosocial, emotional, and spiritual needs of the hospice patients and families facing terminal illness and bereavement. Interdisciplinary group members must provide the care and services offered by the hospice, and the group, in its entirety, must supervise the care and services. The hospice must designate a registered nurse that is a member of the interdisciplinary group to provide coordination of care and to ensure continuous assessment of each patient's and family's needs and implementation of the interdisciplinary plan of care. The interdisciplinary group must include, but is not limited to, individuals who are qualified and competent to practice in the following professional roles:

(i) A doctor of medicine or osteopathy (who is an employee or under contract with the hospice).

(ii) A registered nurse.

(iii) A social worker, marriage and family therapist, or a mental health counselor.

(iv) A pastoral or other counselor.

(2) If the hospice has more than one interdisciplinary group, it must identify a specifically designated interdisciplinary group to establish policies governing the day-to-day provision of hospice care and services.

(b) *Standard: Plan of care.* All hospice care and services furnished to patients and their families must follow an individualized written plan of care established by the hospice interdisciplinary group in collaboration with the attending physician (if any), the patient or representative, and the primary caregiver in accordance with the patient's needs if any of them so desire. The hospice must ensure that each patient and the primary care giver(s) receive education and training provided by the hospice as appropriate to their responsibilities for the care and services identified in the plan of care.

(c) *Standard: Content of the plan of care.* The hospice must develop an individualized written plan of care for each

patient. The plan of care must reflect patient and family goals and interventions based on the problems identified in the initial, comprehensive, and updated comprehensive assessments. The plan of care must include all services necessary for the palliation and management of the terminal illness and related conditions, including the following:

(1) Interventions to manage pain and symptoms.

(2) A detailed statement of the scope and frequency of services necessary to meet the specific patient and family needs.

(3) Measurable outcomes anticipated from implementing and coordinating the plan of care.

(4) Drugs and treatment necessary to meet the needs of the patient.

(5) Medical supplies and appliances necessary to meet the needs of the patient.

(6) The interdisciplinary group's documentation of the patient's or representative's level of understanding, involvement, and agreement with the plan of care, in accordance with the hospice's own policies, in the clinical record.

(d) *Standard: Review of the plan of care.* The hospice interdisciplinary group (in collaboration with the individual's attending physician, if any) must review, revise and document the individualized plan as frequently as the patient's condition requires, but no less frequently than every 15 calendar days. A revised plan of care must include information from the patient's updated comprehensive assessment and must note the patient's progress toward outcomes and goals specified in the plan of care.

(e) *Standard: Coordination of services.* The hospice must develop and maintain a system of communication and integration, in accordance with the hospice's own policies and procedures, to—

(1) Ensure that the interdisciplinary group maintains responsibility for directing, coordinating, and supervising the care and services provided.

(2) Ensure that the care and services are provided in accordance with the plan of care.

(3) Ensure that the care and services provided are based on all assessments of the patient and family needs.

(4) Provide for and ensure the ongoing sharing of information between all disciplines providing care and services in all settings, whether the care and services are provided directly or under arrangement.

(5) Provide for an ongoing sharing of information with other non-hospice healthcare providers furnishing services unrelated to the terminal illness and related conditions.

[73 FR 32204, June 5, 2008, as amended at 88 FR 79539, Nov. 16, 2023]

§ 418.58 Condition of participation: Quality assessment and performance improvement.

The hospice must develop, implement, and maintain an effective, ongoing, hospice-wide data-driven quality assessment and performance improvement program. The hospice's governing body must ensure that the program: Reflects the complexity of its organization and services; involves all hospice services (including those services furnished under contract or arrangement); focuses on indicators related to improved palliative outcomes; and takes actions to demonstrate improvement in hospice performance. The hospice must maintain documentary evidence of its quality assessment and performance improvement program and be able to demonstrate its operation to CMS.

(a) *Standard: Program scope.* (1) The program must at least be capable of showing measurable improvement in indicators related to improved palliative outcomes and hospice services.

(2) The hospice must measure, analyze, and track quality indicators, including adverse patient events, and other aspects of performance that enable the hospice to assess processes of care, hospice services, and operations.

(b) *Standard: Program data.* (1) The program must use quality indicator data, including patient care, and other relevant data, in the design of its program.

(2) The hospice must use the data collected to do the following:

(i) Monitor the effectiveness and safety of services and quality of care.

(ii) Identify opportunities and priorities for improvement.

(3) The frequency and detail of the data collection must be approved by the hospice's governing body.

(c) *Standard: Program activities.* (1) The hospice's performance improvement activities must:

(i) Focus on high risk, high volume, or problem-prone areas.

(ii) Consider incidence, prevalence, and severity of problems in those areas.

(iii) Affect palliative outcomes, patient safety, and quality of care.

(2) Performance improvement activities must track adverse patient events, analyze their causes, and implement preventive actions and mechanisms that include feedback and learning throughout the hospice.

(3) The hospice must take actions aimed at performance improvement and, after implementing those actions, the hospice must measure its success and track performance to ensure that improvements are sustained.

(d) *Standard: Performance improvement projects.* Beginning February 2, 2009 hospices must develop, implement, and evaluate performance improvement projects.

(1) The number and scope of distinct performance improvement projects conducted annually, based on the needs of the hospice's population and internal organizational needs, must reflect the scope, complexity, and past performance of the hospice's services and operations.

(2) The hospice must document what performance improvement projects are being conducted, the reasons for conducting these projects, and the measurable progress achieved on these projects.

(e) *Standard: Executive responsibilities.* The hospice's governing body is responsible for ensuring the following:

(1) That an ongoing program for quality improvement and patient safety is defined, implemented, and maintained, and is evaluated annually.

(2) That the hospice-wide quality assessment and performance improvement efforts address priorities for improved quality of care and patient safety, and that all improvement actions are evaluated for effectiveness.

(3) That one or more individual(s) who are responsible for operating the quality assessment and performance improvement program are designated.

§ 418.60 Condition of participation: Infection control.

The hospice must maintain and document an effective infection control program that protects patients, families, visitors, and hospice personnel by preventing and controlling infections and communicable diseases.

(a) *Standard: Prevention.* The hospice must follow accepted standards of practice to prevent the transmission of infections and communicable diseases, including the use of standard precautions.

(b) *Standard: Control.* The hospice must maintain a coordinated agency-wide program for the surveillance, identification, prevention, control, and investigation of infectious and communicable diseases that—

(1) Is an integral part of the hospice's quality assessment and performance improvement program; and

(2) Includes the following:

(i) A method of identifying infectious and communicable disease problems; and

(ii) A plan for implementing the appropriate actions that are expected to result in improvement and disease prevention.

(c) *Standard: Education.* The hospice must provide infection control education to employees, contracted providers, patients, and family members and other caregivers.

[73 FR 32204, June 5, 2008, as amended at 86 FR 61616, Nov. 5, 2021; 88 FR 36510, June 5, 2023]

§ 418.62 Condition of participation: Licensed professional services.

(a) Licensed professional services provided directly or under arrangement must be authorized, delivered, and supervised only by health care professionals who meet the appropriate qualifications specified under § 418.114 and who practice under the hospice's policies and procedures.

(b) Licensed professionals must actively participate in the coordination of all aspects of the patient's hospice

care, in accordance with current professional standards and practice, including participating in ongoing interdisciplinary comprehensive assessments, developing and evaluating the plan of care, and contributing to patient and family counseling and education; and

(c) Licensed professionals must participate in the hospice's quality assessment and performance improvement program and hospice sponsored in-service training.

CORE SERVICES

§ 418.64 Condition of participation: Core services.

A hospice must routinely provide substantially all core services directly by hospice employees. These services must be provided in a manner consistent with acceptable standards of practice. These services include nursing services, medical social services, and counseling. The hospice may contract for physician services as specified in paragraph (a) of this section. A hospice may use contracted staff, if necessary, to supplement hospice employees in order to meet the needs of patients under extraordinary or other non-routine circumstances. A hospice may also enter into a written arrangement with another Medicare certified hospice program for the provision of core services to supplement hospice employee/staff to meet the needs of patients. Circumstances under which a hospice may enter into a written arrangement for the provision of core services include: Unanticipated periods of high patient loads, staffing shortages due to illness or other short-term temporary situations that interrupt patient care; and temporary travel of a patient outside of the hospice's service area.

(a) *Standard: Physician services.* The hospice medical director, physician employees, and contracted physician(s) of the hospice, in conjunction with the patient's attending physician, are responsible for the palliation and management of the terminal illness and conditions related to the terminal illness.

(1) All physician employees and those under contract, must function under the supervision of the hospice medical director.

(2) All physician employees and those under contract shall meet this requirement by either providing the services directly or through coordinating patient care with the attending physician.

(3) If the attending physician is unavailable, the medical director, contracted physician, and/or hospice physician employee is responsible for meeting the medical needs of the patient.

(b) *Standard: Nursing services.* (1) The hospice must provide nursing care and services by or under the supervision of a registered nurse. Nursing services must ensure that the nursing needs of the patient are met as identified in the patient's initial assessment, comprehensive assessment, and updated assessments.

(2) If State law permits registered nurses to see, treat, and write orders for patients, then registered nurses may provide services to beneficiaries receiving hospice care.

(3) Highly specialized nursing services that are provided so infrequently that the provision of such services by direct hospice employees would be impracticable and prohibitively expensive, may be provided under contract.

(c) *Standard: Medical social services.* Medical social services must be provided by a qualified social worker, under the direction of a physician. Social work services must be based on the patient's psychosocial assessment and the patient's and family's needs and acceptance of these services.

(d) *Standard: Counseling services.* Counseling services must be available to the patient and family to assist the patient and family in minimizing the stress and problems that arise from the terminal illness, related conditions, and the dying process. Counseling services must include, but are not limited to, the following:

(1) *Bereavement counseling.* The hospice must:

(i) Have an organized program for the provision of bereavement services furnished under the supervision of a qualified professional with experience or education in grief or loss counseling.

(ii) Make bereavement services available to the family and other individuals in the bereavement plan of care up to 1 year following the death of the patient. Bereavement counseling also extends to residents of a SNF/NF or ICF/IID when appropriate and identified in the bereavement plan of care.

(iii) Ensure that bereavement services reflect the needs of the bereaved.

(iv) Develop a bereavement plan of care that notes the kind of bereavement services to be offered and the frequency of service delivery. A special coverage provision for bereavement counseling is specified in § 418.204(c).

(2) *Dietary counseling.* Dietary counseling, when identified in the plan of care, must be performed by a qualified individual, which include dietitians as well as nurses and other individuals who are able to address and assure that the dietary needs of the patient are met.

(3) *Spiritual counseling.* The hospice must:

(i) Provide an assessment of the patient's and family's spiritual needs.

(ii) Provide spiritual counseling to meet these needs in accordance with the patient's and family's acceptance of this service, and in a manner consistent with patient and family beliefs and desires.

(iii) Make all reasonable efforts to facilitate visits by local clergy, pastoral counselors, or other individuals who can support the patient's spiritual needs to the best of its ability.

(iv) Advise the patient and family of this service.

§ 418.66 Condition of participation: Nursing services—Waiver of requirement that substantially all nursing services be routinely provided directly by a hospice.

(a) CMS may waive the requirement in § 418.64(b) that a hospice provide nursing services directly, if the hospice is located in a non-urbanized area. The location of a hospice that operates in several areas is considered to be the location of its central office. The hospice must provide evidence to CMS that it has made a good faith effort to hire a sufficient number of nurses to provide services. CMS may waive the requirement that nursing services be furnished by employees based on the following criteria:

(1) The location of the hospice's central office is in a non-urbanized area as determined by the Bureau of the Census.

(2) There is evidence that a hospice was operational on or before January 1, 1983 including the following:

(i) Proof that the organization was established to provide hospice services on or before January 1, 1983.

(ii) Evidence that hospice-type services were furnished to patients on or before January 1, 1983.

(iii) Evidence that hospice care was a discrete activity rather than an aspect of another type of provider's patient care program on or before January 1, 1983.

(3) By virtue of the following evidence that a hospice made a good faith effort to hire nurses:

(i) Copies of advertisements in local newspapers that demonstrate recruitment efforts.

(ii) Job descriptions for nurse employees.

(iii) Evidence that salary and benefits are competitive for the area.

(iv) Evidence of any other recruiting activities (for example, recruiting efforts at health fairs and contacts with nurses at other providers in the area).

(b) Any waiver request is deemed to be granted unless it is denied within 60 days after it is received.

(c) Waivers will remain effective for 1 year at a time from the date of the request.

(d) If a hospice wishes to receive a 1-year extension, it must submit a request to CMS before the expiration of the waiver period, and certify that the conditions under which it originally requested the initial waiver have not changed since the initial waiver was granted.

NON-CORE SERVICES

§ 418.70 Condition of participation: Furnishing of non-core services.

A hospice must ensure that the services described in § 418.72 through § 418.78 are provided directly by the hospice or

under arrangements made by the hospice as specified in § 418.100. These services must be provided in a manner consistent with current standards of practice.

§ 418.72 Condition of participation: Physical therapy, occupational therapy, and speech-language pathology.

Physical therapy services, occupational therapy services, and speech-language pathology services must be available, and when provided, offered in a manner consistent with accepted standards of practice.

§ 418.74 Waiver of requirement—Physical therapy, occupational therapy, speech-language pathology, and dietary counseling.

(a) A hospice located in a non-urbanized area may submit a written request for a waiver of the requirement for providing physical therapy, occupational therapy, speech-language pathology, and dietary counseling services. The hospice may seek a waiver of the requirement that it make physical therapy, occupational therapy, speech-language pathology, and dietary counseling services (as needed) available on a 24-hour basis. The hospice may also seek a waiver of the requirement that it provide dietary counseling directly. The hospice must provide evidence that it has made a good faith effort to meet the requirements for these services before it seeks a waiver. CMS may approve a waiver application on the basis of the following criteria:

(1) The hospice is located in a non-urbanized area as determined by the Bureau of the Census.

(2) The hospice provides evidence that it had made a good faith effort to make available physical therapy, occupational therapy, speech-language pathology, and dietary counseling services on a 24-hour basis and/or to hire a dietary counselor to furnish services directly. This evidence must include the following:

(i) Copies of advertisements in local newspapers that demonstrate recruitment efforts.

(ii) Physical therapy, occupational therapy, speech-language pathology, and dietary counselor job descriptions.

(iii) Evidence that salary and benefits are competitive for the area.

(iv) Evidence of any other recruiting activities (for example, recruiting efforts at health fairs and contact discussions with physical therapy, occupational therapy, speech-language pathology, and dietary counseling service providers in the area).

(b) Any waiver request is deemed to be granted unless it is denied within 60 days after it is received.

(c) An initial waiver will remain effective for 1 year at a time from the date of the request.

(d) If a hospice wishes to receive a 1-year extension, it must submit a request to CMS before the expiration of the waiver period and certify that conditions under which it originally requested the waiver have not changed since the initial waiver was granted.

§ 418.76 Condition of participation: Hospice aide and homemaker services.

All hospice aide services must be provided by individuals who meet the personnel requirements specified in paragraph (a) of this section. Homemaker services must be provided by individuals who meet the personnel requirements specified in paragraph (j) of this section.

(a) *Standard: Hospice aide qualifications.* (1) A qualified hospice aide is a person who has successfully completed one of the following:

(i) A training program and competency evaluation as specified in paragraphs (b) and (c) of this section respectively.

(ii) A competency evaluation program that meets the requirements of paragraph (c) of this section.

(iii) A nurse aide training and competency evaluation program approved by the State as meeting the requirements of § 483.151 through § 483.154 of this chapter, and is currently listed in good standing on the State nurse aide registry.

(iv) A State licensure program.

(2) A hospice aide is not considered to have completed a program, as specified in paragraph (a)(1) of this section, if, since the individual's most recent completion of the program(s), there has

been a continuous period of 24 consecutive months during which none of the services furnished by the individual as described in § 409.40 of this chapter were for compensation. If there has been a 24-month lapse in furnishing services, the individual must complete another program, as specified in paragraph (a)(1) of this section, before providing services.

(b) *Standard: Content and duration of hospice aide classroom and supervised practical training.* (1) Hospice aide training must include classroom and supervised practical training in a practicum laboratory or other setting in which the trainee demonstrates knowledge while performing tasks on an individual under the direct supervision of a registered nurse, or a licensed practical nurse, who is under the supervision of a registered nurse. Classroom and supervised practical training combined must total at least 75 hours.

(2) A minimum of 16 hours of classroom training must precede a minimum of 16 hours of supervised practical training as part of the 75 hours.

(3) A hospice aide training program must address each of the following subject areas:

(i) Communication skills, including the ability to read, write, and verbally report clinical information to patients, care givers, and other hospice staff.

(ii) Observation, reporting, and documentation of patient status and the care or service furnished.

(iii) Reading and recording temperature, pulse, and respiration.

(iv) Basic infection control procedures.

(v) Basic elements of body functioning and changes in body function that must be reported to an aide's supervisor.

(vi) Maintenance of a clean, safe, and healthy environment.

(vii) Recognizing emergencies and the knowledge of emergency procedures and their application.

(viii) The physical, emotional, and developmental needs of and ways to work with the populations served by the hospice, including the need for respect for the patient, his or her privacy, and his or her property.

(ix) Appropriate and safe techniques in performing personal hygiene and grooming tasks, including items on the following basic checklist:

(A) Bed bath.

(B) Sponge, tub, and shower bath.

(C) Hair shampoo (sink, tub, and bed).

(D) Nail and skin care.

(E) Oral hygiene.

(F) Toileting and elimination.

(x) Safe transfer techniques and ambulation.

(xi) Normal range of motion and positioning.

(xii) Adequate nutrition and fluid intake.

(xiii) Any other task that the hospice may choose to have an aide perform. The hospice is responsible for training hospice aides, as needed, for skills not covered in the basic checklist, as described in paragraph (b)(3)(ix) of this section.

(4) The hospice must maintain documentation that demonstrates that the requirements of this standard are met.

(c) *Standard: Competency evaluation.* An individual may furnish hospice aide services on behalf of a hospice only after that individual has successfully completed a competency evaluation program as described in this section.

(1) The competency evaluation must address each of the subjects listed in paragraph (b)(3) of this section. Subject areas specified under paragraphs (b)(3)(i), (iii), (ix), (x), and (xi) of this section must be evaluated by observing an aide's performance of the task with a patient or pseudo-patient. The remaining subject areas may be evaluated through written examination, oral examination, or after observation of a hospice aide with a patient or a pseudo-patient during a simulation.

(2) A hospice aide competency evaluation program may be offered by any organization, except as described in paragraph (f) of this section.

(3) The competency evaluation must be performed by a registered nurse in consultation with other skilled professionals, as appropriate.

(4) A hospice aide is not considered competent in any task for which he or she is evaluated as unsatisfactory. An aide must not perform that task without direct supervision by a registered nurse until after he or she has received training in the task for which he or she

was evaluated as ''unsatisfactory,'' and successfully completes a subsequent evaluation. A hospice aide is not considered to have successfully completed a competency evaluation if the aide has an ''unsatisfactory'' rating in more than one of the required areas.

(5) The hospice must maintain documentation that demonstrates the requirements of this standard are being met.

(d) *Standard: In-service training.* A hospice aide must receive at least 12 hours of in-service training during each 12-month period. In-service training may occur while an aide is furnishing care to a patient.

(1) In-service training may be offered by any organization, and must be supervised by a registered nurse.

(2) The hospice must maintain documentation that demonstrates the requirements of this standard are met.

(e) *Standard: Qualifications for instructors conducting classroom and supervised practical training.* Classroom and supervised practical training must be performed by a registered nurse who possesses a minimum of 2 years nursing experience, at least 1 year of which must be in home care, or by other individuals under the general supervision of a registered nurse.

(f) *Standard: Eligible competency evaluation organizations.* A hospice aide competency evaluation program as specified in paragraph (c) of this section may be offered by any organization except by a home health agency that, within the previous 2 years:

(1) Had been out of compliance with the requirements of §484.80 of this chapter.

(2) Permitted an individual that does not meet the definition of a ''qualified home health aide'' as specified in §484.80(a) of this chapter to furnish home health aide services (with the exception of licensed health professionals and volunteers).

(3) Had been subjected to an extended (or partial extended) survey as a result of having been found to have furnished substandard care (or for other reasons at the discretion of CMS or the State).

(4) Had been assessed a civil monetary penalty of $5,000 or more as an intermediate sanction.

(5) Had been found by CMS to have compliance deficiencies that endangered the health and safety of the home health agency's patients and had temporary management appointed to oversee the management of the home health agency.

(6) Had all or part of its Medicare payments suspended.

(7) Had been found by CMS or the State under any Federal or State law to have:

(i) Had its participation in the Medicare program terminated.

(ii) Been assessed a penalty of $5,000 or more for deficiencies in Federal or State standards for home health agencies.

(iii) Been subjected to a suspension of Medicare payments to which it otherwise would have been entitled.

(iv) Operated under temporary management that was appointed by a governmental authority to oversee the operation of the home health agency and to ensure the health and safety of the home health agency's patients.

(v) Been closed by CMS or the State, or had its patients transferred by the State.

(g) *Standard: Hospice aide assignments and duties.* (1) Hospice aides are assigned to a specific patient by a registered nurse that is a member of the interdisciplinary group. Written patient care instructions for a hospice aide must be prepared by a registered nurse who is responsible for the supervision of a hospice aide as specified under paragraph (h) of this section.

(2) A hospice aide provides services that are:

(i) Ordered by the interdisciplinary group.

(ii) Included in the plan of care.

(iii) Permitted to be performed under State law by such hospice aide.

(iv) Consistent with the hospice aide training.

(3) The duties of a hospice aide include the following:

(i) The provision of hands-on personal care.

(ii) The performance of simple procedures as an extension of therapy or nursing services.

(iii) Assistance in ambulation or exercises.

(iv) Assistance in administering medications that are ordinarily self-administered.

(4) Hospice aides must report changes in the patient's medical, nursing, rehabilitative, and social needs to a registered nurse, as the changes relate to the plan of care and quality assessment and improvement activities. Hospice aides must also complete appropriate records in compliance with the hospice's policies and procedures.

(h) *Standard: Supervision of hospice aides.* (1) A registered nurse must make an on-site visit to the patient's home:

(i) No less frequently than every 14 days to assess the quality of care and services provided by the hospice aide and to ensure that services ordered by the hospice interdisciplinary group meet the patient's needs. The hospice aide does not have to be present during this visit.

(ii) If an area of concern is noted by the supervising nurse, then the hospice must make an on-site visit to the location where the patient is receiving care in order to observe and assess the aide while he or she is performing care.

(iii) If an area of concern is verified by the hospice during the on-site visit, then the hospice must conduct, and the hospice aide must complete, a competency evaluation of the deficient skill and all related skill(s) in accordance with paragraph (c) of this section.

(2) A registered nurse must make an annual on-site visit to the location where a patient is receiving care in order to observe and assess each aide while he or she is performing care.

(3) The supervising nurse must assess an aide's ability to demonstrate initial and continued satisfactory performance in meeting outcome criteria that include, but is not limited to—

(i) Following the patient's plan of care for completion of tasks assigned to the hospice aide by the registered nurse.

(ii) Creating successful interpersonal relationships with the patient and family.

(iii) Demonstrating competency with assigned tasks.

(iv) Complying with infection control policies and procedures.

(v) Reporting changes in the patient's condition.

(i) *Standard: Individuals furnishing Medicaid personal care aide-only services under a Medicaid personal care benefit.* An individual may furnish personal care services, as defined in § 440.167 of this chapter, on behalf of a hospice agency.

(1) Before the individual may furnish personal care services, the individual must be found competent by the State (if regulated by the State) to furnish those services. The individual only needs to demonstrate competency in the services the individual is required to furnish.

(2) Services under the Medicaid personal care benefit may be used to the extent that the hospice would routinely use the services of a hospice patient's family in implementing a patient's plan of care.

(3) The hospice must coordinate its hospice aide and homemaker services with the Medicaid personal care benefit to ensure the patient receives the hospice aide and homemaker services he or she needs.

(j) *Standard: Homemaker qualifications.* A qualified homemaker is—

(1) An individual who meets the standards in § 418.202(g) and has successfully completed hospice orientation addressing the needs and concerns of patients and families coping with a terminal illness; or

(2) A hospice aide as described in § 418.76.

(k) *Standard: Homemaker supervision and duties.* (1) Homemaker services must be coordinated and supervised by a member of the interdisciplinary group.

(2) Instructions for homemaker duties must be prepared by a member of the interdisciplinary group.

(3) Homemakers must report all concerns about the patient or family to the member of the interdisciplinary group who is coordinating homemaker services.

[73 FR 32204, June 5, 2008, as amended at 74 FR 39413, Aug. 6, 2009; 82 FR 4578, Jan. 13, 2017; 84 FR 51815, Sept. 30, 2019; 86 FR 42605, Aug. 4, 2021]

§ 418.78 Conditions of participation—Volunteers.

The hospice must use volunteers to the extent specified in paragraph (e) of

this section. These volunteers must be used in defined roles and under the supervision of a designated hospice employee.

(a) *Standard: Training.* The hospice must maintain, document, and provide volunteer orientation and training that is consistent with hospice industry standards.

(b) *Standard: Role.* Volunteers must be used in day-to-day administrative and/or direct patient care roles.

(c) *Standard: Recruiting and retaining.* The hospice must document and demonstrate viable and ongoing efforts to recruit and retain volunteers.

(d) *Standard: Cost saving.* The hospice must document the cost savings achieved through the use of volunteers. Documentation must include the following:

(1) The identification of each position that is occupied by a volunteer.

(2) The work time spent by volunteers occupying those positions.

(3) Estimates of the dollar costs that the hospice would have incurred if paid employees occupied the positions identified in paragraph (d)(1) of this section for the amount of time specified in paragraph (d)(2) of this section.

(e) *Standard: Level of activity.* Volunteers must provide day-to-day administrative and/or direct patient care services in an amount that, at a minimum, equals 5 percent of the total patient care hours of all paid hospice employees and contract staff. The hospice must maintain records on the use of volunteers for patient care and administrative services, including the type of services and time worked.

Subpart D—Conditions of participation: Organizational Environment

SOURCE: 73 FR 32204, June 5, 2008, unless otherwise noted.

§ 418.100 Condition of Participation: Organization and administration of services.

The hospice must organize, manage, and administer its resources to provide the hospice care and services to patients, caregivers and families necessary for the palliation and management of the terminal illness and related conditions.

(a) *Standard: Serving the hospice patient and family.* The hospice must provide hospice care that—

(1) Optimizes comfort and dignity; and

(2) Is consistent with patient and family needs and goals, with patient needs and goals as priority.

(b) *Standard: Governing body and administrator.* A governing body (or designated persons so functioning) assumes full legal authority and responsibility for the management of the hospice, the provision of all hospice services, its fiscal operations, and continuous quality assessment and performance improvement. A qualified administrator appointed by and reporting to the governing body is responsible for the day-to-day operation of the hospice. The administrator must be a hospice employee and possess education and experience required by the hospice's governing body.

(c) *Standard: Services.* (1) A hospice must be primarily engaged in providing the following care and services and must do so in a manner that is consistent with accepted standards of practice:

(i) Nursing services.

(ii) Medical social services.

(iii) Physician services.

(iv) Counseling services, including spiritual counseling, dietary counseling, and bereavement counseling.

(v) Hospice aide, volunteer, and homemaker services.

(vi) Physical therapy, occupational therapy, and speech-language pathology services.

(vii) Short-term inpatient care.

(viii) Medical supplies (including drugs and biologicals) and medical appliances.

(2) Nursing services, physician services, and drugs and biologicals (as specified in § 418.106) must be made routinely available on a 24-hour basis 7 days a week. Other covered services must be available on a 24-hour basis when reasonable and necessary to meet the needs of the patient and family.

(d) *Standard: Continuation of care.* A hospice may not discontinue or reduce

care provided to a Medicare or Medicaid beneficiary because of the beneficiary's inability to pay for that care.

(e) *Standard: Professional management responsibility.* A hospice that has a written agreement with another agency, individual, or organization to furnish any services under arrangement must retain administrative and financial management, and oversight of staff and services for all arranged services, to ensure the provision of quality care. Arranged services must be supported by written agreements that require that all services be—

(1) Authorized by the hospice;

(2) Furnished in a safe and effective manner by qualified personnel; and

(3) Delivered in accordance with the patient's plan of care.

(f) *Standard: Hospice multiple locations.* If a hospice operates multiple locations, it must meet the following requirements:

(1) Medicare approval.

(i) All hospice multiple locations must be approved by Medicare before providing hospice care and services to Medicare patients.

(ii) The multiple location must be part of the hospice and must share administration, supervision, and services with the hospice issued the certification number.

(iii) The lines of authority and professional and administrative control must be clearly delineated in the hospice's organizational structure and in practice, and must be traced to the location which was issued the certification number.

(iv) The determination that a multiple location does or does not meet the definition of a multiple location, as set forth in this part, is an initial determination, as set forth in §498.3.

(2) The hospice must continually monitor and manage all services provided at all of its locations to ensure that services are delivered in a safe and effective manner and to ensure that each patient and family receives the necessary care and services outlined in the plan of care, in accordance with the requirements of this subpart and subparts A and C of this section.

(g) *Standard: Training.* (1) A hospice must provide orientation about the hospice philosophy to all employees and contracted staff who have patient and family contact.

(2) A hospice must provide an initial orientation for each employee that addresses the employee's specific job duties.

(3) A hospice must assess the skills and competence of all individuals furnishing care, including volunteers furnishing services, and, as necessary, provide in-service training and education programs where required. The hospice must have written policies and procedures describing its method(s) of assessment of competency and maintain a written description of the in-service training provided during the previous 12 months.

[73 FR 32204, June 5, 2008, as amended at 74 FR 39413, Aug. 6, 2009]

§418.102 Condition of participation: Medical director.

The hospice must designate a physician to serve as medical director. The medical director must be a doctor of medicine or osteopathy who is an employee or is under contract with the hospice. When the medical director is not available, a physician designee as defined at §418.3 assumes the same responsibilities and obligations as the medical director.

(a) *Standard: Medical director contract.* (1) A hospice may contract with either of the following—

(i) A self-employed physician; or

(ii) A physician employed by a professional entity or physicians group. When contracting for medical director services, the contract must specify the physician who assumes the medical director responsibilities and obligations.

(b) *Standard: Initial certification of terminal illness.* The medical director (or physician designee, as defined in §418.3, if the medical director is unavailable) or physician member of the IDG reviews the clinical information for each hospice patient and provides written certification that it is anticipated that the patient's life expectancy is 6 months or less if the illness runs its normal course. The physician must consider the following when making this determination:

(1) The primary terminal condition;

(2) Related diagnosis(es), if any;

(3) Current subjective and objective medical findings;

(4) Current medication and treatment orders; and

(5) Information about the medical management of any of the patient's conditions unrelated to the terminal illness.

(c) *Standard: Recertification of the terminal illness.* Before each recertification period for each patient, as described in § 418.21(a), the medical director (or physician designee, as defined in § 418.3, if the medical director is unavailable) or physician member of the IDG must review the patient's clinical information.

(d) *Standard: Medical director responsibility.* The medical director or physician designee has responsibility for the medical component of the hospice's patient care program.

[73 FR 32204, June 5, 2008, as amended at 89 FR 64272, Aug. 6, 2024]

§ 418.104 Condition of participation: Clinical records.

A clinical record containing past and current findings is maintained for each hospice patient. The clinical record must contain correct clinical information that is available to the patient's attending physician and hospice staff. The clinical record may be maintained electronically.

(a) *Standard: Content.* Each patient's record must include the following:

(1) The initial plan of care, updated plans of care, initial assessment, comprehensive assessment, updated comprehensive assessments, and clinical notes.

(2) Signed copies of the notice of patient rights in accordance with § 418.52 and election statement in accordance with § 418.24.

(3) Responses to medications, symptom management, treatments, and services.

(4) Outcome measure data elements, as described in § 418.54(e) of this subpart.

(5) Physician certification and recertification of terminal illness as required in §§ 418.22 and 418.25 and described in §§ 418.102(b) and 418.102(c) respectively, if appropriate.

(6) Any advance directives as described in § 418.52(a)(2).

(7) Physician orders.

(b) *Standard: Authentication.* All entries must be legible, clear, complete, and appropriately authenticated and dated in accordance with hospice policy and currently accepted standards of practice.

(c) *Standard: Protection of information.* The clinical record, its contents and the information contained therein must be safeguarded against loss or unauthorized use. The hospice must be in compliance with the Department's rules regarding personal health information as set out at 45 CFR parts 160 and 164.

(d) *Standard: Retention of records.* Patient clinical records must be retained for 6 years after the death or discharge of the patient, unless State law stipulates a longer period of time. If the hospice discontinues operation, hospice policies must provide for retention and storage of clinical records. The hospice must inform its State agency and its CMS Regional office where such clinical records will be stored and how they may be accessed.

(e) *Standard: Discharge or transfer of care.* (1) If the care of a patient is transferred to another Medicare/Medicaid-certified facility, the hospice must forward to the receiving facility, a copy of—

(i) The hospice discharge summary; and

(ii) The patient's clinical record, if requested.

(2) If a patient revokes the election of hospice care, or is discharged from hospice in accordance with § 418.26, the hospice must forward to the patient's attending physician, a copy of—

(i) The hospice discharge summary; and

(ii) The patient's clinical record, if requested.

(3) The hospice discharge summary as required in paragraph (e)(1) and (e)(2) of this section must include—

(i) A summary of the patient's stay including treatments, symptoms and pain management.

(ii) The patient's current plan of care.

(iii) The patient's latest physician orders. and

(iv) Any other documentation that will assist in post-discharge continuity

of care or that is requested by the attending physician or receiving facility.

(f) *Standard: Retrieval of clinical records.* The clinical record, whether hard copy or in electronic form, must be made readily available on request by an appropriate authority.

§418.106 Condition of participation: Drugs and biologicals, medical supplies, and durable medical equipment.

Medical supplies and appliances, as described in §410.36 of this chapter; durable medical equipment, as described in §410.38 of this chapter; and drugs and biologicals related to the palliation and management of the terminal illness and related conditions, as identified in the hospice plan of care, must be provided by the hospice while the patient is under hospice care.

(a) *Standard: Managing drugs and biologicals.* (1) A hospice that provides inpatient care directly in its own facility must provide pharmacy services under the direction of a qualified licensed pharmacist who is an employee of or under contract with the hospice. The provided pharmacist services must include evaluation of a patient's response to medication therapy, identification of potential adverse drug reactions, and recommended appropriate corrective action.

(2) [Reserved]

(b) *Standard: Ordering of drugs.* (1) Drugs may be ordered by any of the following practitioners:

(i) A physician as defined by section 1861(r)(1) of the Act.

(ii) A nurse practitioner in accordance with state scope of practice requirements.

(iii) A physician assistant in accordance with state scope of practice requirements and hospice policy who is:

(A) The patient's attending physician; and

(B) Not an employee of or under arrangement with the hospice.

(2) If the drug order is verbal or given by or through electronic transmission—

(i) It must be given only to a licensed nurse, nurse practitioner (where appropriate), pharmacist, or physician; and

(ii) The individual receiving the order must record and sign it immediately and have the prescribing person sign it in accordance with State and Federal regulations.

(c) *Standard: Dispensing of drugs and biologicals.* The hospice must—

(1) Obtain drugs and biologicals from community or institutional pharmacists or stock drugs and biologicals itself.

(2) The hospice that provides inpatient care directly in its own facility must:

(i) Have a written policy in place that promotes dispensing accuracy; and

(ii) Maintain current and accurate records of the receipt and disposition of all controlled drugs.

(d) *Standard: Administration of drugs and biologicals.* (1) The interdisciplinary group, as part of the review of the plan of care, must determine the ability of the patient and/or family to safely self-administer drugs and biologicals to the patient in his or her home.

(2) Patients receiving care in a hospice that provides inpatient care directly in its own facility may only be administered medications by the following individuals:

(i) A licensed nurse, physician, or other health care professional in accordance with their scope of practice and State law;

(ii) An employee who has completed a State-approved training program in medication administration; and

(iii) The patient, upon approval by the interdisciplinary group.

(e) *Standard: Labeling, disposing, and storing of drugs and biologicals*—(1) *Labeling.* Drugs and biologicals must be labeled in accordance with currently accepted professional practice and must include appropriate usage and cautionary instructions, as well as an expiration date (if applicable).

(2) *Disposing.* (i) Safe use and disposal of controlled drugs in the patient's home. The hospice must have written policies and procedures for the management and disposal of controlled drugs in the patient's home. At the time when controlled drugs are first ordered the hospice must:

(A) Provide a copy of the hospice written policies and procedures on the management and disposal of controlled drugs to the patient or patient representative and family;

(B) Discuss the hospice policies and procedures for managing the safe use and disposal of controlled drugs with the patient or representative and the family in a language and manner that they understand to ensure that these parties are educated regarding the safe use and disposal of controlled drugs; and

(C) Document in the patient's clinical record that the written policies and procedures for managing controlled drugs was provided and discussed.

(ii) Disposal of controlled drugs in hospices that provide inpatient care directly. The hospice that provides inpatient care directly in its own facility must dispose of controlled drugs in compliance with the hospice policy and in accordance with State and Federal requirements. The hospice must maintain current and accurate records of the receipt and disposition of all controlled drugs.

(3) *Storing.* The hospice that provides inpatient care directly in its own facility must comply with the following additional requirements—

(i) All drugs and biologicals must be stored in secure areas. All controlled drugs listed in Schedules II, III, IV, and V of the Comprehensive Drug Abuse Prevention and Control Act of 1976 must be stored in locked compartments within such secure storage areas. Only personnel authorized to administer controlled drugs as noted in paragraph (d)(2) of this section may have access to the locked compartments; and

(ii) Discrepancies in the acquisition, storage, dispensing, administration, disposal, or return of controlled drugs must be investigated immediately by the pharmacist and hospice administrator and where required reported to the appropriate State authority. A written account of the investigation must be made available to State and Federal officials if required by law or regulation.

(f) *Standard: Use and maintenance of equipment and supplies.* (1) The hospice must ensure that manufacturer recommendations for performing routine and preventive maintenance on durable medical equipment are followed. The equipment must be safe and work as intended for use in the patient's environment. Where a manufacturer recommendation for a piece of equipment does not exist, the hospice must ensure that repair and routine maintenance policies are developed. The hospice may use persons under contract to ensure the maintenance and repair of durable medical equipment.

(2) The hospice must ensure that the patient, where appropriate, as well as the family and/or other caregiver(s), receive instruction in the safe use of durable medical equipment and supplies. The hospice may use persons under contract to ensure patient and family instruction. The patient, family, and/or caregiver must be able to demonstrate the appropriate use of durable medical equipment to the satisfaction of the hospice staff.

(3) Hospices may only contract for durable medical equipment services with a durable medical equipment supplier that meets the Medicare DMEPOS Supplier Quality and Accreditation Standards at 42 CFR 424.57.

[73 FR 32204, June 5, 2008, as amended at 84 FR 51815, Sept. 30, 2019; 84 FR 63202, Nov. 15, 2019]

§ 418.108 Condition of participation: Short-term inpatient care.

Inpatient care must be available for pain control, symptom management, and respite purposes, and must be provided in a participating Medicare or Medicaid facility.

(a) *Standard: Inpatient care for symptom management and pain control.* Inpatient care for pain control and symptom management must be provided in one of the following:

(1) A Medicare-certified hospice that meets the conditions of participation for providing inpatient care directly as specified in § 418.110.

(2) A Medicare-certified hospital or a skilled nursing facility that also meets the standards specified in § 418.110(b) and (f) regarding 24-hour nursing services and patient areas.

(b) *Standard: Inpatient care for respite purposes.* (1) Inpatient care for respite purposes must be provided by one of the following:

(i) A provider specified in paragraph (a) of this section.

(ii) A Medicare or Medicaid-certified nursing facility that also meets the standards specified in §418.110(f).

(2) The facility providing respite care must provide 24-hour nursing services that meet the nursing needs of all patients and are furnished in accordance with each patient's plan of care. Each patient must receive all nursing services as prescribed and must be kept comfortable, clean, well-groomed, and protected from accident, injury, and infection.

(c) *Standard: Inpatient care provided under arrangements.* If the hospice has an arrangement with a facility to provide for short-term inpatient care, the arrangement is described in a written agreement, coordinated by the hospice, and at a minimum specifies—

(1) That the hospice supplies the inpatient provider a copy of the patient's plan of care and specifies the inpatient services to be furnished;

(2) That the inpatient provider has established patient care policies consistent with those of the hospice and agrees to abide by the palliative care protocols and plan of care established by the hospice for its patients;

(3) That the hospice patient's inpatient clinical record includes a record of all inpatient services furnished and events regarding care that occurred at the facility; that a copy of the discharge summary be provided to the hospice at the time of discharge; and that a copy of the inpatient clinical record is available to the hospice at the time of discharge;

(4) That the inpatient facility has identified an individual within the facility who is responsible for the implementation of the provisions of the agreement;

(5) That the hospice retains responsibility for ensuring that the training of personnel who will be providing the patient's care in the inpatient facility has been provided and that a description of the training and the names of those giving the training are documented; and

(6) A method for verifying that the requirements in paragraphs (c)(1) through (c)(5) of this section are met.

(d) *Standard: Inpatient care limitation.* The total number of inpatient days used by Medicare beneficiaries who elected hospice coverage in a 12-month period in a particular hospice may not exceed 20 percent of the total number of hospice days consumed in total by this group of beneficiaries.

(e) *Standard: Exemption from limitation.* Before October 1, 1986, any hospice that began operation before January 1, 1975, is not subject to the limitation specified in paragraph (d) of this section.

[73 FR 32204, June 5, 2008, as amended at 74 FR 39413, Aug. 6, 2009; 81 FR 26897, May 4, 2016]

§418.110 Condition of participation: Hospices that provide inpatient care directly.

A hospice that provides inpatient care directly in its own facility must demonstrate compliance with all of the following standards:

(a) *Standard: Staffing.* The hospice is responsible for ensuring that staffing for all services reflects its volume of patients, their acuity, and the level of intensity of services needed to ensure that plan of care outcomes are achieved and negative outcomes are avoided.

(b) *Standard: Twenty-four hour nursing services.* (1) The hospice facility must provide 24-hour nursing services that meet the nursing needs of all patients and are furnished in accordance with each patient's plan of care. Each patient must receive all nursing services as prescribed and must be kept comfortable, clean, well-groomed, and protected from accident, injury, and infection.

(2) If at least one patient in the hospice facility is receiving general inpatient care, then each shift must include a registered nurse who provides direct patient care.

(c) *Standard: Physical environment.* The hospice must maintain a safe physical environment free of hazards for patients, staff, and visitors.

(1) *Safety management.* The hospice must address real or potential threats to the health and safety of the patients, others, and property.

(2) *Physical plant and equipment.* The hospice must develop procedures for controlling the reliability and quality of—

(i) The routine storage and prompt disposal of trash and medical waste;

(ii) Light, temperature, and ventilation/air exchanges throughout the hospice;

(iii) Emergency gas and water supply; and

(iv) The scheduled and emergency maintenance and repair of all equipment.

(d) *Standard: Fire protection.* (1) Except as otherwise provided in this section—

(i) The hospice must meet the applicable provisions and must proceed in accordance with the Life Safety Code (NFPA 101 and Tentative Interim Amendments TIA 12–1, TIA 12–2, TIA 12–3, and TIA 12–4.)

(ii) Notwithstanding paragraph (d)(1)(i) of this section, corridor doors and doors to rooms containing flammable or combustible materials must be provided with positive latching hardware. Roller latches are prohibited on such doors.

(2) In consideration of a recommendation by the State survey agency or Accrediting Organization or at the discretion of the Secretary, may waive, for periods deemed appropriate, specific provisions of the Life Safety Code, which would result in unreasonable hardship upon a hospice facility, but only if the waiver will not adversely affect the health and safety of the patients.

(3) The provisions of the adopted edition of the Life Safety Code do not apply in a State if CMS finds that a fire and safety code imposed by State law adequately protects patients in hospices.

(4) A hospice may place alcohol-based hand rub dispensers in its facility if the dispensers are installed in a manner that adequately protects against access by vulnerable populations.

(5) When a sprinkler system is shut down for more than 10 hours, the hospice must:

(i) Evacuate the building or portion of the building affected by the system outage until the system is back in service, or

(ii) Establish a fire watch until the system is back in service.

(6) Buildings must have an outside window or outside door in every sleeping room, and for any building constructed after July 5, 2016 the sill height must not exceed 36 inches above the floor. Windows in atrium walls are considered outside windows for the purposes of this requirement.

(e) *Standard: Building Safety.* Except as otherwise provided in this section, the hospice must meet the applicable provisions and must proceed in accordance with the Health Care Facilities Code (NFPA 99 and Tentative Interim Amendments TIA 12–2, TIA 12–3, TIA 12–4, TIA 12–5 and TIA 12–6).

(1) Chapters 7, 8, 12, and 13 of the adopted Health Care Facilities Code do not apply to a hospice.

(2) If application of the Health Care Facilities Code required under paragraph (e) of this section would result in unreasonable hardship for the hospice, CMS may waive specific provisions of the Health Care Facilities Code, but only if the waiver does not adversely affect the health and safety of patients.

(f) *Standard: Patient areas.* The hospice must provide a home-like atmosphere and ensure that patient areas are designed to preserve the dignity, comfort, and privacy of patients.

(1) The hospice must provide—

(i) Physical space for private patient and family visiting;

(ii) Accommodations for family members to remain with the patient throughout the night; and

(iii) Physical space for family privacy after a patient's death.

(2) The hospice must provide the opportunity for patients to receive visitors at any hour, including infants and small children.

(g) *Standard: Patient rooms.* (1) The hospice must ensure that patient rooms are designed and equipped for nursing care, as well as the dignity, comfort, and privacy of patients.

(2) The hospice must accommodate a patient and family request for a single room whenever possible.

(3) Each patient's room must—

(i) Be at or above grade level;

(ii) Contain a suitable bed and other appropriate furniture for each patient;

(iii) Have closet space that provides security and privacy for clothing and personal belongings;

(iv) Accommodate no more than two patients and their family members;

(v) Provide at least 80 square feet for each residing patient in a double room and at least 100 square feet for each patient residing in a single room; and

(vi) Be equipped with an easily-activated, functioning device accessible to the patient, that is used for calling for assistance.

(4) For a facility occupied by a Medicare-participating hospice on December 2, 2008, CMS may waive the space and occupancy requirements of paragraphs (g)(2)(iv) and (g)(2)(v) of this section if it determines that—

(i) Imposition of the requirements would result in unreasonable hardship on the hospice if strictly enforced; or jeopardize its ability to continue to participate in the Medicare program; and

(ii) The waiver serves the needs of the patient and does not adversely affect their health and safety.

(h) *Standard: Toilet and bathing facilities.* Each patient room must be equipped with, or conveniently located near, toilet and bathing facilities.

(i) *Standard: Plumbing facilities.* The hospice must—

(1) Have an adequate supply of hot water at all times; and

(2) Have plumbing fixtures with control valves that automatically regulate the temperature of the hot water used by patients.

(j) *Standard: Infection control.* The hospice must maintain an infection control program that protects patients, staff and others by preventing and controlling infections and communicable disease as stipulated in §418.60.

(k) *Standard: Sanitary environment.* The hospice must provide a sanitary environment by following current standards of practice, including nationally recognized infection control precautions, and avoid sources and transmission of infections and communicable diseases.

(l) *Standard: Linen.* The hospice must have available at all times a quantity of clean linen in sufficient amounts for all patient uses. Linens must be handled, stored, processed, and transported in such a manner as to prevent the spread of contaminants.

(m) *Standard: Meal service and menu planning.* The hospice must furnish meals to each patient that are—

(1) Consistent with the patient's plan of care, nutritional needs, and therapeutic diet;

(2) Palatable, attractive, and served at the proper temperature; and

(3) Obtained, stored, prepared, distributed, and served under sanitary conditions.

(n) *Standard: Restraint or seclusion.* All patients have the right to be free from physical or mental abuse, and corporal punishment. All patients have the right to be free from restraint or seclusion, of any form, imposed as a means of coercion, discipline, convenience, or retaliation by staff. Restraint or seclusion may only be imposed to ensure the immediate physical safety of the patient, a staff member, or others and must be discontinued at the earliest possible time.

(1) Restraint or seclusion may only be used when less restrictive interventions have been determined to be ineffective to protect the patient, a staff member, or others from harm.

(2) The type or technique of restraint or seclusion used must be the least restrictive intervention that will be effective to protect the patient, a staff member, or others from harm.

(3) The use of restraint or seclusion must be—

(i) In accordance with a written modification to the patient's plan of care; and

(ii) Implemented in accordance with safe and appropriate restraint and seclusion techniques as determined by hospice policy in accordance with State law.

(4) The use of restraint or seclusion must be in accordance with the order of a physician authorized to order restraint or seclusion by hospice policy in accordance with State law.

(5) Orders for the use of restraint or seclusion must never be written as a standing order or on an as needed basis (PRN).

(6) The medical director or physician designee must be consulted as soon as possible if the attending physician did not order the restraint or seclusion.

(7) Unless superseded by State law that is more restrictive—

(i) Each order for restraint or seclusion used for the management of violent or self-destructive behavior that

jeopardizes the immediate physical safety of the patient, a staff member, or others may only be renewed in accordance with the following limits for up to a total of 24 hours:

(A) 4 hours for adults 18 years of age or older;

(B) 2 hours for children and adolescents 9 to 17 years of age; or

(C) 1 hour for children under 9 years of age; and

After 24 hours, before writing a new order for the use of restraint or seclusion for the management of violent or self-destructive behavior, a physician authorized to order restraint or seclusion by hospice policy in accordance with State law must see and assess the patient.

(ii) Each order for restraint used to ensure the physical safety of the nonviolent or non-self-destructive patient may be renewed as authorized by hospice policy.

(8) Restraint or seclusion must be discontinued at the earliest possible time, regardless of the length of time identified in the order.

(9) The condition of the patient who is restrained or secluded must be monitored by a physician or trained staff that have completed the training criteria specified in paragraph (o) of this section at an interval determined by hospice policy.

(10) Physician, including attending physician, training requirements must be specified in hospice policy. At a minimum, physicians and attending physicians authorized to order restraint or seclusion by hospice policy in accordance with State law must have a working knowledge of hospice policy regarding the use of restraint or seclusion.

(11) When restraint or seclusion is used for the management of violent or self-destructive behavior that jeopardizes the immediate physical safety of the patient, a staff member, or others, the patient must be seen face-to-face within 1 hour after the initiation of the intervention—

(i) By a—

(A) Physician; or

(B) Registered nurse who has been trained in accordance with the requirements specified in paragraph (n) of this section.

(ii) To evaluate—

(A) The patient's immediate situation;

(B) The patient's reaction to the intervention;

(C) The patient's medical and behavioral condition; and

(D) The need to continue or terminate the restraint or seclusion.

(12) States are free to have requirements by statute or regulation that are more restrictive than those contained in paragraph (m)(11)(i) of this section.

(13) If the face-to-face evaluation specified in § 418.110(n)(11) is conducted by a trained registered nurse, the trained registered nurse must consult the medical director or physician designee as soon as possible after the completion of the 1-hour face-to-face evaluation.

(14) All requirements specified under this paragraph are applicable to the simultaneous use of restraint and seclusion. Simultaneous restraint and seclusion use is only permitted if the patient is continually monitored—

(i) Face-to-face by an assigned, trained staff member; or

(ii) By trained staff using both video and audio equipment. This monitoring must be in close proximity to the patient.

(15) When restraint or seclusion is used, there must be documentation in the patient's clinical record of the following:

(i) The 1-hour face-to-face medical and behavioral evaluation if restraint or seclusion is used to manage violent or self-destructive behavior;

(ii) A description of the patient's behavior and the intervention used;

(iii) Alternatives or other less restrictive interventions attempted (as applicable);

(iv) The patient's condition or symptom(s) that warranted the use of the restraint or seclusion; and the patient's response to the intervention(s) used, including the rationale for continued use of the intervention.

(o) *Standard: Restraint or seclusion staff training requirements.* The patient has the right to safe implementation of restraint or seclusion by trained staff.

(1) *Training intervals.* All patient care staff working in the hospice inpatient facility must be trained and able to

demonstrate competency in the application of restraints, implementation of seclusion, monitoring, assessment, and providing care for a patient in restraint or seclusion—

(i) Before performing any of the actions specified in this paragraph;

(ii) As part of orientation; and

(iii) Subsequently on a periodic basis consistent with hospice policy.

(2) *Training content.* The hospice must require appropriate staff to have education, training, and demonstrated knowledge based on the specific needs of the patient population in at least the following:

(i) Techniques to identify staff and patient behaviors, events, and environmental factors that may trigger circumstances that require the use of a restraint or seclusion.

(ii) The use of nonphysical intervention skills.

(iii) Choosing the least restrictive intervention based on an individualized assessment of the patient's medical, or behavioral status or condition.

(iv) The safe application and use of all types of restraint or seclusion used in the hospice, including training in how to recognize and respond to signs of physical and psychological distress (for example, positional asphyxia).

(v) Clinical identification of specific behavioral changes that indicate that restraint or seclusion is no longer necessary.

(vi) Monitoring the physical and psychological well-being of the patient who is restrained or secluded, including but not limited to, respiratory and circulatory status, skin integrity, vital signs, and any special requirements specified by hospice policy associated with the 1-hour face-to-face evaluation.

(vii) The use of first aid techniques and certification in the use of cardiopulmonary resuscitation, including required periodic recertification.

(3) *Trainer requirements.* Individuals providing staff training must be qualified as evidenced by education, training, and experience in techniques used to address patients' behaviors.

(4) *Training documentation.* The hospice must document in the staff personnel records that the training and demonstration of competency were successfully completed.

(p) *Standard: Death reporting requirements.* Hospices must report deaths associated with the use of seclusion or restraint.

(1) The hospice must report the following information to CMS:

(i) Each unexpected death that occurs while a patient is in restraint or seclusion.

(ii) Each unexpected death that occurs within 24 hours after the patient has been removed from restraint or seclusion.

(iii) Each death known to the hospice that occurs within 1 week after restraint or seclusion where it is reasonable to assume that use of restraint or placement in seclusion contributed directly or indirectly to a patient's death. ''Reasonable to assume'' in this context includes, but is not limited to, deaths related to restrictions of movement for prolonged periods of time, or death related to chest compression, restriction of breathing or asphyxiation.

(2) Each death referenced in this paragraph must be reported to CMS by telephone no later than the close of business the next business day following knowledge of the patient's death.

(3) Staff must document in the patient's clinical record the date and time the death was reported to CMS.

(q) The standards incorporated by reference in this section are approved for incorporation by reference by the Director of the Office of the Federal Register in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. You may inspect a copy at the CMS Information Resource Center, 7500 Security Boulevard, Baltimore, MD or at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202–741–6030, or go to: *http://www.archives.gov/federal_register/code_of_federal_regulations/ibr_locations.html*. If any changes in this edition of the Code are incorporated by reference, CMS will publish a document in the FEDERAL REGISTER to announce the changes.

(1) National Fire Protection Association, 1 Batterymarch Park, Quincy, MA 02169, *www.nfpa.org*, 1.617.770.3000.

(i) NFPA 99, Standards for Health Care Facilities Code of the National

Fire Protection Association 99, 2012 edition, issued August 11, 2011.

(ii) TIA 12–2 to NFPA 99, issued August 11, 2011.

(iii) TIA 12–3 to NFPA 99, issued August 9, 2012.

(iv) TIA 12–4 to NFPA 99, issued March 7, 2013.

(v) TIA 12–5 to NFPA 99, issued August 1, 2013.

(vi) TIA 12–6 to NFPA 99, issued March 3, 2014.

(vii) NFPA 101, Life Safety Code, 2012 edition, issued August 11, 2011;

(viii) TIA 12–1 to NFPA 101, issued August 11, 2011.

(ix) TIA 12–2 to NFPA 101, issued October 30, 2012.

(x) TIA 12–3 to NFPA 101, issued October 22, 2013.

(xi) TIA 12–4 to NFPA 101, issued October 22, 2013.

(2) [Reserved]

[73 FR 32204, June 5, 2008, as amended at 81 FR 26879, May 4, 2016; 81 FR 64024, Sept. 16, 2016]

§ 418.112 Condition of participation: Hospices that provide hospice care to residents of a SNF/NF or ICF/IID.

In addition to meeting the conditions of participation at § 418.10 through § 418.116, a hospice that provides hospice care to residents of a SNF/NF or ICF/IID must abide by the following additional standards.

(a) *Standard: Resident eligibility, election, and duration of benefits.* Medicare patients receiving hospice services and residing in a SNF, NF, or ICF/IID are subject to the Medicare hospice eligibility criteria set out at § 418.20 through § 418.30.

(b) *Standard: Professional management.* The hospice must assume responsibility for professional management of the resident's hospice services provided, in accordance with the hospice plan of care and the hospice conditions of participation, and make any arrangements necessary for hospice-related inpatient care in a participating Medicare/Medicaid facility according to §§ 418.100 and 418.108.

(c) *Standard: Written agreement.* The hospice and SNF/NF or ICF/IID must have a written agreement that specifies the provision of hospice services in the facility. The agreement must be signed by authorized representatives of the hospice and the SNF/NF or ICF/IID before the provision of hospice services. The written agreement must include at least the following:

(1) The manner in which the SNF/NF or ICF/IID and the hospice are to communicate with each other and document such communications to ensure that the needs of patients are addressed and met 24 hours a day.

(2) A provision that the SNF/NF or ICF/IID immediately notifies the hospice if—

(i) A significant change in a patient's physical, mental, social, or emotional status occurs;

(ii) Clinical complications appear that suggest a need to alter the plan of care;

(iii) A need to transfer a patient from the SNF/NF or ICF/IID, and the hospice makes arrangements for, and remains responsible for, any necessary continuous care or inpatient care necessary related to the terminal illness and related conditions; or

(iv) A patient dies.

(3) A provision stating that the hospice assumes responsibility for determining the appropriate course of hospice care, including the determination to change the level of services provided.

(4) An agreement that it is the SNF/NF or ICF/IID responsibility to continue to furnish 24 hour room and board care, meeting the personal care and nursing needs that would have been provided by the primary caregiver at home at the same level of care provided before hospice care was elected.

(5) An agreement that it is the hospice's responsibility to provide services at the same level and to the same extent as those services would be provided if the SNF/NF or ICF/IID resident were in his or her own home.

(6) A delineation of the hospice's responsibilities, which include, but are not limited to the following: Providing medical direction and management of the patient; nursing; counseling (including spiritual, dietary and bereavement); social work; provision of medical supplies, durable medical equipment and drugs necessary for the

palliation of pain and symptoms associated with the terminal illness and related conditions; and all other hospice services that are necessary for the care of the resident's terminal illness and related conditions.

(7) A provision that the hospice may use the SNF/NF or ICF/IID nursing personnel where permitted by State law and as specified by the SNF/NF or ICF/IID to assist in the administration of prescribed therapies included in the plan of care only to the extent that the hospice would routinely use the services of a hospice patient's family in implementing the plan of care.

(8) A provision stating that the hospice must report all alleged violations involving mistreatment, neglect, or verbal, mental, sexual, and physical abuse, including injuries of unknown source, and misappropriation of patient property by anyone unrelated to the hospice to the SNF/NF or ICF/IID administrator within 24 hours of the hospice becoming aware of the alleged violation.

(9) A delineation of the responsibilities of the hospice and the SNF/NF or ICF/IID to provide bereavement services to SNF/NF or ICF/IID staff.

(d) *Standard: Hospice plan of care.* In accordance with §418.56, a written hospice plan of care must be established and maintained in consultation with SNF/NF or ICF/IID representatives. All hospice care provided must be in accordance with this hospice plan of care.

(1) The hospice plan of care must identify the care and services that are needed and specifically identify which provider is responsible for performing the respective functions that have been agreed upon and included in the hospice plan of care.

(2) The hospice plan of care reflects the participation of the hospice, the SNF/NF or ICF/IID, and the patient and family to the extent possible.

(3) Any changes in the hospice plan of care must be discussed with the patient or representative, and SNF/NF or ICF/IID representatives, and must be approved by the hospice before implementation.

(e) *Standard: Coordination of services.* The hospice must:

(1) Designate a member of each interdisciplinary group that is responsible for a patient who is a resident of a SNF/NF or ICF/IID. The designated interdisciplinary group member is responsible for:

(i) Providing overall coordination of the hospice care of the SNF/NF or ICF/IID resident with SNF/NF or ICF/IID representatives; and

(ii) Communicating with SNF/NF or ICF/IID representatives and other health care providers participating in the provision of care for the terminal illness and related conditions and other conditions to ensure quality of care for the patient and family.

(2) Ensure that the hospice IDG communicates with the SNF/NF or ICF/IID medical director, the patient's attending physician, and other physicians participating in the provision of care to the patient as needed to coordinate the hospice care of the hospice patient with the medical care provided by other physicians.

(3) Provide the SNF/NF or ICF/IID with the following information:

(i) The most recent hospice plan of care specific to each patient;

(ii) Hospice election form and any advance directives specific to each patient;

(iii) Physician certification and recertification of the terminal illness specific to each patient;

(iv) Names and contact information for hospice personnel involved in hospice care of each patient;

(v) Instructions on how to access the hospice's 24-hour on-call system;

(vi) Hospice medication information specific to each patient; and

(vii) Hospice physician and attending physician (if any) orders specific to each patient.

(f) *Standard: Orientation and training of staff.* Hospice staff, in coordination with SNF/NF or ICF/IID facility staff, must assure orientation of such staff furnishing care to hospice patients in the hospice philosophy, including hospice policies and procedures regarding methods of comfort, pain control, symptom management, as well as principles about death and dying, individual responses to death, patient rights, appropriate forms, and record keeping requirements.

[73 FR 32204, June 5, 2008, as amended at 84 FR 51815, Sept. 30, 2019]

§ 418.113 Condition of participation: Emergency preparedness.

The hospice must comply with all applicable Federal, State, and local emergency preparedness requirements. The hospice must establish and maintain an emergency preparedness program that meets the requirements of this section. The emergency preparedness program must include, but not be limited to, the following elements:

(a) *Emergency plan.* The hospice must develop and maintain an emergency preparedness plan that must be reviewed, and updated at least every 2 years. The plan must do the following:

(1) Be based on and include a documented, facility-based and community-based risk assessment, utilizing an all-hazards approach.

(2) Include strategies for addressing emergency events identified by the risk assessment, including the management of the consequences of power failures, natural disasters, and other emergencies that would affect the hospice's ability to provide care.

(3) Address patient population, including, but not limited to, the type of services the hospice has the ability to provide in an emergency; and continuity of operations, including delegations of authority and succession plans.

(4) Include a process for cooperation and collaboration with local, tribal, regional, State, or Federal emergency preparedness officials' efforts to maintain an integrated response during a disaster or emergency situation.

(b) *Policies and procedures.* The hospice must develop and implement emergency preparedness policies and procedures, based on the emergency plan set forth in paragraph (a) of this section, risk assessment at paragraph (a)(1) of this section, and the communication plan at paragraph (c) of this section. The policies and procedures must be reviewed and updated at least every 2 years. At a minimum, the policies and procedures must address the following:

(1) Procedures to follow up with on-duty staff and patients to determine services that are needed, in the event that there is an interruption in services during or due to an emergency. The hospice must inform State and local officials of any on-duty staff or patients that they are unable to contact.

(2) Procedures to inform State and local officials about hospice patients in need of evacuation from their residences at any time due to an emergency situation based on the patient's medical and psychiatric condition and home environment.

(3) A system of medical documentation that preserves patient information, protects confidentiality of patient information, and secures and maintains the availability of records.

(4) The use of hospice employees in an emergency and other emergency staffing strategies, including the process and role for integration of State and Federally designated health care professionals to address surge needs during an emergency.

(5) The development of arrangements with other hospices and other providers to receive patients in the event of limitations or cessation of operations to maintain the continuity of services to hospice patients.

(6) The following are additional requirements for hospice-operated inpatient care facilities only. The policies and procedures must address the following:

(i) A means to shelter in place for patients, hospice employees who remain in the hospice.

(ii) Safe evacuation from the hospice, which includes consideration of care and treatment needs of evacuees; staff responsibilities; transportation; identification of evacuation location(s) and primary and alternate means of communication with external sources of assistance.

(iii) The provision of subsistence needs for hospice employees and patients, whether they evacuate or shelter in place, include, but are not limited to the following:

(A) Food, water, medical, and pharmaceutical supplies.

(B) Alternate sources of energy to maintain the following:

(*1*) Temperatures to protect patient health and safety and for the safe and sanitary storage of provisions.

(*2*) Emergency lighting.

(*3*) Fire detection, extinguishing, and alarm systems.

(C) Sewage and waste disposal.

(iv) The role of the hospice under a waiver declared by the Secretary, in accordance with section 1135 of the Act, in the provision of care and treatment at an alternate care site identified by emergency management officials.

(v) A system to track the location of hospice employees' on-duty and sheltered patients in the hospice's care during an emergency. If the on-duty employees or sheltered patients are relocated during the emergency, the hospice must document the specific name and location of the receiving facility or other location.

(c) *Communication plan.* The hospice must develop and maintain an emergency preparedness communication plan that complies with Federal, State, and local laws and must be reviewed and updated at least every 2 years. The communication plan must include all of the following:

(1) Names and contact information for the following:

(i) Hospice employees.

(ii) Entities providing services under arrangement.

(iii) Patients' physicians.

(iv) Other hospices.

(2) Contact information for the following:

(i) Federal, State, tribal, regional, and local emergency preparedness staff.

(ii) Other sources of assistance.

(3) Primary and alternate means for communicating with the following:

(i) Hospice's employees.

(ii) Federal, State, tribal, regional, and local emergency management agencies.

(4) A method for sharing information and medical documentation for patients under the hospice's care, as necessary, with other health care providers to maintain the continuity of care.

(5) A means, in the event of an evacuation, to release patient information as permitted under 45 CFR 164.510(b)(1)(ii).

(6) A means of providing information about the general condition and location of patients under the facility's care as permitted under 45 CFR 164.510(b)(4).

(7) A means of providing information about the hospice's inpatient occupancy, needs, and its ability to provide assistance, to the authority having jurisdiction, the Incident Command Center, or designee.

(d) *Training and testing.* The hospice must develop and maintain an emergency preparedness training and testing program that is based on the emergency plan set forth in paragraph (a) of this section, risk assessment at paragraph (a)(1) of this section, policies and procedures at paragraph (b) of this section, and the communication plan at paragraph (c) of this section. The training and testing program must be reviewed and updated at least every 2 years.

(1) *Training program.* The hospice must do all of the following:

(i) Initial training in emergency preparedness policies and procedures to all new and existing hospice employees, and individuals providing services under arrangement, consistent with their expected roles.

(ii) Demonstrate staff knowledge of emergency procedures.

(iii) Provide emergency preparedness training at least every 2 years.

(iv) Periodically review and rehearse its emergency preparedness plan with hospice employees (including non-employee staff), with special emphasis placed on carrying out the procedures necessary to protect patients and others.

(v) Maintain documentation of all emergency preparedness training.

(vi) If the emergency preparedness policies and procedures are significantly updated, the hospice must conduct training on the updated policies and procedures.

(2) *Testing for hospices that provide care in the patient's home.* The hospice must conduct exercises to test the emergency plan at least annually. The hospice must do the following:

(i) Participate in a full-scale exercise that is community-based every 2 years; or

(A) When a community-based exercise is not accessible, conduct an individual facility-based functional exercise every 2 years; or

(B) If the hospice experiences a natural or man-made emergency that requires activation of the emergency plan, the hospital is exempt from engaging in its next required full-scale community-based exercise or individual facility-based functional exercise following the onset of the emergency event.

(ii) Conduct an additional exercise every 2 years, opposite the year the full-scale or functional exercise under paragraph (d)(2)(i) of this section is conducted, that may include, but is not limited to the following:

(A) A second full-scale exercise that is community-based or a facility-based functional exercise; or

(B) A mock disaster drill; or

(C) A tabletop exercise or workshop that is led by a facilitator and includes a group discussion using a narrated, clinically-relevant emergency scenario, and a set of problem statements, directed messages, or prepared questions designed to challenge an emergency plan.

(3) *Testing for hospices that provide inpatient care directly.* The hospice must conduct exercises to test the emergency plan twice per year. The hospice must do the following:

(i) Participate in an annual full-scale exercise that is community-based; or

(A) When a community-based exercise is not accessible, conduct an annual individual facility-based functional exercise; or

(B) If the hospice experiences a natural or man-made emergency that requires activation of the emergency plan, the hospice is exempt from engaging in its next required full-scale community-based or facility-based functional exercise following the onset of the emergency event.

(ii) Conduct an additional annual exercise that may include, but is not limited to the following:

(A) A second full-scale exercise that is community-based or a facility-based functional exercise; or

(B) A mock disaster drill; or

(C) A tabletop exercise or workshop led by a facilitator that includes a group discussion using a narrated, clinically-relevant emergency scenario, and a set of problem statements, directed messages, or prepared questions designed to challenge an emergency plan.

(iii) Analyze the hospice's response to and maintain documentation of all drills, tabletop exercises, and emergency events and revise the hospice's emergency plan, as needed.

(e) *Integrated healthcare systems.* If a hospice is part of a healthcare system consisting of multiple separately certified healthcare facilities that elects to have a unified and integrated emergency preparedness program, the hospice may choose to participate in the healthcare system's coordinated emergency preparedness program. If elected, the unified and integrated emergency preparedness program must do the following:

(1) Demonstrate that each separately certified facility within the system actively participated in the development of the unified and integrated emergency preparedness program.

(2) Be developed and maintained in a manner that takes into account each separately certified facility's unique circumstances, patient populations, and services offered.

(3) Demonstrate that each separately certified facility is capable of actively using the unified and integrated emergency preparedness program and is in compliance with the program.

(4) Include a unified and integrated emergency plan that meets the requirements of paragraphs (a)(2), (3), and (4) of this section. The unified and integrated emergency plan must also be based on and include the following:

(i) A documented community-based risk assessment, utilizing an all-hazards approach.

(ii) A documented individual facility-based risk assessment for each separately certified facility within the health system, utilizing an all-hazards approach.

(5) Include integrated policies and procedures that meet the requirements set forth in paragraph (b) of this section, a coordinated communication plan and training and testing programs that meet the requirements of paragraphs (c) and (d) of this section, respectively.

[81 FR 64024, Sept. 16, 2016, as amended at 84 FR 51815, Sept. 30, 2019]

§418.114 Condition of participation: Personnel qualifications.

(a) *General qualification requirements.* Except as specified in paragraph (c) of this section, all professionals who furnish services directly, under an individual contract, or under arrangements with a hospice, must be legally authorized (licensed, certified or registered) in accordance with applicable Federal, State and local laws, and must act only within the scope of his or her State license, or State certification, or registration. All personnel qualifications must be kept current at all times.

(b) *Personnel qualifications for certain disciplines.* The following qualifications must be met:

(1) *Physician.* Physicians must meet the qualifications and conditions as defined in section 1861(r) of the Act and implemented at §410.20 of this chapter.

(2) *Hospice aide.* Hospice aides must meet the qualifications required by section 1891(a)(3) of the Act and implemented at §418.76.

(3) *Social worker.* A person who—

(i)(A) Has a Master of Social Work (MSW) degree from a school of social work accredited by the Council on Social Work Education; or

(B) Has a baccalaureate degree in social work from an institution accredited by the Council on Social Work Education; or a baccalaureate degree in psychology, sociology, or other field related to social work and is supervised by an MSW as described in paragraph (b)(3)(i)(A) of this section; and

(ii) Has 1 year of social work experience in a healthcare setting; or

(iii) Has a baccalaureate degree from a school of social work accredited by the Council on Social Work Education, is employed by the hospice before December 2, 2008, and is not required to be supervised by an MSW.

(4) *Speech language pathologist.* A person who meets either of the following requirements:

(i) The education and experience requirements for a Certificate of Clinical Competence in speech-language pathology granted by the American Speech-Language-Hearing Association.

(ii) The educational requirements for certification and is in the process of accumulating the supervised experience required for certification.

(5) *Occupational therapist.* A person who—

(i)(A) Is licensed or otherwise regulated, if applicable, as an occupational therapist by the State in which practicing, unless licensure does not apply;

(B) Graduated after successful completion of an occupational therapist education program accredited by the Accreditation Council for Occupational Therapy Education (ACOTE) of the American Occupational Therapy Association, Inc. (AOTA), or successor organizations of ACOTE; and

(C) Is eligible to take, or has successfully completed the entry-level certification examination for occupational therapists developed and administered by the National Board for Certification in Occupational Therapy, Inc. (NBCOT).

(ii) On or before December 31, 2009—

(A) Is licensed or otherwise regulated, if applicable, as an occupational therapist by the State in which practicing; or

(B) When licensure or other regulation does not apply—

(*1*) Graduated after successful completion of an occupational therapist education program accredited by the accreditation Council for Occupational therapy Education (ACOTE) of the American Occupational Therapy Association, Inc. (AOTA) or successor organizations of ACOTE; and

(*2*) Is eligible to take, or has successfully completed the entry-level certification examination for occupational therapists developed and administered by the National Board for Certification in Occupational Therapy, Inc., (NBCOT).

(iii) On or before January 1, 2008—

(A) Graduated after successful completion of an occupational therapy program accredited jointly by the committee on Allied Health Education and Accreditation of the American Medical Association and the American Occupational Therapy Association; or

(B) Is eligible for the National Registration Examination of the American Occupational Therapy Association or the National Board for Certification in Occupational Therapy.

(iv) On or before December 31, 1977—

(A) Had 2 years of appropriate experience as an occupational therapist; and

(B) Had achieved a satisfactory grade on an occupational therapist proficiency examination conducted, approved, or sponsored by the U.S. Public Health Service.

(v) If educated outside the United States—

(A) Must meet both of the following:

(*1*) Graduated after successful completion of an occupational therapist education program accredited as substantially equivalent to occupational therapist assistant entry level education in the United States by one of the following:

(*i*) The Accreditation Council for Occupational Therapy Education (ACOTE).

(*ii*) Successor organizations of ACOTE.

(*iii*) The World Federation of Occupational Therapists.

(*iv*) A credentialing body approved by the American Occupational Therapy Association.

(*v*) Successfully completed the entry level certification examination for occupational therapists developed and administered by the National Board for Certification in Occupational Therapy, Inc. (NBCOT).

(*2*) On or before December 31, 2009, is licensed or otherwise regulated, if applicable, as an occupational therapist by the State in which practicing.

(6) *Occupational therapy assistant.* A person who

(i) Meets all of the following:

(A) Is licensed or otherwise regulated, if applicable, as an occupational therapy assistant by the State in which practicing, unless licensure does apply.

(B) Graduated after successful completion of an occupational therapy assistant education program accredited by the Accreditation Council for Occupational Therapy Education (ACOTE) of the American Occupational Therapy Association, Inc. (AOTA) or its successor organizations.

(C) Is eligible to take or successfully completed the entry-level certification examination for occupational therapy assistants developed and administered by the National Board for Certification in Occupational Therapy, Inc. (NBCOT).

(ii) On or before December 31, 2009—

(A) Is licensed or otherwise regulated as an occupational therapy assistant, if applicable, by the State in which practicing; or any qualifications defined by the State in which practicing, unless licensure does not apply; or

(B) Must meet both of the following:

(*1*) Completed certification requirements to practice as an occupational therapy assistant established by a credentialing organization approved by the American Occupational Therapy Association.

(*2*) After January 1, 2010, meets the requirements in paragraph (b)(6)(i) of this section.

(iii) After December 31, 1977 and on or before December 31, 2007—

(A) Completed certification requirements to practice as an occupational therapy assistant established by a credentialing organization approved by the American Occupational Therapy Association; or

(B) Completed the requirements to practice as an occupational therapy assistant applicable in the State in which practicing.

(iv) On or before December 31, 1977—

(A) Had 2 years of appropriate experience as an occupational therapy assistant; and

(B) Had achieved a satisfactory grade on an occupational therapy assistant proficiency examination conducted, approved, or sponsored by the U.S. Public Health Service.

(v) If educated outside the United States, on or after January 1, 2008—

(A) Graduated after successful completion of an occupational therapy assistant education program that is accredited as substantially equivalent to occupational therapist assistant entry level education in the United States by—

(*1*) The Accreditation Council for Occupational Therapy Education (ACOTE).

(*2*) Its successor organizations.

(*3*) The World Federation of Occupational Therapists.

(*4*) By a credentialing body approved by the American Occupational Therapy Association; and

(*5*) Successfully completed the entry level certification examination for occupational therapy assistants developed and administered by the National

Board for Certification in Occupational Therapy, Inc. (NBCOT).

(7) *Physical therapist.* A person who is licensed, if applicable, by the State in which practicing, unless licensure does not apply and meets one of the following requirements:

(i) Graduated after successful completion of a physical therapist education program approved by one of the following:

(A) The Commission on Accreditation in Physical Therapy Education (CAPTE).

(B) Successor organizations of CAPTE.

(C) An education program outside the United States determined to be substantially equivalent to physical therapist entry level education in the United States by a credentials evaluation organization approved by the American Physical Therapy Association or an organization identified in 8 CFR 212.15(e) as it relates to physical therapists.

(D) Passed an examination for physical therapists approved by the State in which physical therapy services are provided.

(ii) On or before December 31, 2009—

(A) Graduated after successful completion of a physical therapy curriculum approved by the Commission on Accreditation in Physical Therapy Education (CAPTE); or

(B) Meets both of the following:

(*1*) Graduated after successful completion of an education program determined to be substantially equivalent to physical therapist entry level education in the United States by a credentials evaluation organization approved by the American Physical Therapy Association or identified in 8 CFR 212.15(e) as it relates to physical therapists.

(*2*) Passed an examination for physical therapists approved by the State in which physical therapy services are provided.

(iii) Before January 1, 2008—

(A) Graduated from a physical therapy curriculum approved by one of the following:

(*1*) The American Physical Therapy Association.

(*2*) The Committee on Allied Health Education and Accreditation of the American Medical Association.

(*3*) The Council on Medical Education of the American Medical Association and the American Physical Therapy Association.

(iv) On or before December 31, 1977 was licensed or qualified as a physical therapist and meets both of the following:

(A) Has 2 years of appropriate experience as a physical therapist.

(B) Has achieved a satisfactory grade on a proficiency examination conducted, approved, or sponsored by the U.S. Public Health Service.

(v) Before January 1, 1966—

(A) Was admitted to membership by the American Physical Therapy Association;

(B) Was admitted to registration by the American Registry of Physical Therapists; and

(C) Graduated from a physical therapy curriculum in a 4-year college or university approved by a State department of education.

(vi) Before January 1, 1966 was licensed or registered, and before January 1, 1970, had 15 years of fulltime experience in the treatment of illness or injury through the practice of physical therapy in which services were rendered under the order and direction of attending and referring doctors of medicine or osteopathy.

(vii) If trained outside the United States before January 1, 2008, meets the following requirements:

(A) Was graduated since 1928 from a physical therapy curriculum approved in the country in which the curriculum was located and in which there is a member organization of the World Confederation for Physical Therapy.

(B) Meets the requirements for membership in a member organization of the World Confederation for Physical Therapy.

(8) *Physical therapist assistant.* A person who is licensed, registered or certified as a physical therapist assistant, if applicable, by the State in which practicing, unless licensure does not apply and meets one of the following requirements:

(i) Graduated from a physical therapist assistant curriculum approved by the Commission on Accreditation in Physical Therapy Education of the

American Physical Therapy Association; or if educated outside the United States or trained in the United States military, graduated from an education program determined to be substantially equivalent to physical therapist assistant entry level education in the United States by a credentials evaluation organization approved by the American Physical Therapy Association or identified at 8 CFR 212.15(e); and

(ii) Passed a national examination for physical therapist assistants.

(A) On or before December 31, 2009, meets one of the following:

(*1*) Is licensed, or otherwise regulated in the State in which practicing.

(*2*) In States where licensure or other regulations do not apply, graduated before December 31, 2009, from a 2-year college-level program approved by the American Physical Therapy Association and after January 1, 2010, meets the requirements of paragraph (b)(8) of this section.

(*3*) Before January 1, 2008, where licensure or other regulation does not apply, graduated from a 2-year college level program approved by the American Physical Therapy Association.

(*4*) On or before December 31, 1977, was licensed or qualified as a physical therapist assistant and has achieved a satisfactory grade on a proficiency examination conducted, approved, or sponsored by the U.S. Public Health Service.

(9) Marriage and family therapist as defined at § 410.53.

(10) Mental health counselor as defined at § 410.54.

(c) *Personnel qualifications when no State licensing, certification or registration requirements exist.* If no State licensing laws, certification or registration requirements exist for the profession, the following requirements must be met:

(1) *Registered nurse.* A graduate of a school of professional nursing.

(2) *Licensed practical nurse.* A person who has completed a practical nursing program.

(d) *Standard: Criminal background checks.* (1) The hospice must obtain a criminal background check on all hospice employees who have direct patient contact or access to patient records. Hospice contracts must require that all contracted entities obtain criminal background checks on contracted employees who have direct patient contact or access to patient records.

(2) Criminal background checks must be obtained in accordance with State requirements. In the absence of State requirements, criminal background checks must be obtained within three months of the date of employment for all states that the individual has lived or worked in the past 3 years.

[73 FR 32204, June 5, 2008, as amended at 88 FR 79539, Nov. 16, 2023; 89 FR 64272, Aug. 6, 2024]

§ 418.116 Condition of participation: Compliance with Federal, State, and local laws and regulations related to the health and safety of patients.

The hospice and its staff must operate and furnish services in compliance with all applicable Federal, State, and local laws and regulations related to the health and safety of patients. If State or local law provides for licensing of hospices, the hospice must be licensed.

(a) *Standard: Multiple locations.* Every hospice must comply with the requirements of § 420.206 of this chapter regarding disclosure of ownership and control information. All hospice multiple locations must be approved by Medicare and licensed in accordance with State licensure laws, if applicable, before providing Medicare reimbursed services.

(b) *Standard: Laboratory services.* (1) If the hospice engages in laboratory testing other than assisting a patient in self-administering a test with an appliance that has been approved for that purpose by the FDA, the hospice must be in compliance with all applicable requirements of part 493 of this chapter.

(2) If the hospice chooses to refer specimens for laboratory testing to a reference laboratory, the reference laboratory must be certified in the appropriate specialties and subspecialties of services in accordance with the applicable requirements of part 493 of this chapter.

Subpart E [Reserved]

Subpart F—Covered Services

§ 418.200 Requirements for coverage.

To be covered, hospice services must meet the following requirements. They must be reasonable and necessary for the palliation and management of the terminal illness as well as related conditions. The individual must elect hospice care in accordance with § 418.24. A plan of care must be established and periodically reviewed by the attending physician, the medical director, and the interdisciplinary group of the hospice program as set forth in § 418.56. That plan of care must be established before hospice care is provided. The services provided must be consistent with the plan of care. A certification that the individual is terminally ill must be completed as set forth in section § 418.22.

[74 FR 39413, Aug. 6, 2009]

§ 418.202 Covered services.

All services must be performed by appropriately qualified personnel, but it is the nature of the service, rather than the qualification of the person who provides it, that determines the coverage category of the service. The following services are covered hospice services:

(a) Nursing care provided by or under the supervision of a registered nurse.

(b) Medical social services provided by a social worker under the direction of a physician.

(c) Physicians' services performed by a physician as defined in § 410.20 of this chapter except that the services of the hospice medical director or the physician member of the interdisciplinary group must be performed by a doctor of medicine or osteopathy.

(d) Counseling services provided to the terminally ill individual and the family members or other persons caring for the individual at home. Counseling, including dietary counseling, may be provided both for the purpose of training the individual's family or other caregiver to provide care, and for the purpose of helping the individual and those caring for him or her to adjust to the individual's approaching death.

(e) Short-term inpatient care provided in a participating hospice inpatient unit, or a participating hospital or SNF, that additionally meets the standards in § 418.202 (a) and (e) regarding staffing and patient areas. Services provided in an inpatient setting must conform to the written plan of care. Inpatient care may be required for procedures necessary for pain control or acute or chronic symptom management.

Inpatient care may also be furnished as a means of providing respite for the individual's family or other persons caring for the individual at home. Respite care must be furnished as specified in § 418.108(b). Payment for inpatient care will be made at the rate appropriate to the level of care as specified in § 418.302.

(f) *Medical appliances and supplies, including drugs and biologicals.* Only drugs as defined in section 1861(t) of the Act and which are used primarily for the relief of pain and symptom control related to the individual's terminal illness are covered. Appliances may include covered durable medical equipment as described in § 410.38 of this chapter as well as other self-help and personal comfort items related to the palliation or management of the patient's terminal illness. Equipment is provided by the hospice for use in the patient's home while he or she is under hospice care. Medical supplies include those that are part of the written plan of care and that are for palliation and management of the terminal or related conditions.

(g) *Home health or hospice aide services furnished by qualified aides as designated in § 418.76 and homemaker services.* Home health aides (also known as hospice aides) may provide personal care services as defined in § 409.45(b) of this chapter. Aides may perform household services to maintain a safe and sanitary environment in areas of the home used by the patient, such as changing bed linens or light cleaning and laundering essential to the comfort and cleanliness of the patient. Aide services must be provided under the general supervision of a registered nurse. Homemaker services may include assistance in maintenance of a safe and healthy environment and services to

enable the individual to carry out the treatment plan.

(h) Physical therapy, occupational therapy and speech-language pathology services in addition to the services described in §409.33 (b) and (c) of this chapter provided for purposes of symptom control or to enable the patient to maintain activities of daily living and basic functional skills.

(i) Effective April 1, 1998, any other service that is specified in the patient's plan of care as reasonable and necessary for the palliation and management of the patient's terminal illness and related conditions and for which payment may otherwise be made under Medicare.

[48 FR 56026, Dec. 16, 1983, as amended at 51 FR 41351, Nov. 14, 1986; 55 FR 50835, Dec. 11, 1990; 59 FR 65498, Dec. 20, 1994; 70 FR 70547, Nov. 22, 2005; 73 FR 32220, June 5, 2008; 74 FR 39413, Aug. 6, 2009; 76 FR 47331, Aug. 4, 2011]

§ 418.204 Special coverage requirements.

(a) *Periods of crisis.* Nursing care may be covered on a continuous basis for as much as 24 hours a day during periods of crisis as necessary to maintain an individual at home. Either homemaker or home health aide (also known as hospice aide) services or both may be covered on a 24-hour continuous basis during periods of crisis but care during these periods must be predominantly nursing care. A period of crisis is a period in which the individual requires continuous care to achieve palliation and management of acute medical symptoms.

(b) *Respite care.* (1) Respite care is short-term inpatient care provided to the individual only when necessary to relieve the family members or other persons caring for the individual.

(2) Respite care may be provided only on an occasional basis and may not be reimbursed for more than five consecutive days at a time.

(c) *Bereavement counseling.* Bereavement counseling is a required hospice service but it is not reimbursable.

[48 FR 56026, Dec. 16, 1983, as amended at 55 FR 50835, Dec. 11, 1990; 74 FR 39413, Aug. 6, 2009; 85 FR 19289, Apr. 6, 2020; 88 FR 51199, Aug. 2, 2023]

§ 418.205 Special requirements for hospice pre-election evaluation and counseling services.

(a) *Definition.* As used in this section the following definition applies.

Terminal illness has the same meaning as defined in §418.3.

(b) *General.* Effective January 1, 2005, payment for hospice pre-election evaluation and counseling services as specified in §418.304(d) may be made to a hospice on behalf of a Medicare beneficiary if the requirements of this section are met.

(1) *The beneficiary.* The beneficiary:

(i) Has been diagnosed as having a terminal illness as defined in §418.3.

(ii) Has not made a hospice election.

(iii) Has not previously received hospice pre-election evaluation and consultation services specified under this section.

(2) *Services provided.* The hospice pre-election services include an evaluation of an individual's need for pain and symptom management and counseling regarding hospice and other care options. In addition, the services may include advising the individual regarding advanced care planning.

(3) *Provision of pre-election hospice services.* (i) The services must be furnished by a physician.

(ii) The physician furnishing these services must be an employee or medical director of the hospice billing for this service.

(iii) The services cannot be furnished by hospice personnel other than employed physicians, such as but not limited to nurse practitioners, nurses, or social workers, physicians under contractual arrangements with the hospice or by the beneficiary's physician, if that physician is not an employee of the hospice.

(iv) If the beneficiary's attending physician is also the medical director or a physician employee of the hospice, the attending physician may not provide nor may the hospice bill for this service because that physician already possesses the expertise necessary to furnish end-of-life evaluation and management, and counseling services.

(4) *Documentation.* (i) If the individual's physician initiates the request for services of the hospice medical director

or physician, appropriate documentation is required.

(ii) The request or referral must be in writing, and the hospice medical director or physician employee is expected to provide a written note on the patient's medical record.

(iii) The hospice agency employing the physician providing these services is required to maintain a written record of the services furnished.

(iv) If the services are initiated by the beneficiary, the hospice agency is required to maintain a record of the services and documentation that communication between the hospice medical director or physician and the beneficiary's physician occurs, with the beneficiary's permission, to the extent necessary to ensure continuity of care.

[69 FR 66425, Nov. 15, 2004]

Subpart G—Payment for Hospice Care

§418.301 Basic rules.

(a) Medicare payment for covered hospice care is made in accordance with the method set forth in §418.302.

(b) Medicare reimbursement to a hospice in a cap period is limited to a cap amount specified in §418.309.

(c) The hospice may not charge a patient for services for which the patient is entitled to have payment made under Medicare or for services for which the patient would be entitled to payment, as described in §489.21 of this chapter.

[48 FR 56026, Dec. 16, 1983, as amended at 56 FR 26919, June 12, 1991; 70 FR 70547, Nov. 22, 2005]

§418.302 Payment procedures for hospice care.

(a) CMS establishes payment amounts for specific categories of covered hospice care.

(b) Payment amounts are determined within each of the following categories:

(1) *Routine home care day.* A routine home care day is a day on which an individual who has elected to receive hospice care is at home and is not receiving continuous care as defined in paragraph (b)(2) of this section.

(i) *Service intensity add-on.* Routine home care days that occur during the last 7 days of a hospice election ending with a patient discharged due to death are eligible for a service intensity add-on payment.

(ii) The service intensity add-on payment shall be equal to the continuous home care hourly payment rate, as described in paragraph (e)(4) of this section, multiplied by the amount of direct patient care actually provided by a RN and/or social worker, up to 4 hours total per day.

(2) *Continuous home care day.* A continuous home care day is a day on which an individual who has elected to receive hospice care is not in an inpatient facility and receives hospice care consisting predominantly of nursing care on a continuous basis at home. Home health aide (also known as a hospice aide) or homemaker services or both may also be provided on a continuous basis. Continuous home care is only furnished during brief periods of crisis as described in §418.204(a) and only as necessary to maintain the terminally ill patient at home.

(3) *Inpatient respite care day.* An inpatient respite care day is a day on which the individual who has elected hospice care receives care in an approved facility on a short-term basis for respite.

(4) *General inpatient care day.* A general inpatient care day is a day on which an individual who has elected hospice care receives general inpatient care in an inpatient facility for pain control or acute or chronic symptom management which cannot be managed in other settings.

(c) The payment amounts for the categories of hospice care are fixed payment rates that are established by CMS in accordance with the procedures described in §418.306. Payment rates are determined for the following categories:

(1) Routine home care.

(2) Continuous home care.

(3) Inpatient respite care.

(4) General inpatient care.

(d)(1) The Medicare Administrative Contractor reimburses the hospice its appropriate payment amount for each day for which an eligible Medicare beneficiary is under the hospice's care.

(2) Effective December 8, 2003, if a hospice makes arrangements with another hospice to provide services under

the circumstances specified in section 1861(dd)(5)(D) of the Act, the Medicare Administrative Contractor reimburses the hospice for which the beneficiary has made an election as described in paragraph (d)(1) of this section.

(e) The Medicare Administrative Contractor makes payment according to the following procedures:

(1) Payment is made to the hospice for each day during which the beneficiary is eligible and under the care of the hospice, regardless of the amount of services furnished on any given day (except as set out in paragraph (b)(1)(i) of this section).

(2) Payment is made for only one of the categories of hospice care described in § 418.302(b) for any particular day.

(3) On any day on which the beneficiary is not an inpatient, the hospice is paid the routine home care rate, unless the patient receives continuous care as defined in paragraph (b)(2) of this section for a period of at least 8 hours. In that case, a portion of the continuous care day rate is paid in accordance with paragraph (e)(4) of this section.

(4) The hospice payment on a continuous care day varies depending on the number of hours of continuous services provided. The continuous home care rate is divided by 24 to yield an hourly rate. The number of hours of continuous care provided during a continuous home care day is then multiplied by the hourly rate to yield the continuous home care payment for that day. A minimum of 8 hours of care must be furnished on a particular day to qualify for the continuous home care rate.

(5) Subject to the limitations described in paragraph (f) of this section, on any day on which the beneficiary is an inpatient in an approved facility for inpatient care, the appropriate inpatient rate (general or respite) is paid depending on the category of care furnished. The inpatient rate (general or respite) is paid for the date of admission and all subsequent inpatient days, except the day on which the patient is discharged. For the day of discharge, the appropriate home care rate is paid unless the patient dies as an inpatient. In the case where the beneficiary is discharged deceased, the inpatient rate (general or respite) is paid for the discharge day. Payment for inpatient respite care is subject to the requirement that it may not be provided consecutively for more than 5 days at a time. Payment for the sixth and any subsequent day of respite care is made at the routine home care rate.

(f) Payment for inpatient care is limited as follows:

(1) The total payment to the hospice for inpatient care (general or respite) is subject to a limitation that total inpatient care days for Medicare patients not exceed 20 percent of the total days for which these patients had elected hospice care.

(2) At the end of a cap period, the Medicare Administrative Contractor calculates a limitation on payment for inpatient care to ensure that Medicare payment is not made for days of inpatient care in excess of 20 percent of the total number of days of hospice care furnished to Medicare patients. Only inpatient days that were provided and billed as general inpatient or respite days are counted as inpatient days when computing the inpatient cap.

(3) If the number of days of inpatient care furnished to Medicare patients is equal to or less than 20 percent of the total days of hospice care to Medicare patients, no adjustment is necessary. Overall payments to a hospice are subject to the cap amount specified in § 418.309.

(4) If the number of days of inpatient care furnished to Medicare patients exceeds 20 percent of the total days of hospice care to Medicare patients, the total payment for inpatient care is determined in accordance with the procedures specified in paragraph (f)(5) of this section. That amount is compared to actual payments for inpatient care, and any excess reimbursement must be refunded by the hospice. Overall payments to the hospice are subject to the cap amount specified in § 418.309.

(5) If a hospice exceeds the number of inpatient care days described in paragraph (f)(4), the total payment for inpatient care is determined as follows:

(i) Calculate the ratio of the maximum number of allowable inpatient days to the actual number of inpatient care days furnished by the hospice to Medicare patients.

(ii) Multiply this ratio by the total reimbursement for inpatient care made by the Medicare Administrative Contractor.

(iii) Multiply the number of actual inpatient days in excess of the limitation by the routine home care rate.

(iv) Add the amounts calculated in paragraphs (f)(5)(ii) and (iii) of this section.

(g) Payment for routine home care, continuous home care, general inpatient care and inpatient respite care is made on the basis of the geographic location where the services are provided.

[48 FR 56026, Dec. 16, 1983, as amended at 56 FR 26919, June 12, 1991; 70 FR 45145, Aug. 4, 2005; 70 FR 70547, Nov. 22, 2005; 72 FR 50228, Aug. 31, 2007; 74 FR 39414, Aug. 6, 2009; 80 FR 47206, Aug. 6, 2015]

§418.304 Payment for physician, and nurse practitioner, and physician assistant services.

(a) The following services performed by hospice physicians and nurse practitioners are included in the rates described in §418.302:

(1) General supervisory services of the medical director.

(2) Participation in the establishment of plans of care, supervision of care and services, periodic review and updating of plans of care, and establishment of governing policies by the physician member of the interdisciplinary group.

(b) For services not described in paragraph (a) of this section, a specified Medicare contractor pays the hospice an amount equivalent to 100 percent of the physician fee schedule for those physician services furnished by hospice employees or under arrangements with the hospice. Reimbursement for these physician services is included in the amount subject to the hospice payment limit described in §418.309. Services furnished voluntarily by physicians are not reimbursable.

(c) Services of the patient's attending physician, if he or she is not an employee of the hospice or providing services under arrangements with the hospice, are not considered hospice services and are not included in the amount subject to the hospice payment limit described in §418.309. These services are paid by the carrier under the procedures in subpart B, part 414 of this chapter.

(d) *Payment for hospice pre-election evaluation and counseling services.* The intermediary makes payment to the hospice for the services established in §418.205. Payment for this service is set at an amount established under the physician fee schedule, for an office or other outpatient visit for evaluation and management associated with presenting problems of moderate severity and requiring medical decision-making of low complexity other than the portion of the amount attributable to the practice expense component. Payment for this pre-election service does not count towards the hospice cap amount.

(e)(1) Effective December 8, 2003, Medicare pays for attending physician services provided by nurse practitioners to Medicare beneficiaries who have elected the hospice benefit and who have selected a nurse practitioner as their attending physician. This applies to nurse practitioners without regard to whether they are hospice employees.

(2) Nurse practitioners may bill and receive payment for services only if the—

(i) Nurse practitioner is the beneficiary's attending physician as defined in §418.3;

(ii) Services are medically reasonable and necessary;

(iii) Services are performed by a physician in the absence of the nurse practitioner; and

(iv) Services are not related to the certification of terminal illness specified in §418.22.

(3) Payment for nurse practitioner services are made at 85 percent of the physician fee schedule amount.

(f)(1) Effective January 1, 2019, Medicare pays for attending physician services provided by physician assistants to Medicare beneficiaries who have elected the hospice benefit and who have selected a physician assistant as their attending physician. This applies to physician assistants without regard to whether they are hospice employees.

(2) The employer or a contractor of a physician assistant must bill and receive payment for physician assistant services only if the—

(i) Physician assistant is the beneficiary's attending physician as defined in § 418.3;

(ii) Services are medically reasonable and necessary;

(iii) Services are performed by a physician in the absence of the physician assistant and, the physician assistant services are furnished under the general supervision of a physician; and

(iv) Services are not related to the certification of terminal illness specified in § 418.22.

(3) The payment amount for physician assistant services when serving as the attending physician for hospice patients is 85 percent of what a physician is paid under the Medicare physician fee schedule.

[48 FR 56026, Dec. 16, 1983, as amended at 69 FR 66426, Nov. 15, 2004; 70 FR 45145, Aug. 4, 2005; 70 FR 70547, Nov. 22, 2005; 83 FR 38655, Aug. 6, 2018]

§ 418.306 Annual update of the payment rates and adjustment for area wage differences.

(a) *Applicability.* CMS establishes payment rates for each of the categories of hospice care described in § 418.302(b). The rates are established using the methodology described in section 1814(i)(1)(C) of the Act and in accordance with section 1814(i)(6)(D) of the Act.

(b) *Annual update of the payment rates.* The payment rates for routine home care and other services included in hospice care are the payment rates in effect under this paragraph during the previous fiscal year increased by the hospice payment update percentage increase (as defined in sections1814(i)(1)(C) of the Act), applicable to discharges occurring in the fiscal year.

(1) For fiscal year 2014 and subsequent fiscal years, in accordance with section 1814(i)(5)(A)(i) of the Act, in the case of a Medicare-certified hospice that submits hospice quality data, as specified by the Secretary, the payment rates are equal to the rates for the previous fiscal year increased by the applicable hospice payment update percentage increase.

(2) For fiscal years 2014 and through 2023, in accordance with section 1814(i)(5)(A)(i) of the Act, in the case of a Medicare-certified hospice that does not submit hospice quality data, as specified by the Secretary, the payment rates are equal to the rates for the previous fiscal year increased by the applicable hospice payment update percentage increase, minus 2 percentage points. Beginning with fiscal year 2024 and subsequent fiscal years, the reduction increases to 4 percentage points. Any reduction of the percentage change will apply only to the fiscal year involved and will not be taken into account in computing the payment amounts for a subsequent fiscal year.

(c) *Adjustment for wage differences.* (1) Each hospice's labor market is determined based on definitions of Metropolitan Statistical Areas (MSAs) issued by OMB. CMS will issue annually, in the FEDERAL REGISTER, a hospice wage index based on the most current available CMS hospital wage data, including changes to the definition of MSAs. The urban and rural area geographic classifications are defined in § 412.64(b)(1)(ii)(A) through (C) of this chapter. The payment rates established by CMS are adjusted by the Medicare contractor to reflect local differences in wages according to the revised wage data.

(2) Beginning on October 1, 2022, CMS applies a cap on decreases to the hospice wage index such that the wage index applied to a geographic area is not less than 95 percent of the wage index applied to that geographic area in the prior fiscal year.

(d) *Federal Register notices.* CMS publishes as a notice in the FEDERAL REGISTER any proposal to change the methodology for determining the payment rates.

[56 FR 26919, June 12, 1991, as amended at 59 FR 26960, May 25, 1994; 62 FR 42882, Aug. 8, 1997; 70 FR 70548, Nov. 22, 2005; 73 FR 46486, Aug. 8, 2008; 79 FR 50509, Aug. 22, 2014; 80 FR 47207, Aug. 6, 2015; 86 FR 42605, Aug. 4, 2021; 87 FR 45702, July 29, 2022]

§ 418.307 Periodic interim payments.

Subject to the provisions of § 413.64(h) of this chapter, a hospice may elect to receive periodic interim payments (PIP) effective with claims received on or after July 1, 1987. Payment is made biweekly under the PIP method unless

the hospice requests a longer fixed interval (not to exceed one month) between payments. The biweekly interim payment amount is based on the total estimated Medicare payments for the reporting period (as described in §§ 418.302–418.306). Each payment is made 2 weeks after the end of a biweekly period of service as described in § 413.64(h)(5) of this chapter. Under certain circumstances that are described in § 413.64(g) of this chapter, a hospice that is not receiving PIP may request an accelerated payment.

[59 FR 36713, July 19, 1994]

§ 418.308 Limitation on the amount of hospice payments.

(a) Except as specified in paragraph (b) of this section, the total Medicare payment to a hospice for care furnished during a cap period is limited by the hospice cap amount specified in § 418.309.

(b) Until October 1, 1986, payment to a hospice that began operation before January 1, 1975 is not limited by the amount of the hospice cap specified in § 418.309.

(c) The hospice must file its aggregate cap determination notice with its Medicare contractor no later than 5 months after the end of the cap year and remit any overpayment due at that time. Hospices shall file the aggregate cap using data no earlier than 3 months after the end of the cap period. The Medicare contractor will notify the hospice of the final determination of program reimbursement in accordance with procedures similar to those described in § 405.1803 of this chapter. If a provider fails to file its self-determined cap determination with its Medicare contractor within 5 months after the cap year, payments to the hospice will be suspended in whole or in part, until a self-determined cap determination is filed with the Medicare contractor, in accordance with§ 405.371(e) of this chapter.

(d) Payments made to a hospice during a cap period that exceed the cap amount are overpayments and must be refunded.

[48 FR 56026, Dec. 16, 1983; 48 FR 57282, Dec. 29, 1983, as amended at 79 FR 50509, Aug. 22, 2014; 80 FR 47207, Aug. 6, 2015]

§ 418.309 Hospice aggregate cap.

A hospice's aggregate cap is calculated by multiplying the adjusted cap amount (determined in paragraph (a) of this section) by the number of Medicare beneficiaries, as determined by one of two methodologies for determining the number of Medicare beneficiaries for a given cap year described in paragraphs (b) and (c) of this section.

(a) *Cap Amount.* The cap amount was set at $6,500 in 1983 and is updated using one of two methodologies described in paragraphs (a)(1) and (a)(2) of this section.

(1) For accounting years that end on or before September 30, 2016 and end on or after October 1, 2033, the cap amount is adjusted for inflation by using the percentage change in the medical care expenditure category of the Consumer Price Index (CPI) for urban consumers that is published by the Bureau of Labor Statistics. This adjustment is made using the change in the CPI from March 1984 to the fifth month of the cap year.

(2) For accounting years that end after September 30, 2016, and before October 1, 2033, the cap amount is the cap amount for the preceding accounting year updated by the percentage update to payment rates for hospice care for services furnished during the fiscal year beginning on the October 1 preceding the beginning of the accounting year as determined pursuant to section 1814(i)(1)(C) of the Act (including the application of any productivity or other adjustments to the hospice percentage update).

(b) *Streamlined methodology defined.* A hospice's aggregate cap is calculated by multiplying the adjusted cap amount determined in paragraph (a) of this section by the number of Medicare beneficiaries as determined in paragraphs (b)(1) and (2) of this section. For purposes of the streamlined methodology calculation—

(1) In the case in which a beneficiary received care from only one hospice, the hospice includes in its number of Medicare beneficiaries those Medicare beneficiaries who have not previously been included in the calculation of any

hospice cap, and who have filed an election to receive hospice care in accordance with § 418.24 during the cap period as defined in § 418.3, using the best data available at the time of the calculation.

(2) In the case in which a beneficiary received care from more than one hospice, each hospice includes in its number of Medicare beneficiaries only that fraction which represents the portion of a patient's total days of care in all hospices and all years that was spent in that hospice in that cap year, using the best data available at the time of the calculation. The aggregate cap calculation for a given cap year may be adjusted after the calculation for that year based on updated data.

(c) *Patient-by-patient proportional methodology defined.* A hospice's aggregate cap is calculated by multiplying the adjusted cap amount determined in paragraph (a) of this section by the number of Medicare beneficiaries as described in paragraphs (c)(1) and (2) of this section. For the purposes of the patient-by-patient proportional methodology—

(1) A hospice includes in its number of Medicare beneficiaries only that fraction which represents the portion of a patient's total days of care in all hospices and all years that was spent in that hospice in that cap year, using the best data available at the time of the calculation. The total number of Medicare beneficiaries for a given hospice's cap year is determined by summing the whole or fractional share of each Medicare beneficiary that received hospice care during the cap year, from that hospice.

(2) The aggregate cap calculation for a given cap year may be adjusted after the calculation for that year based on updated data.

(d) *Application of methodologies.* (1) For cap years ending October 31, 2011 and for prior cap years, a hospice's aggregate cap is calculated using the streamlined methodology described in paragraph (b) of this section, subject to the following:

(i) A hospice that has not received a cap determination for a cap year ending on or before October 31, 2011 as of October 1, 2011, may elect to have its final cap determination for such cap years calculated using the patient-by-patient proportional methodology described in paragraph (c) of this section; or

(ii) A hospice that has filed a timely appeal regarding the methodology used for determining the number of Medicare beneficiaries in its cap calculation for any cap year is deemed to have elected that its cap determination for the challenged year, and all subsequent cap years, be calculated using the patient-by-patient proportional methodology described in paragraph (c) of this section.

(2) For cap years ending October 31, 2012, and all subsequent cap years, a hospice's aggregate cap is calculated using the patient-by-patient proportional methodology described in paragraph (c) of this section, subject to the following:

(i) A hospice that has had its cap calculated using the patient-by-patient proportional methodology for any cap year(s) prior to the 2012 cap year is not eligible to elect the streamlined methodology, and must continue to have the patient-by-patient proportional methodology used to determine the number of Medicare beneficiaries in a given cap year.

(ii) A hospice that is eligible to make a one-time election to have its cap calculated using the streamlined methodology must make that election no later than 60 days after receipt of its 2012 cap determination. A hospice's election to have its cap calculated using the streamlined methodology would remain in effect unless:

(A) The hospice subsequently submits a written election to change the methodology used in its cap determination to the patient-by-patient proportional methodology; or

(B) The hospice appeals the streamlined methodology used to determine the number of Medicare beneficiaries used in the aggregate cap calculation.

(3) If a hospice that elected to have its aggregate cap calculated using the streamlined methodology under paragraph (d)(2)(ii) of this section subsequently elects the patient-by-patient proportional methodology or appeals the streamlined methodology, under paragraph (d)(2)(ii)(A) or (B) of this

section, the hospice's aggregate cap determination for that cap year and all subsequent cap years is to be calculated using the patient-by-patient proportional methodology. As such, past cap year determinations may be adjusted to prevent the over-counting of beneficiaries, subject to existing reopening regulations.

[48 FR 56026, Dec. 16, 1983, as amended at 76 FR 47332, Aug. 4, 2011; 80 FR 47207, Aug. 6, 2015; 83 FR 38655, Aug. 6, 2018; 86 FR 42606, Aug. 4, 2021; 88 FR 51199, Aug. 2, 2023; 89 FR 64272, Aug. 6, 2024]

§418.310 Reporting and recordkeeping requirements.

Hospices must provide reports and keep records as the Secretary determines necessary to administer the program.

§418.311 Administrative appeals.

A hospice that believes its payments have not been properly determined in accordance with these regulations may request a review from the intermediary or the Provider Reimbursement Review Board (PRRB) if the amount in controversy is at least $1,000 or $10,000, respectively. In such a case, the procedure in 42 CFR part 405, subpart R, will be followed to the extent that it is applicable. The PRRB, subject to review by the Secretary under §405.1875 of this chapter, shall have the authority to determine the issues raised. The methods and standards for the calculation of the statutorily defined payment rates by CMS are not subject to appeal.

[74 FR 39414, Aug. 6, 2009, as amended at 78 FR 48281, Aug. 7, 2013]

§418.312 Data submission requirements under the hospice quality reporting program.

(a) *General rule.* Except as provided in paragraph (g) of this section, Medicare-certified hospices must submit to CMS data on measures selected under section 1814(i)(5)(C) of the Act in a form and manner, and at a time, specified by the Secretary.

(b) *Submission of Hospice Quality Reporting Program data.* (1) Hospices are required to complete and submit a standardized set of items for each patient to capture patient-level data, regardless of payer or patient age. The standardized set of items must be completed no less frequently than at admission, the hospice update visit (HUV), and discharge, as directed in the associated guidance manual and required by the Hospice Quality Reporting Program. Definitions for changes in patient condition that warrant updated assessment, as well as the data elements to be completed for each applicable change in patient condition, are to be provided in sub-regulatory guidance for the current standardized hospice instrument.

(2) Administrative data, such as Medicare claims data, used for hospice quality measures to capture services throughout the hospice stay, are required and fulfill the HQRP requirements for §418.306(b).

(3) CMS may remove a quality measure from the Hospice QRP based on one or more of the following factors:

(i) Measure performance among hospices is so high and unvarying that meaningful distinctions in improvements in performance can no longer be made.

(ii) Performance or improvement on a measure does not result in better patient outcomes.

(iii) A measure does not align with current clinical guidelines or practice.

(iv) The availability of a more broadly applicable (across settings, populations, or conditions) measure for the particular topic.

(v) The availability of a measure that is more proximal in time to desired patient outcomes for the particular topic.

(vi) The availability of a measure that is more strongly associated with desired patient outcomes for the particular topic.

(vii) Collection or public reporting of a measure leads to negative unintended consequences other than patient harm.

(viii) The costs associated with a measure outweigh the benefit of its continued use in the program.

(c) A hospice that receives notice of its CMS certification number before November 1 of the calendar year before the fiscal year for which a payment determination will be made must submit data for the calendar year.

(d) Medicare-certified hospices must contract with CMS-approved vendors to collect the CAHPS® Hospice Survey

data on their behalf and submit the data to the Hospice CAHPS® Data Center.

(e) If the hospice's total, annual, unique, survey-eligible, deceased patient count for the prior calendar year is less than 50 patients, the hospice is eligible to be exempt from the CAHPS® Hospice Survey reporting requirements in the current calendar year. In order to qualify for this exemption the hospice must submit to CMS its total, annual, unique, survey-eligible, deceased patient count for the prior calendar year.

(f) Vendors that want to become CMS-approved CAHPS® Hospice Survey vendors must meet the minimum business requirements. Survey vendors must have been in business for a minimum of 4 years, have conducted surveys in the approved survey mode for a minimum of 3 years, and have conducted surveys of individual patients for a minimum of 2 years. For Hospice CAHPS®, a ''survey of individual patients'' is defined as the collection of data from at least 600 individual patients selected by statistical sampling methods, and the data collected are used for statistical purposes. Vendors may not use home-based or virtual interviewers to conduct the CAHPS® Hospice Survey, nor may they conduct any survey administration processes (for example, mailings) from a residence.

(g) No organization, firm, or business that owns, operates, or provides staffing for a hospice is permitted to administer its own Hospice CAHPS® survey or administer the survey on behalf of any other hospice in the capacity as a Hospice CAHPS® survey vendor. Such organizations will not be approved by CMS as CAHPS® Hospice Survey vendors.

(h) *Reconsiderations and appeals of Hospice Quality Reporting Program decisions.* (1) A hospice may request reconsideration of a decision by CMS that the hospice has not met the requirements of the Hospice Quality Reporting Program for a particular reporting period. A hospice must submit a reconsideration request to CMS no later than 30 days from the date identified on the annual payment update notification provided to the hospice.

(2) Reconsideration request submission requirements are available on the CMS Hospice Quality Reporting Web site on CMS.gov.

(3) A hospice that is dissatisfied with a decision made by CMS on its reconsideration request may file an appeal with the Provider Reimbursement Review Board under part 405, subpart R of this chapter.

(i) *Exemptions and extensions requirements.* (1) A hospice may request and CMS may grant exemptions or extensions to the reporting requirements under paragraph (b) of this section for one or more quarters, when there are certain extraordinary circumstances beyond the control of the hospice.

(2) A hospice requesting an exemption or extension must do so within 90 days of the date that the extraordinary circumstances occurred by sending an email to CMS Hospice QRP Reconsiderations at *HospiceQRPReconsiderations @cms.hhs.gov* that contains all of the following information:

(i) Hospice CMS Certification Number (CCN).

(ii) Hospice Business Name.

(iii) Hospice Business Address.

(iv) CEO or CEO-designated personnel contact information including name, title, telephone number, email address, and mailing address (the address must be a physical address, not a post office box).

(v) Hospice's reason for requesting the exemption or extension.

(vi) Evidence of the impact of extraordinary circumstances beyond the hospice's control, including, but not limited to photographs, newspaper, other media articles, or independent sources attesting to the incident that can be reasonably corroborated. Include dates of occurrence and other documentation that may support the rationale for seeking extension or exemption.

(vii) Date when the hospice believes it will be able to again submit data under paragraph (b) of this section and a justification for the proposed date.

(3) CMS may grant exemptions or extensions to hospices without a request if it determines that one or more of the following has occurred:

(i) An extraordinary circumstance, such as an act of nature including a

pandemic, affects an entire region or locale.

(ii) A systemic problem with one of CMS' data collection systems directly affect the ability of a hospice to submit data under paragraph (b) of this section.

(j) *Data completion thresholds.* (1) Hospices must meet or exceed data submission threshold set at 90 percent of all required HIS or successor instrument records within 30-days of the beneficiary's admission or discharge and submitted through the CMS designated data submission systems.

(2) A hospice must meet or exceed the data submission compliance threshold in paragraph (j)(1) of this section to avoid receiving a 4-percentage point reduction to its annual payment update for a given FY as described under § 418.306(b)(2) of this chapter.

[79 FR 50510, Aug. 22, 2014, as amended at 85 FR 53680, Aug. 31, 2020; 86 FR 42606, Aug. 4, 2021; 88 FR 51199, Aug. 2, 2023; 89 FR 64272, Aug. 6, 2024; 90 FR 37431, Aug. 5, 2025]

Subpart H—Coinsurance

§ 418.400 Individual liability for coinsurance for hospice care.

An individual who has filed an election for hospice care in accordance with § 418.24 is liable for the following coinsurance payments. Hospices may charge individuals the applicable coinsurance amounts.

(a) *Drugs and biologicals.* An individual is liable for a coinsurance payment for each palliative drug and biological prescription furnished by the hospice while the individual is not an inpatient. The amount of coinsurance for each prescription approximates 5 percent of the cost of the drug or biological to the hospice determined in accordance with the drug copayment schedule established by the hospice, except that the amount of coinsurance for each prescription may not exceed $5. The cost of the drug or biological may not exceed what a prudent buyer would pay in similar circumstances. The drug copayment schedule must be reviewed for reasonableness and approved by the intermediary before it is used.

(b) *Respite care.* (1) The amount of coinsurance for each respite care day is equal to 5 percent of the payment made by CMS for a respite care day.

(2) The amount of the individual's coinsurance liability for respite care during a hospice coinsurance period may not exceed the inpatient hospital deductible applicable for the year in which the hospice coinsurance period began.

(3) The individual hospice coinsurance period—

(i) Begins on the first day an election filed in accordance with § 418.24 is in effect for the beneficiary; and

(ii) Ends with the close of the first period of 14 consecutive days on each of which an election is not in effect for the beneficiary.

§ 418.402 Individual liability for services that are not considered hospice care.

Medicare payment to the hospice discharges an individual's liability for payment for all services, other than the hospice coinsurance amounts described in § 418.400, that are considered covered hospice care (as described in § 418.202). The individual is liable for the Medicare deductibles and coinsurance payments and for the difference between the reasonable and actual charge on unassigned claims on other covered services that are not considered hospice care. Examples of services not considered hospice care include: Services furnished before or after a hospice election period; services of the individual's attending physician, if the attending physician is not an employee of or working under an arrangement with the hospice; or Medicare services received for the treatment of an illness or injury not related to the individual's terminal condition.

§ 418.405 Effect of coinsurance liability on Medicare payment.

The Medicare payment rates established by CMS in accordance with § 418.306 are not reduced when the individual is liable for coinsurance payments. Instead, when establishing the payment rates, CMS offsets the estimated cost of services by an estimate of average coinsurance amounts hospices collect.

[56 FR 26919, June 12, 1991]

PART 419—PROSPECTIVE PAYMENT SYSTEMS FOR HOSPITAL OUTPATIENT DEPARTMENT SERVICES

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AUTHORITY: 42 U.S.C. 1302, 1395l(t), and 1395hh.

SOURCE: 65 FR 18542, Apr. 7, 2000, unless otherwise noted.

Subpart A—General Provisions

§ 419.1 Basis and scope.

(a) *Basis.* This part implements section 1833(t) of the Act by establishing a prospective payment system for services furnished on or after July 1, 2000 by hospital outpatient departments to

Medicare beneficiaries who are registered on hospital records as outpatients.

(b) *Scope.* This subpart describes the basis of payment for outpatient hospital services under the prospective payment system. Subpart B sets forth the categories of hospitals and services that are subject to the outpatient hospital prospective payment system and those categories of hospitals and services that are excluded from the outpatient hospital prospective payment system. Subpart C sets forth the basic methodology by which prospective payment rates for hospital outpatient services are determined. Subpart D describes Medicare payment amounts, beneficiary copayment amounts, and methods of payment to hospitals under the hospital outpatient prospective payment system. Subpart E describes how the hospital outpatient prospective payment system may be updated. Subpart F describes limitations on administrative and judicial review. Subpart G describes the transitional payment adjustments that are made before 2004 to limit declines in payment for outpatient services.

§ 419.2 Basis of payment.

(a) *Unit of payment.* Under the hospital outpatient prospective payment system, predetermined amounts are paid for designated services furnished to Medicare beneficiaries. These services are identified by codes established under the Centers for Medicare & Medicaid Services Common Procedure Coding System (HCPCS). The prospective payment rate for each service or procedure for which payment is allowed under the hospital outpatient prospective payment system is determined according to the methodology described in subpart C of this part. The manner in which the Medicare payment amount and the beneficiary copayment amount for each service or procedure are determined is described in subpart D of this part.

(b) *Determination of hospital outpatient prospective payment rates: Packaged costs.* The prospective payment system establishes a national payment rate, standardized for geographic wage differences, that includes operating and capital-related costs that are integral, ancillary, supportive, dependent, or adjunctive to performing a procedure or furnishing a service on an outpatient basis. In general, these packaged costs may include, but are not limited to, the following items and services, the payment for which are packaged or conditionally packaged into the payment for the related procedures or services.

(1) Use of an operating suite, procedure room, or treatment room;

(2) Use of recovery room;

(3) Observation services;

(4) Anesthesia, certain drugs, biologicals, and other pharmaceuticals; medical and surgical supplies and equipment; surgical dressings; and devices used for external reduction of fractures and dislocations;

(5) Supplies and equipment for administering and monitoring anesthesia or sedation;

(6) Intraocular lenses (IOLs);

(7) Ancillary services;

(8) Capital-related costs;

(9) Implantable items used in connection with diagnostic X-ray tests, diagnostic laboratory tests, and other diagnostic tests;

(10) Durable medical equipment that is implantable;

(11) Implantable and insertable medical items and devices, including, but not limited to, prosthetic devices (other than dental) which replace all or part of an internal body organ (including colostomy bags and supplies directly related to colostomy care), including replacement of these devices;

(12) Costs incurred to procure donor tissue other than corneal tissue.

(13) Image guidance, processing, supervision, and interpretation services;

(14) Intraoperative items and services;

(15) Drugs, biologicals, and radiopharmaceuticals that function as supplies when used in a diagnostic test or procedure (including but not limited to, diagnostic radiopharmaceuticals with per-day costs at or below the per-day diagnostic radiopharmaceutical packaging threshold for the applicable year, contrast agents, and pharmacologic stress agents);

(16) Drugs and biologicals that function as supplies when used in a surgical procedure (including, but not limited

to, skin substitutes and similar products that aid wound healing and implantable biologicals);

(17) Certain clinical diagnostic laboratory tests; and

(18) Certain services described by add-on codes.

(c) *Determination of hospital outpatient prospective payment rates: Excluded costs.* The following costs are excluded from the hospital outpatient prospective payment system.

(1) The costs of direct graduate medical education activities as described in §§ 413.75 through 413.83 of this chapter.

(2) The costs of nursing and allied health programs as described in § 413.85 of this chapter.

(3) The costs associated with interns and residents not in approved teaching programs as described in § 415.202 of this chapter.

(4) The costs of teaching physicians attributable to Part B services for hospitals that elect cost-based reimbursement for teaching physicians under § 415.160.

(5) The reasonable costs of anesthesia services furnished to hospital outpatients by qualified nonphysician anesthetists (certified registered nurse anesthetists and anesthesiologists' assistants) employed by the hospital or obtained under arrangements, for hospitals that meet the requirements under § 412.113(c) of this chapter.

(6) Bad debts for uncollectible deductibles and coinsurances as described in § 413.89(b) of this chapter.

(7) Organ acquisition costs paid under Part B.

(8) Corneal tissue acquisition or procurement costs for corneal transplant procedures.

[65 FR 18542, Apr. 7, 2000, as amended at 66 FR 59922, Nov. 30, 2001; 70 FR 47490, Aug. 12, 2005; 77 FR 68558, Nov. 15, 2012; 78 FR 75196, Dec. 10, 2013; 79 FR 67031, Nov. 10, 2014; 80 FR 70606, Nov. 13, 2015; 89 FR 94589, Nov. 27, 2024]

Subpart B—Categories of Hospitals and Services Subject to and Excluded From the Hospital Outpatient Prospective Payment System

§ 419.20 Hospitals subject to the hospital outpatient prospective payment system.

(a) *Applicability.* The hospital outpatient prospective payment system is applicable to any hospital participating in the Medicare program, except those specified in paragraph (b) of this section, for services furnished on or after August 1, 2000.

(b) *Hospitals excluded from the outpatient prospective payment system.* (1) Those services furnished by Maryland hospitals that are paid under a cost containment waiver in accordance with section 1814(b)(3) of the Act are excluded from the hospital outpatient prospective payment system.

(2) Critical access hospitals (CAHs) are excluded from the hospital outpatient prospective payment system.

(3) A hospital located outside one of the 50 States, the District of Columbia, and Puerto Rico is excluded from the hospital outpatient prospective payment system.

(4) A hospital of the Indian Health Service.

(5) A rural emergency hospital (REH).

[65 FR 18542, Apr. 7, 2000, as amended at 66 FR 59922, Nov. 30, 2001; 88 FR 82180, Nov. 22, 2023]

§ 419.21 Hospital services subject to the outpatient prospective payment system.

Except for services described in § 419.22, effective for services furnished on or after July 1, 2000, payment is made under the hospital outpatient prospective payment system for the following:

(a) Medicare Part B services furnished to hospital outpatients designated by the Secretary under this part.

(b) Services designated by the Secretary that are covered under Medicare Part B when furnished to hospital inpatients who are either not entitled to benefits under Part A or who have exhausted their Part A benefits but are

entitled to benefits under Part B of the program.

(c) Partial hospitalization services and intensive outpatient services furnished by community mental health centers (CMHCs).

(d) The following medical and other health services furnished by a home health agency (HHA) to patients who are not under an HHA plan or treatment or by a hospice program furnishing services to patients outside the hospice benefit:

(1) Antigens.

(2) Splints and casts.

(3) Hepatitis B vaccine.

(e)(1) Effective January 1, 2005 through December 31, 2008, an initial preventive physical examination, as defined in § 410.16 of this chapter, if the examination is performed no later than 6 months after the individual's initial Part B coverage date that begins on or after January 1, 2005.

(2) Effective January 1, 2009, an initial preventive physical examination, as defined in § 410.16 of this chapter, if the examination is performed no later than 12 months after the date of the individual's initial enrollment in Part B.

[65 FR 18542, Apr. 7, 2000, as amended at 67 FR 66813, Nov. 1, 2002; 69 FR 65863, Nov. 15, 2004; 71 FR 68227, Nov. 24, 2006: 75 FR 72265, Nov. 24, 2010; 88 FR 82180, Nov. 22, 2023]

§ 419.22 Hospital services excluded from payment under the hospital outpatient prospective payment system.

The following services are not paid for under the hospital outpatient prospective payment system (except when packaged as a part of a bundled payment):

(a) Physician services that meet the requirements of § 415.102(a) of this chapter for payment on a fee schedule basis.

(b) Nurse practitioner and clinical nurse specialist services, as defined in section 1861(s)(2)(K)(ii) of the Act.

(c) Physician assistant services, as defined in section 1861(s)(2)(K)(i) of the Act.

(d) Certified nurse-midwife services, as defined in section 1861(gg) of the Act.

(e) Services of qualified psychologists, as defined in section 1861(ii) of the Act.

(f) Services of an anesthetist as defined in § 410.69 of this chapter.

(g) Clinical social worker services as defined in section 1861(hh)(2) of the Act.

(h) Physical therapy services, speech-language pathology services, and occupational therapy services described in section 1833(a)(8) of the Act for which payment is made under the fee schedule described in section 1834(k) of the Act.

(i) Ambulance services, as described in section 1861(v)(1)(U) of the Act, or, if applicable, the fee schedule established under section 1834(l).

(j) Except as provided in § 419.2(b)(11), prosthetic devices and orthotic devices.

(k) Except as provided in § 419.2(b)(10), durable medical equipment supplied by the hospital for the patient to take home.

(l) Except as provided in § 419.2(b)(17), clinical diagnostic laboratory tests.

(m)(1) Services provided on or before December 31, 2010, for patients with ESRD that are paid under the ESRD composite rate and drugs and supplies furnished during dialysis but not included in the composite rate.

(2) Renal dialysis services provided on or after January 1, 2011, for patients with ESRD that are paid under the ESRD benefit, as described in subpart H of part 413 of this chapter.

(n) Services and procedures that the Secretary designates as requiring inpatient care.

(o) Hospital outpatient services furnished to SNF residents (as defined in § 411.15(p) of this chapter) as part of the patient's resident assessment or comprehensive care plan (and thus included under the SNF PPS) that are furnished by the hospital ''under arrangements'' but billable only by the SNF, regardless of whether or not the patient is in a Part A SNF stay.

(p) Services that are not covered by Medicare by statute.

(q) Services that are not reasonable or necessary for the diagnosis or treatment of an illness or disease.

(r) Services defined in § 419.21(b) that are furnished to inpatients of hospitals that do not submit claims for outpatient services under Medicare Part B.

(s) Effective December 8, 2003, screening mammography services and effective January 1, 2005, diagnostic mammography services.

(t) Effective January 1, 2011, annual wellness visit providing personalized prevention plan services as defined in § 410.15 of this chapter.

(u) Outpatient diabetes self-management training.

(v) Effective January 1, 2017, items and services that do not meet the definition of excepted items and services under § 419.48(a).

(w) Services of marriage and family therapists, as defined in section 1861(lll)(1) of the Act.

(x) Services of mental health counselors, as defined in section 1861(lll)(3) of the Act.

[65 FR 18542, Apr. 7, 2000, as amended at 66 FR 59922, Nov. 30, 2001; 69 FR 65863, Nov. 15, 2004; 75 FR 72265, Nov. 24, 2010; 78 FR 50969, Aug. 19, 2013; 78 FR 75196, Dec. 10, 2013; 79 FR 67031, Nov. 10, 2014; 81 FR 79879, Nov. 14, 2016; 82 FR 35, Jan. 3, 2017; 85 FR 86302, Dec. 29, 2020; 86 FR 63993, Nov. 16, 2021; 88 FR 82180, Nov. 22, 2023]

§ 419.23 Removal of services and procedures from the Inpatient Only List.

(a) *Inpatient Only List.* CMS maintains a list of services and procedures that the Secretary designates as requiring inpatient care under § 419.22(n) that are not paid under the hospital outpatient prospective payment system. This list is referred to as the Inpatient Only List.

(b) *Removals from the Inpatient Only List.* CMS assesses annually whether a service or procedure on the Inpatient Only List described in paragraph (a) of this section should be removed from the list by determining whether the service or procedure meets at least one of the following criteria:

(1) Most outpatient departments are equipped to provide the service or procedure to the Medicare population.

(2) The simplest service or procedure described by the code may be performed in most outpatient departments.

(3) The service or procedure is related to codes that CMS has already removed from the Inpatient Only List described in paragraph (a) of this section.

(4) CMS determines that the service or procedure is being performed in numerous hospitals on an outpatient basis.

(5) CMS determines that the service or procedure can be appropriately and safely performed in an ambulatory surgical center, and is specified as a covered ambulatory surgical procedure under § 416.166 of this chapter, or CMS has proposed to specify it as a covered ambulatory surgical procedure under § 416.166 of this chapter.

[86 FR 63993, Nov. 16, 2021]

Subpart C—Basic Methodology for Determining Prospective Payment Rates for Hospital Outpatient Services

§ 419.30 Base expenditure target for calendar year 1999.

(a) CMS estimates the aggregate amount that would be payable for hospital outpatient services in calendar year 1999 by summing—

(1) The total amounts that would be payable from the Trust Fund for covered hospital outpatient services without regard to the outpatient prospective payment system described in this part; and

(2) The total amounts of coinsurance that would be payable by beneficiaries to hospitals for covered hospital outpatient services without regard to the outpatient prospective payment system described in this part.

(b) The estimated aggregate amount under paragraph (a) of this section is determined as though the deductible required under section 1833(b) of the Act did not apply.

§ 419.31 Ambulatory payment classification (APC) system and payment weights.

(a) *APC groups.* (1) CMS classifies outpatient services and procedures that are comparable clinically and in terms of resource use into APC groups. Except as specified in paragraph (a)(2) of this section, items and services within a group are not comparable with respect to the use of resources if the highest geometric mean cost for an item or service within the group is more than 2 times greater than the

lowest geometric mean cost for an item or service within the group.

(2) CMS may make exceptions to the requirements set forth in paragraph (a)(1) in unusual cases, such as low volume items and services, but may not make such an exception in the case of a drug or biological that has been designated as an orphan drug under section 526 of the Federal Food, Drug and Cosmetic Act.

(3) The payment rate determined for an APC group in accordance with § 419.32, and the copayment amount and program payment amount determined for an APC group in accordance with subpart D of this part, apply to

(b) *APC weighting factors.* (1) Using hospital outpatient claims data from calendar year 1996 and data from the most recent available hospital cost reports, CMS determines the geometric mean costs for the services and procedures within each APC group.

(2) CMS assigns to each APC group an appropriate weighting factor to reflect the relative geometric mean costs for the services within the APC group compared to the geometric mean costs for the services in all APC groups.

(c) *Standardizing amounts.* (1) CMS determines the portion of costs determined in paragraph (b)(1) of this section that is labor-related. This is known as the ''labor-related portion'' of hospital outpatient costs.

(2) CMS standardizes the geometric mean costs determined in paragraph (b)(1) of this section by adjusting for variations in hospital labor costs across geographic areas.

[65 FR 18542, Apr. 7, 2000, as amended at 77 FR 68558, Nov. 15, 2012]

§ 419.32 Calculation of prospective payment rates for hospital outpatient services.

(a) *Conversion factor for 1999.* CMS calculates a conversion factor in such a manner that payment for hospital outpatient services furnished in 1999 would have equaled the base expenditure target calculated in § 419.30, taking into account APC group weights and estimated service frequencies and reduced by the amounts that would be payable in 1999 as outlier payments under § 419.43(d) and transitional pass-through payments under § 419.43(e).

(b) *Conversion factor for calendar year 2000 and subsequent years.* (1) Subject to paragraph (b)(2) of this section, the conversion factor for a calendar year is equal to the conversion factor calculated for the previous year adjusted as follows:

(i) For calendar year 2000, by the hospital inpatient market basket percentage increase applicable under section 1886(b)(3)(B)(iii) of the Act reduced by one percentage point.

(ii) For calendar year 2001—

(A) For services furnished on or after January 1, 2001 and before April 1, 2001, by the hospital inpatient market basket percentage increase applicable under section 1886(b)(3)(B)(iii) of the Act reduced by one percentage point; and

(B) For services furnished on or after April 1, 2001 and before January 1, 2002, by the hospital inpatient market basket percentage increase applicable under section 1886(b)(3)(B)(iii) of the Act, and increased by a transitional percentage allowance equal to 0.32 percent.

(iii) For the portion of calendar year 2002 that is affected by these rules, by the hospital inpatient market basket percentage increase applicable under section 1886(b)(3)(B)(iii) of the Act reduced by one percentage point, without taking into account the transitional percentage allowance referenced in § 419.32(b)(ii)(B).

(iv)(A) For calendar year 2003 and subsequent years, by the OPD fee schedule increase factor, which, subject to the adjustments specified in paragraph (b)(1)(iv)(B) of this section, is the hospital inpatient market basket percentage increase applicable under section 1886(b)(3)(B)(iii) of the Act.

(B) The percentage increase determined under paragraph (b)(1)(iv)(A) of this section is reduced by the following for the specific calendar year:

(*1*) For calendar year 2010, 0.25 percentage point;

(*2*) For calendar year 2011, 0.25 percentage point; and

(*3*) For calendar year 2012, a multifactor productivity adjustment (as determined by CMS) and 0.1 percentage point.

(*4*) For calendar year 2013, a multifactor productivity adjustment (as determined by CMS) and 0.1 percentage point.

(*5*) For calendar year 2014, a multifactor productivity adjustment (as determined by CMS) and 0.3 percentage point.

(*6*) For calendar year 2015, a multifactor productivity adjustment (as determined by CMS) and 0.2 percentage point.

(*7*) For calendar year 2016, a multifactor productivity adjustment (as determined by CMS), and 0.2 percentage point.

(*8*) For calendar year 2017, a multiproductivity adjustment (as determined by CMS) and 0.75 percentage point.

(*9*) For calendar year 2018, a multiproductivity adjustment (as determined by CMS) and 0.75 percentage point.

(*10*) For calendar year 2019, a multifactor productivity adjustment (as determined by CMS) and 0.75 percentage point.

(*11*) For calendar year 2020 through calendar year 2025, a multifactor productivity adjustment (as determined by CMS).

(*12*) Beginning in calendar year 2026, a multifactor productivity adjustment (as determined by CMS), and 0.5 percentage point reduction, except that the 0.5 percentage point reduction shall not apply to hospital outpatient items and services, not including separately payable drugs or biologicals, furnished by a hospital with a CMS certification number (CCN) effective date of January 2, 2018, or later. This reduction and associated exception to the reduction will be in effect until the estimated payment reduction reaches $7.769 billion, as further described in each calendar year's rule.

(2) Beginning in calendar year 2000, CMS may substitute for the hospital inpatient market basket percentage in paragraph (b) of this section a market basket percentage increase that is determined and applied to hospital outpatient services in the same manner that the hospital inpatient market basket percentage increase is determined and applied to inpatient hospital services.

(c) *Payment rates.* The payment rate for services and procedures for which payment is made under the hospital outpatient prospective payment system is the product of the conversion factor calculated under paragraph (a) or paragraph (b) of this section and the relative weight determined under § 419.31(b).

(d) *Budget neutrality.* (1) CMS adjusts the conversion factor as needed to ensure that updates and adjustments under § 419.50(a) are budget neutral.

(2) In determining adjustments for 2004 and 2005, CMS will not take into account any additional expenditures per section 1833(t)(14) of the Act that would not have been made but for enactment of section 621 of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003.

[65 FR 18542, Apr. 7, 2000, as amended at 66 FR 59922, Nov. 30, 2001; 67 FR 9568, Mar. 1, 2002; 69 FR 832, Jan. 6, 2004; 75 FR 72265, Nov. 24, 2010; 76 FR 74582, Nov. 30, 2011; 77 FR 68559, Nov. 15, 2012; 78 FR 75196, Dec. 10, 2013; 79 FR 67031, Nov. 10, 2014; 80 FR 70606, Nov. 13, 2015; 81 FR 79879, Nov. 14, 2016; 82 FR 52637, Nov. 13, 2017; 82 FR 59497, Dec. 14, 2017; 83 FR 59179, Nov. 21, 2018; 85 FR 86302, Dec. 29, 2020; 88 FR 77193, Nov. 8, 2023]

EFFECTIVE DATE NOTE: At 66 FR 59922, Nov. 30, 2001, § 419.32 was amended by revising paragraph (b)(1), effective Jan. 1, 2002. At 66 FR 67494, Dec. 31, 2001, paragraph (b)(1)(iii) was delayed indefinitely.

Subpart D—Payments to Hospitals

§ 419.40 Payment concepts.

(a) In addition to the payment rate described in § 419.32, for each APC group there is a predetermined beneficiary copayment amount as described in § 419.41(a). The Medicare program payment amount for each APC group is calculated by applying the program payment percentage as described in § 419.41(b).

(b) For purposes of this section—

(1) Coinsurance percentage is calculated as the difference between the program payment percentage and 100 percent. The coinsurance percentage in any year is thus defined for each APC group as the greater of the following: the ratio of the APC group unadjusted copayment amount to the annual APC group payment rate, or 20 percent.

(2) Program payment percentage is calculated as the lower of the following: the ratio of the APC group payment rate minus the APC group unadjusted copayment amount, to the APC group payment rate, or 80 percent.

(3) Unadjusted copayment amount is calculated as 20 percent of the wage-adjusted national median of charges for services within an APC group furnished during 1996, updated to 1999 using an actuarial projection of charge increases for hospital outpatient department services during the period 1996 to 1999.

(c) *Limitation of copayment amount to inpatient hospital deductible amount.* The copayment amount for a procedure performed in a year cannot exceed the amount of the inpatient hospital deductible established under section 1813(b) of the Act for that year.

[66 FR 59922, Nov. 30, 2001]

§ 419.41 Calculation of national beneficiary copayment amounts and national Medicare program payment amounts.

(a) To calculate the unadjusted copayment amount for each APC group, CMS—

(1) Standardizes 1996 hospital charges for the services within each APC group to offset variations in hospital labor costs across geographic areas;

(2) Identifies the median of the wage-neutralized 1996 charges for each APC group; and

(3) Determines the value equal to 20 percent of the wage-neutralized 1996 median charge for each APC group and multiplies that value by an actuarial projection of increases in charges for hospital outpatient department services during the period 1996 to 1999. The result is the unadjusted beneficiary copayment amount for the APC group.

(b) CMS calculates annually the program payment percentage for every APC group on the basis of each group's unadjusted copayment amount and its payment rate after the payment rate is adjusted in accordance with § 419.32.

(c) To determine payment amounts due for a service paid under the hospital outpatient prospective payment system, CMS makes the following calculations:

(1) Makes the wage index adjustment in accordance with § 419.43.

(2) Subtracts the amount of the applicable Part B deductible provided under § 410.160 of this chapter.

(3) Multiplies the remainder by the program payment percentage for the group to determine the preliminary Medicare program payment amount.

(4) Subtracts the program payment amount from the amount determined in paragraph (c)(2) of this section to determine the copayment amount.

(i) The copayment amount for an APC cannot exceed the amount of the inpatient hospital deductible, established in accordance with § 409.82 of this chapter, for that year. For purposes of this paragraph (c)—

(A) Effective for drugs and biologicals furnished on or after January 1, 2001, the copayment amount for multiple APCs for a single drug or biological furnished on the same day will be aggregated and treated as the copayment amount for one APC.

(B) Effective for drugs and biologicals furnished on or after July 1, 2001, the copayment amount for the APC or APCs for a drug or biological furnished on the same day will be aggregated with the copayment amount for the APC that reflects the administration of the drug or biological furnished on that day and treated as the copayment amount for one APC.

(ii) Effective for services furnished from April 1, 2001 through December 31, 2001, the national unadjusted coinsurance rate for an APC cannot exceed 57 percent of the prospective payment rate for that APC.

(iii) The national unadjusted coinsurance rate for an APC cannot exceed 55 percent in calendar years 2002 and 2003; 50 percent in calendar year 2004; 45 percent in calendar year 2005; and 40 percent in calendar year 2006 and thereafter.

(iv) The copayment amount is computed as if the adjustment under §§ 419.43(d) and (e) (and any adjustments made under § 419.43(f) in relation to these adjustments) and § 419.43(h) had not been paid.

(5) Adds the amount by which the copayment amount would have exceeded the inpatient hospital deductible for that year to the preliminary Medicare

program payment amount determined in paragraph (c)(3) of this section to determine the final Medicare program payment amount.

(d) Notwithstanding paragraphs (a) through (c) of this section, for a drug or biological for which payment is not packaged into a payment for a covered outpatient department (OPD) service (or group of services) and is not a rebatable drug (as defined in section 1847A(i)(2)(A) of the Act), to calculate the program payment and copayment amounts CMS does the following:

(1) Determines the payment rate for the drug or biological for the quarter established under the methodology described by section 1842(o), section 1847A, or section 1847B of the Act, as the case may be, as calculated and adjusted by the Secretary as necessary for purposes of paragraph (14) of section 1833(t) of the Act.

(2) Subtracts from the amount determined under paragraph (d)(1) of this section the amount of the applicable Part B deductible provided under §410.160 of this chapter.

(3) Multiples the amount determined under paragraph (d)(1) of this section (less any applicable deductible under paragraph (d)(2) of this section) by 20 percent. This is the beneficiary's copayment amount for the drug or biological.

(4) Subtracts the amount determined under paragraph (d)(3) of this section from the amount determined under paragraph (d)(1) of this section (less any applicable deductible determined under paragraph (d)(2) of this section). This amount is the preliminary program amount.

(5) Adds to the preliminary program amount determined under paragraph (d)(4) of this section the amount by which the copayment amount would have exceeded the inpatient hospital deductible for that year. This amount is the final Medicare program payment amount.

(e) In the case of a rebatable drug (as defined in section 1847A(i)(2)(A) of the Act), except if such drug does not have a copayment amount as a result of application of section 1833(t)(8)(E) of the Act, for which payment is not packaged into payment for a covered OPD service (or group of services) furnished on or after April 1, 2023, and the payment for such drug under the outpatient prospective payment system (OPPS) is the same as the amount for a calendar quarter under section 1847A(i)(3)(A)(ii)(I) of the Act, in lieu of the calculation of the copayment amount and the Medicare program payment amount otherwise applicable under paragraph (d) of this section (other than application of the limitation described in paragraph (c)(4)(i) of this section), the copayment and Medicare program payment amounts determined under §§410.152(m) and 489.30(b)(6) of this chapter shall apply.

(f) In the case of a qualifying biosimilar biological product (as defined in §414.902 of this chapter) that is furnished during the applicable five-year period (as defined in §414.902 of this chapter) for such product, the payment amount for such product with respect to such period is the amount determined in §414.904(j)(2) of this chapter.

(g) For dates of service on or after July 1, 2024, the payment amount for a biosimilar biological product (as defined in §414.902 of this chapter) during the initial period is the amount determined in §414.904(e)(4)(ii) of this chapter.

(h) For a therapeutic radiopharmaceutical for which payment is not packaged into a payment for a covered outpatient department (OPD) service (or group of services) and that does have on transitional pass-through payment status as described in §419.64, to calculate the program payment and copayment amounts CMS does the following:

(1) Determines the average sales price (ASP) for the therapeutic radiopharmaceutical for the quarter established under the methodology described by section 1847A of the Act. If that amount is not available, then CMS calculates the mean unit cost (MUC) using the most recently available claims data for that therapeutic radiopharmaceutical.

(2) Subtracts from the amount determined under paragraph (h)(1) of this section the amount of the applicable Part B deductible provided under §410.160 of this chapter.

(3) Multiplies the amount determined under paragraph (h)(1) of this section

(less any applicable deductible under paragraph (h)(2) of this section) by 20 percent. This is the beneficiary's copayment amount for the drug or biological.

(4) Subtracts the amount determined under paragraph (h)(3) of this section from the amount determined under paragraph (h)(1) of this section (less any applicable deductible determined under paragraph (h)(2) of this section). This amount is the preliminary program amount.

(5) Adds to the preliminary program amount determined under paragraph (h)(4) of this section the amount by which the copayment amount would have exceeded the inpatient hospital deductible for that year. This amount is the final Medicare program payment amount.

(i) For a diagnostic radiopharmaceutical for which payment is not packaged into a payment for a covered OPD service (or group of services) and that does not have transitional pass-through payment status as described in §419.64, to calculate the program payment and copayment amounts CMS does the following:

(1) Calculates the MUC using the most recently available claims data for that diagnostic radiopharmaceutical, if claims data are available. If claims data are not available, determines the ASP for the diagnostic radiopharmaceutical for the quarter established under the methodology described by section 1847A of the Act. If ASP data are not available, then based on the wholesale acquisition cost (WAC), under the methodology described by section 1847A of the Act. If WAC data are not available, then based on 95 percent of the average wholesale price.

(2) Subtracts from the amount determined under paragraph (i)(1) of this section the amount of the applicable Part B deductible provided under §410.160 of this chapter.

(3) Multiplies the amount determined under paragraph (i)(1) of this section (less any applicable deductible under paragraph (i)(2) of this section) by 20 percent. This is the beneficiary's copayment amount for the drug or biological.

(4) Subtracts the amount determined under paragraph (i)(3) of this section from the amount determined under paragraph (i)(1) of this section (less any applicable deductible determined under paragraph (i)(2) of this section). This amount is the preliminary program amount.

(5) Adds to the preliminary program amount determined under paragraph (i)(4) of this section the amount by which the copayment amount would have exceeded the inpatient hospital deductible for that year. This amount is the final Medicare program payment amount.

(j) For a drug covered as an additional preventive service (DCAPS), as defined at §410.64 of this chapter, the program payment amount is 100 percent of the payment amount determined as follows:

(1) If ASP data is available for the drug, consistent with part 414, subpart J, of this chapter, then the payment amount is determined using the methodology set forth in section 1847A of the Act and according to the provisions in part 414, subpart K, of this chapter.

(2) If ASP data is not available, then the payment amount is determined according to the most recently published National Average Drug Acquisition Cost (NADAC) prices for the drug and is the lesser of the median NADAC price of all generic forms of the drug or the lowest NADAC price brand name product.

(3) If ASP data and NADAC prices are not available, then the payment amount is determined according to the most recently published pharmaceutical pricing data for the drug as included in the Federal Supply Schedule (FSS), as managed by the Department of Veterans Affairs per 48 CFR part 38, and is the lesser of the median FSS price of all generic forms of the drug or the lowest FSS price brand name product.

(4) If ASP data, NADAC prices, and FSS pharmaceutical prices are not available, then, for the period beginning January 1, 2025, through December 31, 2025, the payment amount is WAC plus 6 percent, or 3 percent if in an initial sales period consistent with 1847A(c)(4) of the Act, and beginning January 1, 2026, the payment amount is the invoice price determined by the

Medicare Administrative Contractor (MAC).

[65 FR 18542, Apr. 7, 2000, as amended at 65 FR 67829, Nov. 13, 2000; 66 FR 59923, Nov. 30, 2001; 73 FR 68814, Nov. 18, 2008; 88 FR 82180, Nov. 22, 2023; 89 FR 94589, Nov. 27, 2024]

§ 419.42 Hospital election to reduce coinsurance.

(a) A hospital may elect to reduce coinsurance for any or all APC groups on a calendar year basis. A hospital may not elect to reduce copayment amounts for some, but not all, services within the same group.

(b) A hospital must notify its fiscal intermediary of its election to reduce coinsurance no later than—

(1) June 1, 2000, for coinsurance elections for the period July 1, 2000 through December 31, 2000; or

(2) December 1 preceding the beginning of each subsequent calendar year.

(c) The hospital's election must be properly documented. It must specifically identify the APCs to which it applies and the copayment amount (within the limits identified below) that the hospital has selected for each group.

(d) The election of reduced coinsurance remains in effect unchanged during the year for which the election was made.

(e) In electing reduced coinsurance, a hospital may elect a copayment amount that is less than that year's wage-adjusted copayment amount for the group but not less than 20 percent of the APC payment rate as determined under § 419.32 or, in the case of payments calculated under § 419.43(h), not less than 20 percent of the APC payment rate as determined under § 419.43(h).

(f) The hospital may advertise and otherwise disseminate information concerning the reduced level of coinsurance that it has elected. All advertisements and information furnished to Medicare beneficiaries must specify that the coinsurance reductions advertised apply only to the specified services of that hospital and that coinsurance reductions are available only for hospitals that choose to reduce coinsurance for hospital outpatient services and are not allowed in any other ambulatory settings or physician offices.

[65 FR 18542, Apr. 7, 2000, as amended at 65 FR 67829, Nov. 13, 2000; 66 FR 59923, Nov. 30, 2001; 73 FR 68814, Nov. 18, 2008]

§ 419.43 Adjustments to national program payment and beneficiary copayment amounts.

(a) *General rule.* CMS determines national prospective payment rates for hospital outpatient department services and determines a wage adjustment factor to adjust the portion of the APC payment and national beneficiary copayment amount attributable to labor-related costs for relative differences in labor and labor-related costs across geographic regions in a budget neutral manner.

(b) *Labor-related portion of payment and copayment rates for hospital outpatient services.* CMS determines the portion of hospital outpatient costs attributable to labor and labor-related costs (known as the ''labor-related portion'' of hospital outpatient costs) in accordance with § 419.31(c)(1).

(c) *Wage index factor.* (1) CMS uses the hospital inpatient prospective payment system wage index established in accordance with Part 412 of this chapter to make the adjustment specified under paragraph (a) of this section.

(2) For services furnished beginning January 1, 2011, the wage index factor provided for in paragraph (c)(1) of this section applicable to any hospital outpatient department that is located in a frontier State, as defined in § 412.64(m) of this chapter, may not be less than 1.00.

(3) The additional payments made under the provisions of paragraph (c)(2) of this section are not implemented in a budget neutral manner.

(d) *Outlier adjustment*—(1) *General rule.* Subject to paragraph (d)(4) of this section, CMS provides for an additional payment for a hospital outpatient service (or group of services) not excluded under paragraph (f) of this section for which a hospital's charges, adjusted to cost, exceed the following:

(i) A fixed multiple of the sum of—

(A) The applicable Medicare hospital outpatient payment amount determined under § 419.32(c), as adjusted

under § 419.43 (other than for adjustments under this paragraph (d) or paragraph (e) of this section); and

(B) Any transitional pass-through payment under § 419.66.

(ii) At the option of CMS, a fixed dollar amount.

(2) *Amount of adjustment.* The amount of the additional payment under paragraph (d)(1) of this section is determined by CMS and approximates the marginal cost of care beyond the applicable cutoff point under paragraph (d)(1) of this section.

(3) *Limit on aggregate outlier adjustments*—(i) *In general.* The total of the additional payments made under this paragraph (d) for covered hospital outpatient department services furnished in a year (as estimated by CMS before the beginning of the year) may not exceed the applicable percentage specified in paragraph (d)(3)(ii) of this section of the total program payments (sum of both the Medicare and beneficiary payments to the hospital) estimated to be made under this part for all hospital outpatient services furnished in that year. If this paragraph is first applied to less than a full year, the limit applies only to the portion of the year.

(ii) *Applicable percentage.* For purposes of paragraph (d)(3)(i) of this section, the term ''applicable percentage'' means a percentage specified by CMS up to (but not to exceed)—

(A) For a year (or portion of a year) before 2004, 2.5 percent; and

(B) For 2004 and thereafter, 3.0 percent.

(4) *Transitional authority.* In applying paragraph (d)(1) of this section for hospital outpatient services furnished before January 1, 2002, CMS may—

(i) Apply paragraph (d)(1) of this section to a bill for these services related to an outpatient encounter (rather than for a specific service or group of services) using hospital outpatient payment amounts and transitional pass-through payments covered under the bill; and

(ii) Use an appropriate cost-to-charge ratio for the hospital or CMHC (as determined by CMS), rather than for specific departments within the hospital.

(5) *Cost-to-charge ratios for calculating charges adjusted to cost.* For hospital outpatient services (or groups of services) as defined in paragraph (d)(1) of this section performed on or after January 1, 2009—

(i) CMS may specify an alternative to the overall ancillary cost-to-charge ratio otherwise applicable under paragraph (d)(5)(ii) of this section. A hospital may also request that its Medicare contractor use a different (higher or lower) cost-to-charge ratio based on substantial evidence presented by the hospital. Such a request must be approved by the CMS.

(ii) The overall ancillary cost-to-charge ratio applied at the time a claim is processed is based on either the most recent settled cost report or the most recent tentative settled cost report, whichever is from the latest cost reporting period.

(iii) The Medicare contractor may use a statewide average cost-to-charge ratio if it is unable to determine an accurate overall ancillary cost-to-charge ratio for a hospital in one of the following circumstances:

(A) A new hospital that has not yet submitted its first Medicare cost report. (For purposes of this paragraph, a new hospital is defined as an entity that has not accepted assignment of an existing hospital's provider agreement in accordance with § 489.18 of this chapter.)

(B) A hospital whose overall ancillary cost-to-charge ratio is in excess of 3 standard deviations above the corresponding national geometric mean. This mean is recalculated annually by CMS and published in the annual notice of prospective payment rates issued in accordance with § 419.50(a).

(C) Any other hospital for whom accurate data to calculate an overall ancillary cost-to-charge ratio are not available to the Medicare contractor.

(6) *Reconciliation.* For hospital outpatient services furnished during cost reporting periods beginning on or after January 1, 2009—

(i) Any reconciliation of outlier payments will be based on an overall ancillary cost-to-charge ratio calculated based on a ratio of costs to charges computed from the relevant cost report and charge data determined at the time the cost report coinciding with the service is settled.

(ii) At the time of any reconciliation under paragraph (d)(6)(i) of this section, outlier payments may be adjusted to account for the time value of any underpayments or overpayments. Any adjustment will be based on a widely available index to be established in advance by CMS, and will be applied from the midpoint of the cost reporting period to the date of reconciliation.

(7) *Community mental health center (CMHC) outlier payment cap.* Outlier payments made to CMHCs for services provided on or after January 1, 2017 are subject to a cap, applied at the individual CMHC level, so that each CMHC's total outlier payments for the calendar year do not exceed 8 percent of that CMHC's total per diem payments for the calendar year. Total per diem payments are total Medicare per diem payments plus the total beneficiary share of those per diem payments.

(e) *Budget neutrality.* CMS establishes payment under paragraph (d) of this section in a budget-neutral manner excluding services and groups specified in paragraph (f) of this section.

(f) *Excluded services and groups.* The following services or groups are excluded from qualification for the payment adjustment under paragraph (d)(1) of this section:

(1) Drugs and biologicals that are paid under a separate APC; and

(2) Items and services paid at charges adjusted to costs by application of a hospital-specific cost-to-charge ratio.

(g) *Payment adjustment for certain rural hospitals*—(1) *General rule.* CMS provides for additional payment for covered hospital outpatient services not excluded under paragraph (g)(4) of this section, furnished on or after January 1, 2006, if the hospital—

(i) Is a sole community hospital under § 412.92 of this chapter or is an essential access community hospital under § 412.109 of this chapter; and

(ii) Is located in a rural area as defined in § 412.64(b) of this chapter or is treated as being located in a rural area under § 412.103 of this chapter.

(2) *Amount of adjustment.* The amount of the additional payment under paragraph (g)(1) of this section is determined by CMS and is based on the difference between costs incurred by hospitals that meet the criteria in paragraphs (g)(1)(i) and (g)(1)(ii) of this section and costs incurred by hospitals located in urban areas.

(3) *Budget neutrality.* CMS establishes the payment adjustment under paragraph (g)(2) of this section in a budget neutral manner, excluding services and groups specified in paragraph (g)(4) of this section.

(4) *Excluded services and groups.* The following services or groups are excluded from qualification for the payment adjustment in paragraph (g)(2) of this section:

(i) Drugs and biologicals that are paid under a separate APC;

(ii) Devices paid under 419.66; and

(iii) Items and services paid at charges adjusted to costs by application of a hospital-specific cost-to-charge ratio.

(5) *Copayment.* The payment adjustment in paragraph (g)(2) of this section is applied before calculating copayment amounts.

(6) *Outliers.* The payment adjustment in paragraph (g)(2) of this section is applied before calculating outlier payments.

(h) *Applicable adjustments to conversion factor for CY 2009 and for subsequent calendar years*—(1) *General rule.* For CY 2009 and for subsequent calendar years, the applicable adjustment to the conversion factor specified in § 419.32(b)(1)(iv) is reduced by 2.0 percentage points for any hospital that fails to meet the standards for reporting of hospital outpatient quality measures as established by the Secretary for the corresponding calendar year.

(2) *Limitation.* Any reduction to a hospital's adjustment to its conversion factor specified in § 419.32(b)(1)(iv) which occurs as a result of paragraph (h)(1) of this section will apply only to the calendar year involved and will not be taken into account in computing that hospital's applicable adjustment for a subsequent calendar year.

(3) *Budget neutrality.* For CY 2009 and for each subsequent calendar year, CMS makes an adjustment to the conversion factor, so that estimated aggregate payments under the OPPS for such calendar year are not affected by any reductions to hospital adjustments

which occur as a result of paragraph (h)(1) of this section.

(4) *Beneficiary copayment.* The beneficiary copayment for services to which the adjustment to the conversion factor specified under paragraph (h)(1) of this section applies is the product of the national beneficiary copayment amount calculated under § 419.41 and the ratio of the adjusted conversion factor calculated under paragraph (h)(1) of this section divided by the conversion factor specified under § 419.32(b)(1).

(i) *Payment adjustment for certain cancer hospitals*—(1) *General rule.* CMS provides for a payment adjustment for covered hospital outpatient department services furnished on or after January 1, 2012, by a hospital described in section 1886(d)(1)(B)(v) of the Act.

(2) *Amount of payment adjustment.* The amount of the payment adjustment under paragraph (i)(1) of this section is determined by the Secretary as follows:

(i) If a hospital described in section 1886(d)(1)(B)(v) of the Act has a payment-to-cost ratio (PCR) before the cancer hospital payment adjustment (as determined by the Secretary at cost report settlement) that is less than the weighted average PCR of other hospitals furnishing services under section 1833(t) of the Act (as determined by the Secretary at the time of the applicable CY Hospital Outpatient Prospective Payment System/Ambulatory Surgical Center final rule with comment period) (referred to as the Target PCR), for covered hospital outpatient department services, the aggregate payment amount provided at cost report settlement to such hospital is equal to the amount needed to make the hospital's PCR at cost report settlement (as determined by the Secretary) equal to the target PCR (as determined by the Secretary).

(ii) If a hospital described in section 1886(d)(1)(B)(v) of the Act has a payment-to-cost ratio (PCR) before the cancer hospital payment adjustment (as determined by the Secretary at cost report settlement) that is greater than the weighted average PCR of other hospitals furnishing services under section 1833(t) of the Act (as determined by the Secretary at the time of the applicable CY Hospital Outpatient Prospective Payment System/Ambulatory Surgical Center final rule with comment period) (referred to as the Target PCR), for covered hospital outpatient department services, the aggregate payment amount provided at cost report settlement to such hospital is equal to zero.

(3) *Budget neutrality.* CMS establishes the payment adjustment under paragraph (i)(1) of this section in a budget neutral manner.

(j) *Additional resource costs of domestic National Institute for Occupational Safety and Health approved surgical N95 respirators*—(1) *General rule.* For cost reporting periods beginning on or after January 1, 2023, CMS provides for a payment adjustment for the additional resource costs of domestic National Institute for Occupational Safety and Health approved surgical N95 respirators as described in paragraph (j)(2) of this section.

(2) *Amount of adjustment.* The payment adjustment is based on the estimated difference in the reasonable cost incurred by the hospital for domestic National Institute for Occupational Safety and Health approved surgical N95 respirators purchased during the cost reporting period as compared to other National Institute for Occupational Safety and Health approved surgical N95 respirators purchased during the cost reporting period.

(3) *Budget neutrality.* CMS establishes the payment adjustment under paragraph (j)(2) of this section in a budget neutral manner.

(k) *Payment for non-opioid pain management drugs and biologicals*—(1) *Eligibility for separate payment for non-opioid pain management drugs and biologicals.* From January 1, 2025, through December 31, 2027, a drug or biological is eligible for separate payment for an applicable calendar year if CMS determines it meets the following requirements through that year's rulemaking:

(i) The drug is approved under a new drug application under section 505(c) of the Federal Food, Drug, and Cosmetic Act (FDCA), under an abbreviated new drug application under section 505(j) of the FDCA, or, in the case of a biological product, is licensed under section 351 of the Public Health Service Act.

The product has a label indication approved by the Food and Drug Administration to reduce postoperative pain, or produce postsurgical or regional analgesia, without acting upon the body's opioid receptors.

(ii) The drug or biological does not have transitional pass-through payment status under §419.64. In the case where a drug or biological otherwise meets the requirements under this section and has transitional pass-through payment status that expires during the calendar year, the drug or biological will qualify for separate payment as specified in this paragraph (k) during such calendar year on the first day of the next calendar year quarter following the expiration of its pass-through status.

(iii) The drug or biological has payment that is packaged into a payment for a covered OPD service (or group of services) under a policy in this section.

(2) *Eligibility for separate payment for non-opioid medical devices.* From January 1, 2025, through December 31, 2027, a medical device is eligible for separate payment for an applicable calendar year if CMS determines it meets the following requirements through that year's rulemaking:

(i) The medical device, is used to deliver a therapy to reduce postoperative pain, or produce postsurgical or regional analgesia, and has an application under section 515 of the FDCA that has been approved with respect to the device, been cleared for market under section 510(k) of the FDCA, or is exempt from the requirements of 510(k) of the FDCA pursuant to section 510(l) or (m) or 520(g) of the FDCA.

(ii) The medical device has demonstrated the ability to replace, reduce, or avoid intraoperative or postoperative opioid use or the quantity of opioids prescribed in a clinical trial or through data published in a peer-reviewed journal.

(iii) The medical device does not have transitional pass-through payment status under §419.66. In the case where a medical device otherwise meets the requirements under this section and has transitional pass-through payment status that expires during the calendar year, the medical device will qualify for separate payment as specified in this paragraph (k)(2) during such calendar year on the first day of the next calendar year quarter following the expiration of its pass-through status.

(iv) The medical device has payment that is packaged into a payment for a covered OPD service (or group of services) under a policy in this section.

(3) *Payment amount.* From January 1, 2025, through December 31, 2027, the amount of payment for a qualifying non-opioid treatment for pain relief is as follows:

(i) For a qualifying drug or biological as defined in paragraph (k)(1) of this section, the amount of payment is the amount determined under section 1847A for the drug or biological that exceeds the portion of the otherwise applicable Medicare OPD fee schedule that the Secretary determines is associated with the drug or biological, subject to paragraph (k)(3)(iii) of this section.

(ii) For a qualifying medical device as defined in paragraph (k)(2) of this section, the amount of payment is the amount of the hospital's charges for the device, adjusted to cost, that exceeds the portion of the otherwise applicable Medicare OPD fee schedule that the Secretary determines is associated with the device, subject to paragraph (k)(3)(iii) of this section.

(iii) The payment amounts in paragraph (k)(3)(i) and (ii) of this section shall not exceed the estimated average of 18 percent of the OPD fee schedule amount of the volume weighted average of the most frequent five OPD primary procedures into which a non-opioid treatment for pain relief would be packaged.

[65 FR 18542, Apr. 7, 2000, as amended at 65 FR 47677, Aug. 3, 2000; 66 FR 55856, Nov. 2, 2001; 69 FR 832, Jan. 6, 2004; 70 FR 68727, Nov. 10, 2005; 70 FR 76178, Dec. 23, 2005; 71 FR 68227, Nov. 24, 2006; 72 FR 66932, Nov. 27, 2007; 73 FR 68814, Nov. 18, 2008; 75 FR 72265, Nov. 24, 2010; 76 FR 74583, Nov. 30, 2011; 81 FR 79879, Nov. 14, 2016; 87 FR 72291, Nov. 23, 2022; 89 FR 94590, Nov. 27, 2024]

§ 419.44 Payment reductions for procedures.

(a) *Multiple surgical procedures.* When more than one surgical procedure for which payment is made under the hospital outpatient prospective payment system is performed during a single

surgical encounter, the Medicare program payment amount and the beneficiary copayment amount are based on—

(1) The full amounts for the procedure with the highest APC payment rate; and

(2) One-half of the full program and the beneficiary payment amounts for all other covered procedures.

(b) *Interrupted procedures.* (1) Subject to the provisions of paragraph (b)(2) of this section, when a procedure is terminated prior to completion due to extenuating circumstances or circumstances that threaten the well-being of the patient, the Medicare program payment amount and the beneficiary copayment amount are based on—

(i) The full program and beneficiary copayment amounts if the procedure for which anesthesia is planned is discontinued after the induction of anesthesia or after the procedure is started;

(ii) One-half the full program and the beneficiary copayment amounts if the procedure for which anesthesia is planned is discontinued after the patient is prepared and taken to the room where the procedure is to be performed but before anesthesia is induced; or

(iii) One-half of the full program and beneficiary copayment amounts if a procedure for which anesthesia is not planned is discontinued after the patient is prepared and taken to the room where the procedure is to be performed.

(2) For all device-intensive procedures (defined as having a device offset of greater than 40 percent), the device offset portion of the device-intensive procedure payment is subtracted prior to determining the program payment and beneficiary copayment amounts identified in paragraph (b)(1)(ii) of this section.

[65 FR 18542, Apr. 7, 2000, as amended at 72 FR 66933, Nov. 27, 2007; 80 FR 70606, Nov. 13, 2015; 81 FR 79879, Nov. 14, 2016]

§ 419.45 Payment and copayment reduction for devices replaced without cost or when full or partial credit is received.

(a) *General rule.* CMS reduces the amount of payment for an implanted device made under the hospital outpatient prospective payment system in accordance with § 419.66 for which CMS determines that a significant portion of the payment is attributable to the cost of an implanted device, when one of the following situations occur:

(1) The device is replaced without cost to the provider or the beneficiary;

(2) The provider receives full credit for the cost of a replaced device; or

(3) The provider receives partial credit for the cost of a replaced device but only where the amount of the device credit is greater than or equal to 50 percent of the cost of the new replacement device being implanted.

(b) *Amount of reduction to the APC payment.* (1) The amount of the reduction to the APC payment made under paragraphs (a)(1) and (2) of this section is calculated as the lesser of the device offset amount that would be applied if the device implanted during a procedure assigned to the APC had transitional pass-through status under § 419.66 or the amount of the credit described in paragraph (a)(2) of this section.

(2) The amount of the reduction to the APC payment made under paragraph (a)(3) of this section is calculated as the lesser of the device offset amount that would be applied if the device implanted during a procedure assigned to the APC had transitional pass-through status under § 419.66 or the amount of the credit described in paragraph (a)(3) of this section.

(c) *Amount of beneficiary copayment.* The beneficiary copayment is calculated based on the APC payment after application of the reduction under paragraph (b) of this section.

[71 FR 68228, Nov. 24, 2006, as amended at 72 FR 66933, Nov. 27, 2007; 85 FR 86302, Dec. 29, 2020]

§ 419.46 Requirements under the Hospital Outpatient Quality Reporting (OQR) Program.

(a) *Statutory authority.* Section 1833(t)(17) of the Act authorizes the Secretary to implement a quality reporting program in a manner so as to provide for a 2.0 percentage point reduction in the OPD fee schedule increase factor for a subsection (d) hospital (as defined in section 1886(d)(1)(B)) that does not submit data required to be submitted on measures

in accordance with the Secretary's requirements in this part.

(b) *Participation in the Hospital OQR Program.* To participate in the Hospital OQR Program, a hospital as defined in section 1886(d)(1)(B) of the Act and is paid under the OPPS must—

(1) Register on the CMS-designated information system before beginning to report data;

(2) Identify and register a CMS-designated information system security official as part of the registration process under paragraph (b)(1) of this section; and

(3) Submit at least one data element.

(c) *Withdrawal from the Hospital OQR Program.* A participating hospital may withdraw from the Hospital OQR Program by submitting to CMS a withdrawal form that can be found in the secure portion of the CMS-designated information system. The hospital may withdraw any time up to and including August 31 of the year prior to the affected annual payment updates. A withdrawn hospital will not be able to later sign up to participate in that payment update, is subject to a reduced annual payment update as specified under paragraph (i) of this section and is required to renew participation as specified in paragraph (b) of this section in order to participate in any future year of the Hospital OQR Program.

(d) *Submission of Hospital OQR Program data*—(1) *General rule.* Except as provided in paragraph (e) of this section, hospitals that participate in the Hospital OQR Program must submit to CMS data on measures selected under section 1833(t)(17)(C) of the Act in a form and manner, and at a time, specified by CMS. Hospitals sharing the same CCN must combine data collection and submission across their multiple campuses for all clinical measures for public reporting purposes.

(2) *Submission deadlines.* Submission deadlines by measure and by data type are posted on the CMS website. All deadlines occurring on a Saturday, Sunday, or legal holiday, or on any other day all or part of which is declared to be a non-work day for Federal employees by statute or Executive order are extended to the first day thereafter which is not a Saturday, Sunday, or legal holiday or any other day all or part of which is declared to be a non-work day for Federal employees by statute or Executive order.

(3) *Initial submission deadlines for a hospital that did not participate in the previous year's Hospital OQR Program.* (i) Hospitals that did not participate in the previous year's Hospital OQR Program must initially submit data beginning with encounters occurring during the first calendar quarter of the year prior to the affected annual payment update.

(ii) Hospitals that did not participate in the previous year's Hospital OQR Program must follow data submission deadlines as specified in paragraph (d)(2) of this section.

(iii) Hospitals with a Medicare acceptance date before or after January 1 of the year prior to an affected annual payment update must follow data submission deadlines as specified in paragraph (d)(2) of this section.

(4) *Review and corrections period.* For both chart-abstracted and web-based measures, hospitals have a review and corrections period, which runs concurrently with the data submission period. During this timeframe, hospitals can enter, review, and correct data submitted. However, after the submission deadline, this data cannot be changed.

(e) *Exception.* CMS may grant an exception to one or more data submission deadlines and requirements in the event of extraordinary circumstances beyond the control of the hospital, such as when an act of nature affects an entire region or locale or a systemic problem with one of CMS' data collection systems directly or indirectly affects data submission. CMS may grant an exception as follows:

(1) *Upon request by the hospital.* Specific requirements for submission of a request for an exception are available on the CMS website.

(2) *At the discretion of CMS.* CMS may grant exceptions to hospitals that have not requested them when CMS determines that an extraordinary circumstance has occurred.

(f) *Validation of Hospital OQR Program data.* CMS may validate one or more measures selected under section 1833(t)(17)(C) of the Act by reviewing documentation of patient encounters

submitted by selected participating hospitals.

(1) Upon written request by CMS or its contractor, a hospital must submit to CMS supporting medical record documentation that the hospital used for purposes of data submission under the program. The specific sample that a hospital must submit will be identified in the written request. A hospital must submit the supporting medical record documentation to CMS or its contractor within 30 days of the date identified on the written request, in the form and manner specified in the written request.

(2) A hospital meets the validation requirement with respect to a calendar year if it achieves at least a 75-percent reliability score, as determined by CMS.

(3) CMS will select a random sample of 450 hospitals for validation purposes, and will select an additional 50 hospitals for validation purposes based on the following criteria:

(i) The hospital fails the validation requirement that applies to the previous year's payment determination; or

(ii) The hospital has an outlier value for a measure based on the data it submits. An ''outlier value'' is a measure value that is greater than 5 standard deviations from the mean of the measure values for other hospitals, and indicates a poor score; or

(iii) Any hospital that has not been randomly selected for validation in any of the previous 3 years; or

(iv) Any hospital that passed validation in the previous year but had a two-tailed confidence interval that included 75 percent; or

(v) Any hospital with a two-tailed confidence interval that is less than 75 percent, and that had less than four quarters of data due to receiving an extraordinary circumstance exception (ECE) for one or more quarters.

(4) Hospitals that are selected and receive a score for validation of chart-abstracted measures may request an educational review in order to better understand the results within 30 calendar days from the date the validation results are made available. If the results of an educational review indicate that a hospital's medical records selected for validation for chart-abstracted measures was incorrectly scored, the corrected quarterly validation score will be used to compute the hospital's final validation score at the end of the calendar year.

(g) *Reconsiderations and appeals of Hospital OQR Program decisions.* (1) A hospital may request reconsideration of a decision by CMS that the hospital has not met the requirements of the Hospital OQR Program in paragraph (b) of this section for a particular calendar year. Except as provided in paragraph (e) of this section, a hospital must submit a reconsideration request to CMS via the CMS-designated information system, no later than March 17, or if March 17 falls on a nonwork day, on the first day after March 17 which is not a nonwork day as defined in paragraph (d)(2) of this section, of the affected payment year as determined using the date the request was mailed or submitted to CMS.

(2) A reconsideration request must contain the following information:

(i) The hospital's CMS Certification Number (CCN);

(ii) The name of the hospital;

(iii) The CMS-identified reason for not meeting the requirements of the affected payment year's Hospital OQR Program as provided in any CMS notification to the hospital;

(iv) The hospital's basis for requesting reconsideration. The hospital must identify its specific reason(s) for believing it should not be subject to the reduced annual payment update;

(v) The hospital-designated personnel contact information, including name, email address, telephone number, and mailing address (must include physical mailing address, not just a post office box);

(vi) The hospital-designated personnel's signature;

(vii) A copy of all materials that the hospital submitted to comply with the requirements of the affected Hospital OQR Program payment determination year; and

(viii) If the hospital is requesting reconsideration on the basis that CMS determined it did not meet the affected payment determination year's validation requirement set forth in paragraph (f)(1) of this section, the hospital must provide a written justification for

each appealed data element classified during the validation process as a mismatch. Only data elements that affect a hospital's validation score are eligible to be reconsidered.

(3) A hospital that is dissatisfied with a decision made by CMS on its reconsideration request may file an appeal with the Provider Reimbursement Review Board under part 405, subpart R, of this chapter.

(h) *Requirements for Outpatient and Ambulatory Surgery Consumer Assessment of Healthcare Providers and Systems (OAS CAHPS) Survey.* OAS CAHPS is the Outpatient and Ambulatory Surgical Center Consumer Assessment of Healthcare Providers and Systems Survey that measures patient experience of care after a recent surgery or procedure at either a hospital outpatient department or an ambulatory surgical center. Hospital outpatient departments must use an approved OAS CAHPS survey vendor to administer and submit OAS CAHPS data to CMS.

(1) [Reserved]

(2) CMS approves an application for an entity to administer the OAS CAHPS Survey as a vendor on behalf of one or more hospital outpatient departments when the applicant has met the Minimum Survey Requirements and Rules of Participation that can be found on the official OAS CAHPS website, and agrees to comply with the current survey administration protocols that can be found on the official OAS CAHPS Survey website. An entity must be an approved OAS CAHPS Survey vendor in order to administer and submit OAS CAHPS Survey data to CMS on behalf of one or more hospital outpatient departments.

(i) *Retention and removal of quality measures under the Hospital OQR Program*—(1) *General rule for the retention of quality measures.* Quality measures adopted for the Hospital OQR Program measure set for a previous payment determination year are retained for use in subsequent payment determination years, except when they are removed, suspended, or replaced as set forth in paragraphs (i)(2) and (3) of this section.

(2) *Immediate measure suspension.* If CMS determines that the collection and reporting activities related to a measure potentially raise patient safety concerns, CMS will immediately suspend the measure from the Hospital OQR Program and promptly notify hospitals and the public of the suspension. CMS will propose to retain, modify, or remove the suspended measure in the next feasible rulemaking cycle.

(3) *Measure removal, suspension, or replacement through the rulemaking process.* Unless a measure raises specific safety concerns as set forth in paragraph (i)(2) of this section, CMS will use the regular rulemaking process to remove, suspend, or replace quality measures in the Hospital OQR Program to allow for public comment.

(i) *Factors for consideration of removal of quality measures.* CMS will weigh whether to remove measures based on the following factors:

(A) *Factor 1.* Measure performance among hospitals is so high and unvarying that meaningful distinctions and improvements in performance can no longer be made (''topped out'' measures);

(B) *Factor 2.* Performance or improvement on a measure does not result in better patient outcomes;

(C) *Factor 3.* A measure does not align with current clinical guidelines or practice;

(D) *Factor 4.* The availability of a more broadly applicable (across settings, populations, or conditions) measure for the topic;

(E) *Factor 5.* The availability of a measure that is more proximal in time to desired patient outcomes for the particular topic;

(F) *Factor 6.* The availability of a measure that is more strongly associated with desired patient outcomes for the particular topic;

(G) *Factor 7.* Collection or public reporting of a measure leads to negative unintended consequences other than patient harm; and

(H) *Factor 8.* The costs associated with a measure outweigh the benefit of its continued use in the program.

(ii) *Criteria to determine topped-out measures.* For the purposes of the Hospital OQR Program, a measure is considered to be topped-out under paragraph (i)(3)(i)(A) of this section when it meets both of the following criteria:

(A) Statistically indistinguishable performance at the 75th and 90th percentiles (defined as when the difference between the 75th and 90th percentiles for a hospital's measure is within two times the standard error of the full data set); and

(B) A truncated coefficient of variation less than or equal to 0.10.

(iii) *Application of measure removal factors.* The benefits of removing a measure from the Hospital OQR Program will be assessed on a case-by-case basis. Under this case-by-case approach, a measure will not be removed solely on the basis of meeting any specific factor.

(j) *Requirements for submission of electronic clinical quality measures (eCQMs) under the Hospital OQR Program.* (1) Hospitals must utilize certified technology updated to be consistent with the Office of the National Coordinator for Health Information Technology's health information technology (IT) certification criteria, as adopted and updated in 45 CFR 170.315.

(2) Hospitals must use electronic health record technology certified to all eCQMs that are available to report under the Hospital OQR Program.

(3) Hospitals must use the most recent version of the eCQM electronic measure specifications for the applicable reporting period available on the Electronic Clinical Quality Improvement Resource Center website at *https://ecqi.healthit.gov/*, or another website as designated by CMS.

[78 FR 75196, Dec. 10, 2013, as amended at 79 FR 67031, Nov. 10, 2014; 80 FR 70606, Nov. 13, 2015; 81 FR 79879, Nov. 14, 2016; 82 FR 52637, Nov. 13, 2017; 82 FR 59497, Dec. 14, 2017; 83 FR 59179, Nov. 21, 2018; 85 FR 86302, Dec. 29, 2020; 86 FR 63993, Nov. 16, 2021; 87 FR 72291, Nov. 23, 2022; 88 FR 82180, Nov. 22, 2023; 89 FR 94590, Nov. 27, 2024]

§ 419.47 Coding and payment for Category B Investigational Device Exemption (IDE) studies and devices/drugs studies.

(a) *Creation of a new HCPCS code for Category B IDE studies that have a treatment arm and a placebo control arm.* CMS will create a new HCPCS code, or revise an existing HCPCS code, to describe a Category B IDE study, which will include both the treatment and placebo control arms, related device(s) of the study, as well as routine care items and services, as specified under § 405.201 of this chapter, when CMS determines that:

(b) *Payment for Category B IDE Studies.* Where CMS creates a new HCPCS code or revises an existing HCPCS code under paragraph (a) of this section, CMS will:

(1) Make a single packaged payment for the HCPCS code that includes payment for the investigational device, placebo control, and routine care items and services of a Category B IDE study, as specified under § 405.201 of this chapter; and

(2) Calculate the single packaged payment rate for the HCPCS code based on the average resources utilized for each study participant, including the frequency with which the investigational device is used in the study population.

[87 FR 72291, Nov. 23, 2022, as amended at 89 FR 94590, Nov. 27, 2024]

§ 419.48 Definition of excepted items and services.

(a) Excepted items and services are items or services that are furnished on or after January 1, 2017—

(1) By a dedicated emergency department (as defined at § 489.24(b) of this chapter); or

(2) By an excepted off-campus provider-based department defined in paragraph (b) of this section that has not impermissibly relocated or changed ownership.

(b) For the purpose of this section, ''excepted off-campus provider-based department'' means a ''department of a provider'' (as defined at § 413.65(a)(2) of this chapter) that is located on the campus (as defined in § 413.65(a)(2) of this chapter) or within the distance described in such definition from a ''remote location of a hospital'' (as defined in § 413.65(a)(2) of this chapter) that meets the requirements for provider-based status under § 413.65 of this chapter. This definition also includes an off-campus department of a provider that was furnishing services prior to November 2, 2015 that were billed under the OPPS in accordance with timely filing limits.

(c) Payment for items and services that do not meet the definition in paragraph (a) of this section will generally be made under the Medicare Physician Fee Schedule on or after January 1, 2017.

[81 FR 79880, Nov. 14, 2016; 82 FR 36, Jan. 3, 2017]

Subpart E—Updates

§ 419.50 Annual review.

(a) *General rule.* Not less often than annually, CMS reviews and updates groups, relative payment weights, and the wage and other adjustments to take into account changes in medical practice, changes in technology, the addition of new services, new cost data, and other relevant information and factors.

(b) *Consultation requirement.* CMS will consult with an expert outside advisory panel composed of an appropriate selection of representatives of providers to review (and advise CMS concerning) the clinical integrity of the groups and weights. The panel may use data collected or developed by entities and organizations (other than the Department of Health and Human Services) in conducting the review.

(c) *Effective dates.* CMS conducts the first annual review under paragraph (a) of this section in 2001 for payments made in 2002.

Subpart F—Limitations on Review

§ 419.60 Limitations on administrative and judicial review.

There can be no administrative or judicial review under sections 1869 and 1878 of the Act or otherwise of the following:

(a) The development of the APC system, including—

(1) Establishment of the groups and relative payment weights;

(2) Wage adjustment factors;

(3) Other adjustments; and

(4) Methods for controlling unnecessary increases in volume.

(b) The calculation of base amounts described in section 1833(t)(3) of the Act.

(c) Periodic adjustments described in section 1833(t)(9) of the Act.

(d) The establishment of a separate conversion factor for hospitals described in section 1886(d)(1)(B)(v) of the Act.

(e) The determination of the fixed multiple, or a fixed dollar cutoff amount, the marginal cost of care, or applicable percentage under § 419.43(d) or the determination of insignificance of cost, the duration of the additional payments (consistent with subpart G of this part), the determination of initial and new categories under § 419.66, the portion of the Medicare hospital outpatient fee schedule amount associated with particular devices, drugs, or biologicals, and the application of any pro rata reduction under § 419.62(c).

[65 FR 18542, Apr. 7, 2000, as amended at 66 FR 55856, Nov. 2, 2001]

Subpart G—Transitional Pass-through Payments

SOURCE: 66 FR 55856, Nov. 2, 2001, unless otherwise noted.

§ 419.62 Transitional pass-through payments: General rules.

(a) *General.* CMS provides for additional payments under §§ 419.64 and 419.66 for certain innovative medical devices, drugs, and biologicals.

(b) *Budget neutrality.* CMS establishes the additional payments under §§ 419.64 and 419.66 in a budget neutral manner.

(c) *Uniform prospective reduction of pass-through payments.* (1) If CMS estimates before the beginning of a calendar year that the total amount of pass-through payments under §§ 419.64 and 419.66 for the year would exceed the applicable percentage (as described in paragraph (c)(2) of this section) of the total amount of Medicare payments under the outpatient prospective payment system. CMS will reduce, pro rata, the amount of each of the additional payments under §§ 419.64 and 419.66 for that year to ensure that the applicable percentage is not exceeded.

(2) The applicable percentages are as follows:

(i) For a year before CY 2004, the applicable percentage is 2.5 percent.

(ii) For 2004 and subsequent years, the applicable percentage is a percentage specified by CMS up to (but not to exceed) 2.0 percent.

(d) *CY 2002 incorporated amount.* For the portion of CY 2002 affected by these rules, CMS incorporated 75 percent of the estimated pass-through costs (before the incorporation and any pro rata reduction) for devices into the procedure APCs associated with these devices.

[66 FR 55856, 55865, Nov. 2, 2001; 67 FR 9568, Mar. 1, 2002]

EFFECTIVE DATE NOTE: At 66 FR 55865, Nov. 2, 2001, § 419.62 was amended by adding paragraph (d), effective Jan. 1, 2002. At 66 FR 67494, Dec. 31, 2001, the amendment was delayed indefinitely.

§ 419.64 Transitional pass-through payments: Drugs and biologicals.

(a) *Eligibility for pass-through payment.* CMS makes a transitional pass-through payment for the following drugs and biologicals that are furnished as part of an outpatient hospital service:

(1) *Orphan drugs.* A drug or biological that is used for a rare disease or condition and has been designated as an orphan drug under section 526 of the Federal Food, Drug and Cosmetic Act if payment for the drug or biological as an outpatient hospital service was being made on August 1, 2000.

(2) *Cancer therapy drugs and biologicals.* A drug or biological that is used in cancer therapy, including, but not limited to, a chemotherapeutic agent, an antiemetic, a hematopoietic growth factor, a colony stimulating factor, a biological response modifier, and a bisphosphonate if payment for the drug or biological as an outpatient hospital service was being made on August 1, 2000.

(3) *Radiopharmaceutical drugs and biological products.* A radiopharmaceutical drug or biological product used in diagnostic, monitoring, and therapeutic nuclear medicine services if payment for the drug or biological as an outpatient hospital service was being made on August 1, 2000.

(4) *Other drugs and biologicals.* A drug or biological that meets the following conditions:

(i) It was first payable as an outpatient hospital service after December 31, 1996.

(ii) CMS has determined the cost of the drug or biological is not insignificant in relation to the amount payable for the applicable APC (as calculated under § 419.32(c)) as defined in paragraph (b) of this section.

(iii) A biological that is not surgically implanted or inserted into the body.

(iv) A biological that is not a skin substitute or similar product that aids wound healing.

(b) *Cost.* CMS determines the cost of a drug or biological to be not insignificant if it meets the following requirements:

(1) *Services furnished before January 1, 2003.* The expected reasonable cost of a drug or biological must exceed 10 percent of the applicable APC payment amount for the service related to the drug or biological.

(2) *Services furnished after December 31, 2002.* CMS considers the average cost of a new drug or biological to be not insignificant if it meets the following conditions:

(i) The estimated average reasonable cost of the drug or biological in the category exceeds 10 percent of the applicable APC payment amount for the service related to the drug or biological.

(ii) The estimated average reasonable cost of the drug or biological exceeds the cost of the drug or biological portion of the APC payment amount for the related service by at least 25 percent.

(iii) The difference between the estimated reasonable cost of the drug or biological and the estimated portion of the APC payment amount for the drug or biological exceeds 10 percent of the APC payment amount for the related service.

(c) *Limited period of payment.* CMS limits the eligibility for a pass-through payment under this section to a period of at least 2 years, but not more than 3 years, that begins as follows:

(1) For a drug or biological described in paragraphs (a)(1) through (a)(3) of this section—August 1, 2000.

(2) For a drug or biological described in paragraph (a)(4) of this section—the

date that CMS makes its first pass-through payment for the drug or biological.

(d) *Amount of pass-through payment.* Subject to any reduction determined under § 419.62(b), the pass-through payment for a drug or biological equals the amount determined under section 1842(o) of the Social Security Act, minus the portion of the APC payment amount that CMS determines is associated with the drug or biological.

[65 FR 18542, Apr. 7, 2000, as amended at 69 FR 832, Jan. 6, 2004; 69 FR 65863, Nov. 15, 2004; 74 FR 60680, Nov. 20, 2009; 79 FR 67031, Nov. 10, 2014]

§ 419.66 Transitional pass-through payments: Medical devices.

(a) *General rule.* CMS makes a pass-through payment for a medical device that meets the requirements in paragraph (b) of this section and that is described by a category of devices established by CMS under the criteria in paragraph (c) of this section.

(b) *Eligibility.* A medical device must meet the following requirements:

(1) If required by the FDA, the device must have received FDA premarket approval or clearance (except for a device that has received an FDA investigational device exemption (IDE) and has been classified as a Category B device by the FDA in accordance with §§ 405.203 through 405.207 and 405.211 through 405.215 of this chapter), or meet another appropriate FDA exemption for premarket approval or clearance. Under this provision, the pass-through payment application for a medical device must be submitted within 3 years from the date of the initial FDA approval or clearance, if required, unless there is a documented, verifiable delay in U.S. market availability after FDA approval or clearance is granted, in which case CMS will consider the pass-through payment application if it is submitted within 3 years from the date of market availability.

(2) The device is determined to be reasonable and necessary for the diagnosis or treatment of an illness or injury or to improve the functioning of a malformed body part (as required by section 1862(a)(1)(A) of the Act).

(3) The device is an integral part of the service furnished, is used for one patient only, comes in contact with human tissue, and is surgically implanted or inserted (either permanently or temporarily) or applied in or on a wound or other skin lesion.

(4) The device is not any of the following:

(i) Equipment, an instrument, apparatus, implement, or item of this type for which depreciation and financing expenses are recovered as depreciable assets as defined in Chapter 1 of the Medicare Provider Reimbursement Manual (CMS Pub. 15–1).

(ii) A material or supply furnished incident to a service (for example, a suture, customized surgical kit, or clip, other than radiological site marker).

(c) *Criteria for establishing device categories.* CMS uses the following criteria to establish a category of devices under this section:

(1) CMS determines that a device to be included in the category is not appropriately described by any of the existing categories or by any category previously in effect, and was not being paid for as an outpatient service as of December 31, 1996.

(2) CMS determines either of the following:

(i) The device to be included in the category has demonstrated that it will substantially improve the diagnosis or treatment of an illness or injury or improve the functioning of a malformed body part compared to the benefits of a device or devices in a previously established category or other available treatment; or

(ii) For devices for which pass-through payment status will begin on or after January 1, 2020, as an alternative pathway to paragraph (c)(2)(i) of this section, a new device is part of the Food and Drug Administration's (FDA's) Breakthrough Devices Program and has received marketing authorization for the indication covered by the Breakthrough Device designation.

(3) Except for medical devices identified in paragraph (e) of this section, CMS determines the cost of the device is not insignificant as described in paragraph (d) of this section.

(d) *Cost criteria.* CMS considers the average cost of a category of devices to

be not insignificant if it meets the following conditions:

(1) The estimated average reasonable cost of devices in the category exceeds 25 percent of the applicable APC payment amount for the service related to the category of devices.

(2) The estimated average reasonable cost of the devices in the category exceeds the cost of the device-related portion of the APC payment amount for the related service by at least 25 percent.

(3) The difference between the estimated average reasonable cost of the devices in the category and the portion of the APC payment amount for the device exceeds 10 percent of the APC payment amount for the related service.

(e) *Devices exempt from cost criteria.* The following medical devices are not subject to the cost requirements described in paragraph (d) of this section, if payment for the device was being made as an outpatient service on August 1, 2000:

(1) A device of brachytherapy.

(2) A device of temperature-monitored cryoablation.

(f) *Identifying a category for a device.* A device is described by a category, if it meets the following conditions:

(1) Matches the long descriptor of the category code established by CMS.

(2) Conforms to guidance issued by CMS relating to the definition of terms and other information in conjunction with the category descriptors and codes.

(g) *Limited period of payment for devices.* CMS limits the eligibility of a pass-through payment established under this section to a period of at least 2 years, but not more than 3 years, beginning on the first date on which pass-through payment is made.

(h) *Amount of pass-through payment.* Subject to any reduction determined under §419.62(b), the pass-through payment for a device is the hospital's charge for the device, adjusted to the actual cost for the device, minus the amount included in the APC payment amount for the device.

[66 FR 55856, Nov. 2, 2001, as amended at 67 FR 66813, Nov. 1, 2002; 70 FR 68728, Nov. 10, 2005; 74 FR 60680, Nov. 20, 2009; 78 FR 75198, Dec. 10, 2013; 79 FR 67031, Nov. 10, 2014; 80 FR 70606, Nov. 13, 2015; 81 FR 79880, Nov. 14, 2016; 84 FR 61491, Nov. 12, 2019; 85 FR 86303, Dec. 29, 2020]

Subpart H—Transitional Corridors

SOURCE: 65 FR 18542, Apr. 7, 2000, unless otherwise noted. Redesignated at 66 FR 55856, Nov. 2, 2001.

§419.70 Transitional adjustments to limit decline in payments.

(a) *Before 2002.* Except as provided in paragraph (d) of this section, for covered hospital outpatient services furnished before January 1, 2002, for which the prospective payment system amount (as defined in paragraph (e) of this section) is—

(1) At least 90 percent, but less than 100 percent, of the pre-BBA amount (as defined in paragraph (f) of this section), the amount of payment under this part is increased by 80 percent of the amount of this difference;

(2) At least 80 percent, but less than 90 percent, of the pre-BBA amount, the amount of payment under this part is increased by the amount by which the product of 0.71 and the pre-BBA amount exceeds the product of 0.70 and the prospective payment system amount;

(3) At least 70 percent, but less than 80 percent, of the pre-BBA amount, the amount of payment under this part is increased by the amount by which the product of 0.63 and the pre-BBA amount, exceeds the product of 0.60 and the PPS amount; or

(4) Less than 70 percent of the pre-BBA amount, the amount of payment under this part shall be increased by 21 percent of the pre-BBA amount.

(b) *For 2002.* Except as provided in paragraph (d) of this section, for covered hospital outpatient services furnished during 2002, for which the prospective payment system amount is—

(1) At least 90 percent, but less than 100 percent, of the pre-BBA amount, the amount of payment under this part

is increased by 70 percent of the amount of this difference;

(2) At least 80 percent, but less than 90 percent, of the pre-BBA amount, the amount of payment under this part is increased by the amount by which the product of 0.61 and the pre-BBA amount exceeds the product of 0.60 and the prospective payment system amount; or

(3) Less than 80 percent of the pre-BBA amount, the amount of payment under this part is increased by 13 percent of the pre-BBA amount.

(c) *For 2003.* Except as provided in paragraph (d) of this section, for covered hospital outpatient services furnished during 2003, for which the prospective payment system amount is—

(1) At least 90 percent, but less than 100 percent, of the pre-BBA amount, the amount of payment under this part is increased by 60 percent of the amount of this difference; or

(2) Less than 90 percent of the pre-BBA amount, the amount of payment under this part is increased by 6 percent of the pre-BBA amount.

(d) *Hold harmless provisions*—(1) *Temporary treatment for small rural hospitals before January 1, 2006.* For covered hospital outpatient services furnished in a calendar year before January 1, 2006, for which the prospective payment system amount is less than the pre-BBA amount, the amount of payment under this part is increased by the amount of that difference if the hospital—

(i) Is located in a rural area as defined in § 412.64(b) of this chapter or is treated as being located in a rural area under section 1886(d)(8)(E) of the Act; and

(ii) Has 100 or fewer beds as defined in § 412.105(b) of this chapter.

(2) *Temporary treatment for small rural hospitals on or after January 1, 2006.* For covered hospital outpatient services furnished in a calendar year from January 1, 2006 through December 31, 2012, for which the prospective payment system amount is less than the pre-BBA amount, the amount of payment under this part is increased by 95 percent of that difference for services furnished during CY 2006, 90 percent of that difference for services furnished during CY 2007, and 85 percent of that difference for services furnished during CYs 2008, 2009, 2010, 2011, and 2012 if the hospital—

(i) Is located in a rural area as defined in § 412.64(b) of this chapter or is treated as being located in a rural area under section 1886(d)(8)(E) of the Act;

(ii) Has 100 or fewer beds as defined in § 412.105(b) of this chapter;

(iii) Is not a sole community hospital as defined in § 412.92 of this chapter; and

(iv) Is not an essential access community hospital under § 412.109 of this chapter.

(3) *Permanent treatment for cancer hospitals and children's hospitals.* In the case of a hospital described in § 412.23(d) or § 412.23(f) of this chapter for which the prospective payment system amount is less than the pre-BBA amount for covered hospital outpatient services, the amount of payment under this part is increased by the amount of this difference.

(4) *Temporary treatment for sole community hospitals located in rural areas for covered hospital outpatient services furnished during cost reporting periods beginning on or after January 1, 2004 and before January 1, 2006.* For covered hospital outpatient services furnished during cost reporting periods beginning on or after January 1, 2004, and continuing through December 31, 2005, for which the prospective payment system amount is less than the pre-BBA amount, the amount of payment under this part is increased by the amount of that difference if the hospital—

(i) Is a sole community hospital, under § 412.92 of this chapter; and

(ii) Is located in a rural area as defined in § 412.63(b) or § 412.64(b), as applicable, of this chapter or is treated as being located in a rural area under section 1886(d)(8)(E) of the Act.

(5) *Temporary treatment for small sole community hospitals on or after January 1, 2009 and through December 31, 2009.* For covered hospital outpatient services furnished on or after January 1, 2009, and continuing through December 31, 2009, for which the prospective payment system amount is less than the pre-BBA amount, the amount of payment under this part is increased by 85 percent of that difference if the hospital—

(i) Is a sole community hospital as defined in § 412.92 of this chapter or is an essential access community hospital as described under § 412.109 of this chapter; and

(ii) Has 100 or fewer beds as defined in § 412.105(b) of this chapter.

(6) *Temporary treatment for sole community hospitals on or after January 1, 2010, and through December 31, 2011.* For covered hospital outpatient services furnished on or after January 1, 2010, through December 31, 2011, for which the prospective payment system amount is less than the pre-BBA amount, the amount of payment under this part is increased by 85 percent of that difference if the hospital is a sole community hospital as defined in § 412.92 of this chapter or is an essential access community hospital as described under § 412.109 of this chapter.

(7) *Temporary treatment of small sole community hospitals on or after January 1, 2012 through December 31, 2012.* (i) For covered hospital outpatient services furnished on or after January 1, 2012 through December 31, 2012, for which the prospective payment system amount is less than the pre-BBA amount, the amount of payment under this part is increased by 85 percent of that difference if the hospital—

(A) Is a sole community hospital as defined in § 412.92 of this chapter or is an essential access community hospital as described under § 412.109 of this chapter; and

(B) Has 100 or fewer beds as defined in § 412.105(b) of this chapter, except as provided in paragraph (d)(7)(ii) of this section.

(ii) For covered hospital outpatient services furnished on or after January 1, 2012 through February 29, 2012, the bed size limitation under paragraph (d)(7)(i)(B) of this section does not apply.

(e) *Prospective payment system amount defined.* In this section, the term ''prospective payment system amount'' means, with respect to covered hospital outpatient services, the amount payable under this part for these services (determined without regard to this section or any reduction in coinsurance elected under § 419.42), including amounts payable as copayment under § 419.41, coinsurance under section 1866(a)(2)(A)(ii) of the Act, and the deductible under section 1833(b) of the Act.

(f) *Pre-BBA amount defined*—(1) *General rule.* In this paragraph, the ''pre-BBA amount'' means, with respect to covered hospital outpatient services furnished by a hospital or a community mental health center (CMHC) in a year, an amount equal to the product of the reasonable cost of the provider for these services for the portions of the provider's cost reporting period (or periods) occurring in the year and the base provider outpatient payment-to-cost ratio for the provider (as defined in paragraph (f)(2) of this section).

(2) *Base payment-to-cost-ratio defined.* For purposes of this paragraph, CMS shall determine these ratios as if the amendments to sections 1833(i)(3)(B)(i)(II) and 1833(n)(1)(B)(i) of the Act made by section 4521 of the BBA, to require that the full amount beneficiaries paid as coinsurance under section 1862(a)(2)(A) of the Act are taken into account in determining Medicare Part B Trust Fund payment to the hospital, were in effect in 1996. The ''base payment-to-cost ratio'' for a hospital or CMHC means the ratio of—

(i) The provider's payment under this part for covered outpatient services furnished during one of the following periods, including any payment for these services through cost-sharing described in paragraph (e) of this section:

(A) The cost reporting period ending in 1996; or

(B) If the provider does not have a cost reporting period ending in 1996, the first cost reporting period ending on or after January 1, 1997, and before January 1, 2001; and

(ii) The reasonable costs of these services for the same cost reporting period.

(g) *Interim payments.* CMS makes payments under this section to hospitals and CMHCs on an interim basis, subject to retrospective adjustments based on settled cost reports.

(h) *No effect on coinsurance.* No payment made under this section affects the unadjusted coinsurance amount or the coinsurance amount described in § 419.41.

(i) *Application without regard to budget neutrality.* The additional payments made under this section—

(1) Are not considered an adjustment under § 419.43(f); and

(2) Are not implemented in a budget neutral manner.

[65 FR 18542, Apr. 7, 2000, as amended at 65 FR 67829, Nov. 13, 2000; 66 FR 59923, Nov. 30, 2001; 69 FR 832, Jan. 6, 2004; 69 FR 65863, Nov. 15, 2004; 71 FR 68228, Nov. 24, 2006; 72 FR 66933, Nov. 27, 2007; 73 FR 68814, Nov. 18, 2008; 74 FR 60681, Nov. 20, 2009; 75 FR 72265, Nov. 24, 2010; 76 FR 74583, Nov. 30, 2011; 77 FR 68559, Nov. 15, 2012]

§ 419.71 Payment reduction for certain X-ray imaging services.

(a) *Definition.* For purposes of this section, the term ''computed radiography technology'' means cassette-based imaging which utilizes an imaging plate to create the image involved.

(b) *Payment reduction for film X-ray imaging services.* For an imaging service that is an X-ray taken using film and that is furnished during 2017 or a subsequent year, the payment amount for such service (including the X-ray component of a packaged service) is reduced by 20 percent.

(c) *Payment reduction for computed radiography imaging services.* The payment amount for an imaging service that is an X-ray taken using computed radiography technology (including the X-ray component of a packaged service) is reduced by—

(1) 7 percent, for such services furnished in CY 2018, 2019, 2020, 2021, or 2022.

(2) 10 percent, for such services furnished in CY 2023 or a subsequent calendar year.

(d) *Application without regard to budget neutrality.* The reductions taken under this section are not considered adjustments under section 1833(t)(2)(E) of the Act and are not implemented in a budget neutral manner.

[82 FR 52637, Nov. 13, 2017; 82 FR 59497, Dec. 14, 2017]

Subpart I—Prior Authorization for Outpatient Department Services

SOURCE: 84 FR 61491, Nov. 12, 2019, unless otherwise noted.

§ 419.80 Basis and scope of this subpart.

(a) *Basis.* The provisions in this subpart are issued under the authority of section 1833(t)(2)(F) of the Act, which authorizes the Secretary to develop a method for controlling unnecessary increases in the volume of covered hospital outpatient department services.

(b) *Scope.* This subpart specifies the process and requirements for prior authorization for certain hospital outpatient department services as a condition of Medicare payment.

§ 419.81 Definitions.

As used in this subpart, unless otherwise specified, the following definitions apply:

List of hospital outpatient department services requiring prior authorization means the list of hospital outpatient department services described in § 419.83(a) that CMS adopts in accordance with § 419.83(b) that require prior authorization as a condition of Medicare payment.

Prior authorization means the process through which a request for provisional affirmation of coverage is submitted to CMS or its contractors for review before the service is provided to the beneficiary and before the claim is submitted for processing.

Provisional affirmation means a preliminary finding that a future claim meets the Medicare coverage, coding, and payment rules in chapter IV of this title or in Title XVIII of the Social Security Act.

§ 419.82 Prior authorization for certain covered hospital outpatient department services.

(a) *Prior authorization as condition of payment.* As a condition of Medicare payment for the services in the categories of services on the list of hospital outpatient department services requiring prior authorization as specified in § 419.83(a), a provider must submit to CMS or its contractors a prior authorization request in accordance with the requirements of paragraph (c) of this section.

(b) *Denial of claim.* (1) CMS or its contractors will deny a claim for a service that requires prior authorization if the provider has not received a provisional

affirmation of coverage on the claim from CMS or its contractor unless the provider is exempt under § 419.83(c).

(2) CMS or its contractor may deny a claim that has received a provisional affirmation based on either of the following:

(i) Technical requirements that can only be evaluated after the claim has been submitted for formal processing; or

(ii) Information not available at the time of a prior authorization request.

(3) CMS or its contractor may deny claims for services related to services on the list of hospital outpatient department services for which the provider has received a denial.

(c) *Submission of prior authorization request.* A provider must submit to CMS or its contractor a prior authorization request for any service on the list of outpatient department services requiring prior authorization.

(1) *Prior authorization request requirements.* A prior authorization request must—

(i) Include all documentation necessary to show that the service meets applicable Medicare coverage, coding, and payment rules in chapter IV of this title or in Title XVIII of the Social Security Act.

(ii) Be submitted before the service is provided to the beneficiary and before the claim is submitted.

(2) *Request for expedited review.* A provider may submit a request for expedited review of a prior authorization request. The request for expedited review must comply with the requirements in paragraphs (c)(1)(i) and (ii) of this section and include documentation showing that the processing of the prior authorization request must be expedited due to the beneficiary's life, health, or ability to regain maximum function being in serious jeopardy.

(d) *Reviews*—(1) *Review of prior authorization request.* Upon receipt of a prior authorization request, CMS or its contractor will review the request for compliance with applicable Medicare coverage, coding, and payment rules in chapter IV of this title or in Title XVIII of the Social Security Act.

(i) CMS or its contractor will issue a provisional affirmation to the provider if it is determined that applicable Medicare coverage, coding, and payment rules in chapter IV of this title or in Title XVIII of the Social Security Act are met.

(ii) CMS or its contractor will issue a non-affirmation to the provider if it is determined that applicable Medicare coverage, coding, and payment rules in chapter IV of this title or in Title XVIII of the Social Security Act are not met.

(iii) The provisional affirmation or non-affirmation will be issued within 7-calendar days of receipt of the prior authorization request.

(2) *Review of expedited review request.* Upon receipt of a request for expedited review, CMS or its contractor will complete an expedited review of the prior authorization request if it is determined that a delay could seriously jeopardize the beneficiary's life, health, or ability to regain maximum function, and issue a provisional affirmation or non-affirmation decision in accordance with paragraph (d)(1) of this section within 2 business days of the expedited review request.

(e) *Resubmission.* (1) A provider may resubmit a prior authorization request, upon receipt of a non-affirmation, consistent with the requirements in paragraph (c)(1) of this section.

(2) A provider may resubmit a request for expedited review consistent with the requirements in paragraph (c)(1) of this section.

[84 FR 61491, Nov. 12, 2019, as amended at 89 FR 94591, Nov. 27, 2024]

§ 419.83 List of hospital outpatient department services requiring prior authorization.

(a) *Service categories for the list of hospital outpatient department services requiring prior authorization.* (1) The following service categories comprise the list of hospital outpatient department services requiring prior authorization beginning for service dates on or after July 1, 2020:

(i) Blepharoplasty.

(ii) Botulinum toxin injections.

(iii) Panniculectomy.

(iv) Rhinoplasty.

(v) Vein ablation.

(2) The following service categories comprise the list of hospital outpatient

department services requiring prior authorization beginning for service dates on or after July 1, 2021:

(i) Cervical Fusion with Disc Removal.

(ii) Implanted Spinal Neurostimulators.

(3) The Facet Joint Interventions service category requires prior authorization beginning for service dates on or after July 1, 2023.

(b) *Adoption of the list of services and technical updates.* (1) CMS will adopt the list of hospital outpatient department service categories requiring prior authorization and any updates or geographic restrictions through formal notice-and-comment rulemaking.

(2) Technical updates to the list of services, such as changes to the name of the service or Current Procedural Terminology (CPT) code, will be published on the CMS website.

(c) *Exemptions.* CMS may elect to exempt a provider from the prior authorization process in §419.82 upon a provider's demonstration of compliance with Medicare coverage, coding, and payment rules in chapter IV of this title or in Title XVIII of the Social Security Act through such prior authorization process.

(1) An exemption will remain in effect until CMS elects to withdraw the exemption.

(2) Notice of an exemption or withdraw of an exemption will be provided at least 60 days prior to the effective date.

(d) *Suspension of prior authorization process or services.* CMS may suspend the outpatient department services prior authorization process requirements generally or for a particular service(s) at any time by issuing notification on the CMS website.

[84 FR 61491, Nov. 12, 2019, as amended at 85 FR 86303, Dec. 29, 2020; 87 FR 72292, Nov. 23, 2022]

§§ 419.84–419.89 [Reserved]

Subpart J—Payments to Rural Emergency Hospitals (REHs)

SOURCE: 87 FR 72292, Nov. 23, 2022, unless otherwise noted.

§ 419.90 Basis and scope of subpart.

(a) *Basis.* This subpart implements sections 1861(kkk) and 1834(x) of the Act, which establish the rural emergency hospital Medicare provider type and the payment requirements applying to such entities.

(b) *Scope.* This subpart describes the methodologies used to determine payment for REH services and the monthly facility payment amount paid to REHs.

§ 419.91 Definitions.

As used in this subpart—

Rural emergency hospital or REH means an entity as defined in §485.502 of this chapter.

Rural emergency hospital (REH) services means all covered outpatient department (OPD) services, as defined in section 1833(t)(1)(B) of the Act, excluding services described in section 1833(t)(1)(B)(ii), furnished by an REH that would be paid under the outpatient prospective payment system (OPPS) when provided in a hospital paid under the OPPS for outpatient services, provided that such services are furnished consistent with the conditions of participation at §§485.510 through 485.544 of this chapter.

§ 419.92 Payment to rural emergency hospitals.

(a) *Payment for REH services*—(1) *Medicare payment.* A rural emergency hospital that furnishes a REH service on or after January 1, 2023, is paid an amount equal to the amount of payment that would otherwise apply under section 1833(t) of the Act for the equivalent covered OPD service, increased by 5 percent.

(2) *Beneficiary copayment.* The beneficiary copayment for a REH service is the amount determined under section 1833(t)(8) of the Act for the equivalent covered OPD service, excluding the 5 percent payment increase described in paragraph (a)(1) of this section.

(b) *Monthly facility payment.* Effective January 1, 2023, REHs are paid a monthly facility payment equal to 1/12 of the annual additional facility payment amount described in paragraphs (b)(1) and (2) of this section.

(1) *Calculation of monthly facility payment for 2023.* For calendar year 2023,

the annual additional facility payment amount is:

(i) The total amount that the Secretary determines was paid by the Medicare program and from beneficiary copayments to all critical access hospitals in calendar year 2019; minus

(ii) The estimated total amount that the Secretary determines would have been paid by the Medicare program and from beneficiary copayments to critical access hospitals in calendar year 2019 if payment were made for inpatient hospital, outpatient hospital, and skilled nursing facility services under the applicable prospective payment systems for such services during calendar year 2019; divided by

(iii) The total number of critical access hospitals enrolled in Medicare in calendar year 2019.

(2) *Calculation of monthly facility payment for 2024 and subsequent years.* For calendar year 2024 and each subsequent calendar year, the amount of the additional annual facility payment is the amount of the preceding year's additional annual facility payment, increased by the hospital market basket percentage increase as described under section 1886(b)(3)(B)(iii) of the Act.

(3) *Recording and Reporting the use of the monthly facility payment.* A rural emergency hospital receiving the monthly facility payment must maintain detailed information as specified by the Secretary as to how the facility has used the monthly facility payments and must make this information available to the Secretary upon request.

(c) *Payment for services furnished by an REH that do not meet the definition of REH services.* A service furnished by an REH that does not meet the definition of an REH service under § 419.91, including a hospital service that is excluded from payment under the OPPS as described in § 419.22, is paid for under the payment system applicable to the service, provided the requirements for payment under that system are met.

(1) *Payment for ambulance services.* Ambulance services furnished by an entity owned and operated by a rural emergency hospital are paid under the ambulance fee schedule as described at section 1834(l) of the Act.

(2) *Payment for post-hospital extended care services.* Post-hospital extended care services furnished by a rural emergency hospital that has a unit that is a distinct part licensed as a skilled nursing facility are paid under the skilled nursing facility prospective payment system described at section 1888(e) of the Act.

(d) *REH payment for the costs of graduate medical education.* (1) For portions of cost reporting periods beginning on or after October 1, 2023, an REH that incurs costs of training full-time equivalent (FTE) residents that rotate to the REH may receive direct graduate medical education payments for those costs.

(2) Payment is equal to the Medicare reasonable costs that the REH incurs to train the FTE residents that rotate to the REH, as determined in accordance with section 1861(v)(1)(A) of the Act and the applicable principles of cost reimbursement in part 413 of this chapter, except that the following payment principles are excluded:

(i) Lesser of cost or charges.

(ii) Ceilings on hospital operating costs.

(3) An REH that does not incur costs of training FTE residents that rotate to the REH is considered a nonprovider setting for purposes of graduate medical education payments, consistent with §§ 412.105(f)(1)(ii)(E) and 413.78(g) of this chapter.

(4) Direct graduate medical education payments to REHs made under this section are made from the Federal Hospital Insurance Trust Fund.

(e) *Payment for Indian Health Service (IHS) or tribal REHs.* An IHS or tribal REH, as defined in paragraph (f) of this section will be paid under the outpatient hospital All-Inclusive Rate that is established and published annually by the IHS rather than the rates for REH services described in paragraph (a)(1) of this section.

(f) *IHS or tribal REHs.* An IHS or tribal REH is an REH, as defined in § 485.502 of this chapter, that is operated by the IHS or by a tribe or tribal organization with funding authorized by Title I or V of the Indian Self-Determination and

Education Assistance Act (Pub. L. 93–638).

[87 FR 72292, Nov. 23, 2022, as amended at 88 FR 59335, Aug. 28, 2023; 88 FR 82181, Nov. 22, 2023]

§ 419.93 Payment for an off-campus provider-based department of a rural emergency hospital.

(a) Items and services furnished by an off-campus provider-based department of an REH, as defined in paragraph (b) of this section, are not applicable items and services under sections 1833(t)(1)(B)(v) and (t)(21) of the Act and are paid as follows:

(1) REH services furnished by an off-campus provider-based department of an REH are paid as described in § 419.92(a)(1).

(2) Services that do not meet the definition of REH services under § 419.91 that are furnished by an off-campus provider-based department of an REH are paid as described under § 419.92(c) or, if applicable, § 419.92(e).

(b) For the purpose of this section, ''off-campus provider-based department of an REH'' means a ''department of a provider'' (as defined at § 413.65(a)(2) of this chapter) that is not located on the campus (as defined in § 413.65(a)(2) of this chapter) or within the distance described in such definition from a ''remote location of a hospital'' (as defined in § 413.65(a)(2) of this chapter) that meets the requirements for provider-based status under § 413.65 of this chapter.

[87 FR 72292, Nov. 23, 2022, as amended at 88 FR 82181, Nov. 22, 2023]

§ 419.94 Preclusion of administrative and judicial review.

There is no administrative or judicial review under section 1869 of the Act, section 1878 of the Act, or otherwise of the following:

(a) The determination of whether a rural emergency hospital meets the requirements of this subpart.

(b) The determination of payment amounts under this subpart.

(c) The requirements established by this subpart.

§ 419.95 Requirements under the Rural Emergency Hospital Quality Reporting (REHQR) Program.

(a) *Statutory authority.* Section 1861(kkk)(7) of the Social Security Act authorizes the Secretary to implement a quality reporting program requiring Rural Emergency Hospitals (REHs) to submit data on measures in accordance with the Secretary's requirements in this part.

(b) *Participation in the REHQR Program.* To participate in the REHQR Program, an REH as defined in section 1861(kkk)(2) of the Act must—

(1) Register on a CMS website before beginning to report data;

(2) Identify and register a security official as part of the registration process under paragraph (b)(1) of this section; and

(3) Submit data on all quality measures to CMS as specified under paragraph (c) of this section.

(c) *Submission of REHQR Program data*—(1) *General rule.* REHs that participate in the REHQR Program must submit to CMS data on measures selected under section 1861(kkk)(7)(C) of the Act in a form and manner and at a time specified by CMS. REHs sharing the same CMS Certification Number (CCN) must combine data collection and submission across their multiple campuses for all clinical measures for public reporting purposes.

(2) *Submission deadlines.* Submission deadlines by measure and by data type are posted on a CMS website. All deadlines occurring on a Saturday, Sunday, or legal holiday, or on any other day all or part of which is declared to be a non-work day for Federal employees by statute or Executive order are extended to the first day thereafter which is not a Saturday, Sunday, or legal holiday or any other day all or part of which is declared to be a non-work day for Federal employees by statute or Executive order.

(3) *Review and corrections period.* For all quality data submitted, REHs will have a review and corrections period, which runs concurrently with the data submission period. During this timeframe, REHs can enter, review, and correct data submitted. However, after the submission deadline, these data cannot be changed.

(d) *Technical specifications and measure maintenance under the REHQR Program.* (1) CMS will update the specifications manual for measures in the REHQR Program at least every 12 months.

(2) CMS follows different procedures to update the measure specifications of a measure previously adopted under the REHQR Program based on whether the change is substantive or non-substantive. CMS will determine what constitutes a substantive versus a non-substantive change to a measure's specifications.

(i) *Substantive changes.* CMS will use rulemaking to adopt substantive updates to measures in the REHQR Program.

(ii) *Non-substantive changes.* If CMS determines that a change to a measure previously adopted in the REHQR Program is non-substantive, CMS will use a sub-regulatory process to revise the specifications manual for the REHQR Program so that it clearly identifies the change to that measure and provide links to where additional information on the change can be found. When a measure undergoes sub-regulatory maintenance, CMS will provide notification of the measure specification update on a designated website and in the specifications manual and will provide sufficient lead time for REHs to implement the revisions where changes to the data collection systems would be necessary.

(e) *Retention and removal of quality measures under the REHQR Program*—(1) *General rule for the retention of quality measures.* Quality measures adopted for the REHQR Program measure set are retained for use, except when they are removed, suspended, or replaced as set forth in paragraphs (e)(2) and (3) of this section.

(2) *Immediate measure suspension from reporting.* In cases where CMS believes that the collection and reporting activities related to a quality measure as specified raises patient safety concerns, CMS will immediately suspend the measure from the REHQR Program and will promptly notify REHs and the public of the suspension of the measure. CMS will address the suspension and propose any permanent action regarding the measure in the next appropriate rulemaking cycle.

(3) *Measure removal, suspension, or replacement through the rulemaking process.* Unless a measure raises specific safety concerns as set forth in paragraph (e)(2) of this section, CMS will use rulemaking to remove, suspend, or replace quality measures in the REHQR Program.

(i) *Factors for consideration for removal of quality measures.* CMS will weigh whether to remove measures based on the following factors:

(A) *Factor 1.* Measure performance among REHs is so high and unvarying that meaningful distinctions and improvements in performance can no longer be made (''topped-out'' measures);

(B) *Factor 2.* Performance or improvement on a measure does not result in better patient outcomes;

(C) *Factor 3.* A measure does not align with current clinical guidelines or practice;

(D) *Factor 4.* The availability of a more broadly applicable (across settings, populations, or conditions) measure for the topic;

(E) *Factor 5.* The availability of a measure that is more proximal in time to desired patient outcomes for the particular topic;

(F) *Factor 6.* The availability of a measure that is more strongly associated with desired patient outcomes for the particular topic;

(G) *Factor 7.* Collection or public reporting of a measure leads to negative unintended consequences other than patient harm; and

(H) *Factor 8.* The costs associated with a measure outweigh the benefit of its continued use in the program.

(ii) *Criteria to determine topped-out measures.* For the purposes of the REHQR Program, a measure is considered to be topped-out under paragraph (e)(3)(i)(A) of this section when it meets both of the following criteria:

(A) Statistically indistinguishable performance at the 75th and 90th percentiles (defined as when the difference between the 75th and 90th percentiles for an REH's measure is within two times the standard error of the full data set); and

(B) A truncated coefficient of variation less than or equal to 0.10.

(iii) *Application of measure removal factors.* The benefits of removing a measure from the REHQR Program will be assessed on a case-by-case basis. Under this case-by-case approach, a measure will not be removed solely on the basis of meeting any specific factor.

(f) *Public reporting of data under the REHQR Program.* Data that an REH submits for the REHQR Program will be made publicly available on a CMS website in an easily understandable format after providing the REH an opportunity to review the data to be made public. CMS will publicly display REH data by the CCN when data are submitted under the CCNs.

(g) *Exception.* CMS may grant an exception to one or more data submission deadlines and requirements in the event of extraordinary circumstances beyond the control of the hospital, such as when an act of nature affects an entire region or locale or a systemic problem with one of CMS' data collection systems directly or indirectly affects data submission. CMS may grant an exception as follows:

(1) *Upon request by the REH.* Specific requirements for submission of a request for an exception are available on a CMS website.

(2) *At the discretion of CMS.* CMS may grant exceptions to REHs that have not requested them when CMS determines that an extraordinary circumstance has occurred.

[88 FR 82181, Nov. 22, 2023]

PART 420—PROGRAM INTEGRITY: MEDICARE

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AUTHORITY: Secs. 1102 and 1871 of the Social Security Act (42 U.S.C. 1302 and 1395hh).

SOURCE: 44 FR 31142, May 30, 1979, unless otherwise noted.

Subpart A—General Provisions

§ 420.1 Scope and purpose.

This part sets forth requirements for Medicare providers, intermediaries, and carriers to disclose ownership and control information. It also deals with access to records pertaining to certain contracts entered into by Medicare providers. These rules are aimed at protecting the integrity of the Medicare program. The statutory basis for these requirements is explained in each of the other subparts.

[51 FR 34787, Sept. 30, 1986]

§ 420.3 Other related regulations.

(a) *Appeals procedures.* Part 498 of this chapter sets forth the appeals procedures available to providers whose provider agreements CMS terminates for failure to comply with the disclosure of information requirements set forth in subpart C of this part.

(b) *Exclusion, termination, or suspension.* Part 1001 of this title sets forth the rules applicable to exclusion, termination, or suspension from the Medicare program because of fraud or abuse or conviction of program-related crimes.

[51 FR 34787, Sept. 30, 1986, as amended at 52 FR 22454, June 12, 1987]

Subpart B [Reserved]

Subpart C—Disclosure of Ownership and Control Information

§ 420.200 Purpose.

This subpart implements sections 1124, 1124A, 1126, and 1861(v)(1)(i) of the Social Security Act. It sets forth requirements for providers, Part B suppliers, intermediaries, and carriers to disclose ownership and control information and the identities of managing employees. It also sets forth requirements for disclosure of information about a provider's or Part B supplier's owners, those with a controlling interest, or managing employees convicted of criminal offenses against Medicare, Medicaid, or the title V (Maternal and Child Health Services) and title XX (Social Services) programs.

[57 FR 27306, June 18, 1992, as amended at 60 FR 50442, Sept. 29, 1995]

§ 420.201 Definitions.

As used in this subpart unless the context indicates otherwise:

Agent means any person who has been delegated the authority to obligate or act on behalf of a provider.

Disclosing entity means:

(1) A provider of services, an independent clinical laboratory, a renal disease facility, a rural health clinic, a Federally qualified health center, or a health maintenance organization (as defined in section 1301(a) of the Public Health Service Act);

(2) A carrier or other agency or organization that is acting for one or more providers of services for purposes of part A and part B of Medicare; and

(3) A part B supplier, as defined in § 400.202 of this chapter.

Group of practitioners means two or more health care practitioners who practice their profession at a common location (whether or not they share common facilities, common supporting staff, or common equipment).

Indirect ownership interest means any ownership interest in an entity that has an ownership interest in the disclosing entity. The term includes an ownership interest in any entity that has an indirect ownership interest in the disclosing entity.

Managing employee means a general manager, business manager, administrator, director, or other individual that exercises operational or managerial control over, or who directly or indirectly conducts, the day-to-day operation of the institution, organization, or agency, either under contract or through some other arrangement, whether or not the individual is a W–2 employee.

Other disclosing entity means any other Medicare disclosing entity and any entity that does not participate in Medicare, but is required to disclose certain ownership and control information because of participation in any of the programs established under title V, XIX, or XX of the Act. This includes:

(1) An entity (other than an individual practitioner or group of practitioners) that furnishes, or arranges for the furnishing of, items or services for which payment may be claimed by the entity under any plan or program established under title V of the Social Security Act or under an approved State Medicaid plan;

(2) An entity (other than an individual practitioner or group of practitioners) that furnishes, or arranges for the furnishing of, health-related services for which payment may be claimed by the entity under an approved State plan and services program under title XX of the Act; or

(3) A Medicaid fiscal agent.

Ownership interest means the possession of equity in the capital, the stock, or the profits of the disclosing entity.

Person with an ownership or control interest means a person or corporation that—

(1) Has an ownership interest totaling 5 percent or more in a disclosing entity;

(2) Has an indirect ownership interest equal to 5 percent or more in a disclosing entity;

(3) Has a combination of direct and indirect ownership interests equal to 5 percent or more in a disclosing entity;

(4) Owns an interest of 5 percent or more in any mortgage, deed of trust, note, or other obligation secured by the disclosing entity if that interest equals at least 5 percent of the value of the property or assets of the disclosing entity;

(5) Is an officer or director of a disclosing entity that is organized as a corporation; or

(6) Is a partner in a disclosing entity that is organized as a partnership.

Significant business transaction means any business transaction or series of transactions during any one fiscal year, the total of which exceeds the lesser of $25,000 and 5 percent of the total operating expenses of the provider.

Subcontractor means—

(1) An individual, agency, or organization to which a disclosing entity has contracted or delegated some of its management functions or responsibilities of providing medical care to its patients; or

(2) An individual, agency, or organization with which an intermediary or carrier has entered into a contract, agreement, purchase order or lease (or leases of real property) to obtain space, supplies, equipment, or services provided under the Medicare agreement.

Wholly owned supplier means a supplier whose total ownership interest is held by a provider or by a person, persons, or other entity with an ownership or control interest in a provider.

[44 FR 41642, July 17, 1979, as amended at 57 FR 24982, June 12, 1992; 57 FR 27306, June 18, 1992; 57 FR 35760, Aug. 11, 1992; 71 FR 20775, Apr. 21, 2006]

§ 420.202 Determination of ownership or control percentages.

(a) *Indirect ownership interest.* The amount of indirect ownership interest is determined by multiplying the percentages of ownership in each entity. For example, if A owns 10 percent of the stock in a corporation that owns 80 percent of the disclosing entity, A's interest equates to an 8 percent indirect ownership interest in the disclosing entity and must be reported. Conversely, if B owns 80 percent of the stock of a corporation that owns 5 percent of the stock of the disclosing entity, B's interest equates to a 4 percent indirect ownership interest in the disclosing entity and need not be reported.

(b) *Person with an ownership or control interest.* In order to determine the percentage of ownership interest in any mortgage, deed of trust, note, or other obligation, the percentage of interest owned in obligation is multiplied by the percentage of the disclosing entity's assets used to secure the obligation. For example, if A owns 10 percent of a note secured by 60 percent of the provider's assets, A's interest in the provider's assets equates to 6 percent and must be reported. Conversely, if B owns 40 percent of a note secured by 10 percent of the provider's assets, B's interest in the provider's assets equates to 4 percent and need not be reported.

§ 420.203 Disclosure of hiring of intermediary's former employees.

A provider must notify the Secretary promptly if it, or its home office (in the case of a chain organization), employs or obtains the services of an individual who, at any time during the year preceding such employment, was employed in a managerial, accounting, auditing, or similar capacity by an agency or organization which currently serves, or at any time during the preceding year, served as a Medicare fiscal intermediary or carrier for the provider. *Similar capacity* means the performance of essentially the same work functions as those of a manager, accountant, or auditor even though the individual is not so designated by title.

§ 420.204 Principals convicted of a program-related crime.

(a) *Information required.* Prior to CMS's acceptance of a provider agreement or issuance or reissuance of a supplier billing number, or at any time

upon written request by CMS, the provider or part B supplier must furnish CMS with the identity of any person who:

(1) Has an ownership or control interest in the provider or part B supplier;

(2) Is an agent or managing employee of the provider or part B supplier; or

(3) Is a person identified in paragraph (a)(1) or (a)(2) of this section and has been convicted of, or was an owner of, had a controlling interest in, or was a managing employee of a corporation that has been convicted of a criminal offense, subjected to any civil monetary penalty, or excluded from the programs for any activities related to involvement in the Medicare, Medicaid, title V or title XX social services program, since the inception of those programs.

(b) *Refusal to enter into or renew agreement or to issue or reissue billing numbers.* CMS may refuse to enter into or renew an agreement with a provider of services, or to issue or reissue a billing number to a part B supplier, if any person who has an ownership or control interest in the provider or supplier, or who is an agent or managing employee, has been convicted of a criminal offense or subjected to any civil penalty or sanction related to the involvement of that person in Medicare, Medicaid, title V or title XX social services programs. In making this decision, CMS considers the facts and circumstances of the specific case, including the nature and severity of the crime, penalty or sanction and the extent to which it adversely affected beneficiaries and the programs involved. CMS also considers whether it has been given reasonable assurance that the person will not commit any further criminal or civil offense against the programs.

(c) *Notification of Inspector General.* CMS promptly notifies the Inspector General of the Department of the receipt of any application or request for participation, certification, re-certification, or for a billing number that identifies any person described in paragraph (a)(3) of this section and the action taken on that application or request.

[57 FR 27306, June 18, 1992]

§ 420.205 Disclosure by providers and part B suppliers of business transaction information.

A provider or part B supplier must submit to CMS, within 35 days after the date of a written request, full and complete information on—

(a) The ownership of a subcontractor with which the provider or part B supplier has had, during the previous 12 months, business transactions in an aggregate amount in excess of $25,000;

(b) Any significant business transactions between the provider or part B supplier and any wholly owned supplier or between the provider or part B supplier and any subcontractor, during the 5 year period ending on the date of the request;

(c) The names of managing employees of the subcontractors;

(d) The identity of any other entities to which payment may be made by Medicare, which a person with an ownership or control interest or a managing employee in the subcontractor has or has had an ownership or control interest in the 3-year period preceding disclosure; and

(e) Any penalties, assessments, or exclusions under sections 1128, 1128A and 1128B of the Act incurred by the subcontractor, its owners, managing employees or those with a controlling interest in the subcontract.

[57 FR 27306, June 18, 1992]

§ 420.206 Disclosure of persons having ownership, financial, or control interest.

(a) *Information that must be disclosed.* A disclosing entity must submit the following information in the manner specified in paragraph (b) of this section:

(1) The name and address of each person with an ownership or control interest in the entity or in any subcontractor in which the entity has direct or indirect ownership interest totaling 5 percent or more. In the case of a part B supplier that is a joint venture, ownership of 5 percent or more of any company participating in the joint venture should be reported. Any physician who has been issued a Unique Physician Identification Number by the Medicare program must provide this number.

(2) Whether any of the persons named, in compliance with paragraph (a)(1) of this section, is related to another as spouse, parent, child, or sibling.

(3) The name of any other disclosing entity in which any person with an ownership or control interest, or who is a managing employee in the reporting disclosing entity, has, or has had in the previous three-year period, an ownership or control interest or position as managing employee, and the nature of the relationship with the other disclosing entity. If any of these other disclosing entities has been convicted of a criminal offense or received a civil monetary or other administrative sanction related to participation in Medicare, Medicaid, title V (Maternal and Child Health) or title XX (Social Services) programs, such as penalties assessments and exclusions under sections 1128, 1128A or 1128B of the Act, the disclosing entity must also provide that information.

(b) *Time and manner of disclosure.* (1) Any disclosing entity that is subject to periodic survey and certification of its compliance with Medicare standards must supply the information specified in paragraph (a) of this section to the State survey agency at the time it is surveyed. The survey agency will promptly furnish the information to the Secretary.

(2) Any disclosing entity that is not subject to periodic survey and certification must supply the information specified in paragraph (a) of this section to CMS before entering into a contract or agreement with Medicare or before being issued or reissued a billing number as a part B supplier.

(3) A disclosing entity must furnish updated information to CMS at intervals between recertification, or re-enrollment, or contract renewals, within 35 days of a written request. In the case of a part B supplier, the supplier must report also within 35 days, on its own initiative, any changes in the information it previously supplied.

(c) *Consequences of failure to disclose.* (1) CMS does not approve an agreement or contract with, or make a determination of eligibility for, or (in the case of a part B supplier) issue or reissue a billing number to, any disclosing entity that fails to comply with paragraph (b) of this section.

(2) CMS terminates any existing agreement or contract with, or withdraws a determination of eligibility for or (in the case of a part B supplier) revokes the billing number of, any disclosing entity that fails to comply with paragraph (b) of this section.

(d) *Public disclosure.* Information furnished to the Secretary under the provisions of this section shall be subject to public disclosure as specified in 20 CFR part 422.

[44 FR 41642, July 17, 1979, as amended at 57 FR 27306, June 18, 1992]

Subpart D—Access to Books, Documents, and Records of Subcontractors

SOURCE: 47 FR 58267, Dec. 30, 1982, unless otherwise noted.

§ 420.300 Basis, purpose, and scope.

This subpart implements section 1861(v)(1)(I) of the Act, which requires, for Medicare payment under certain provider contracts, access by the Secretary, upon written request, and the Comptroller General, and their duly authorized representatives, to certain contracts for services and to books, documents, and records necessary to verify the costs of the services. The contracts affected are those between providers and their subcontractors, and between the subcontractors and organizations related to the subcontractor by control or common ownership. It also specifies the criteria by which HHS will determine whether to request access to books, documents, and records.

§ 420.301 Definitions.

For purposes of this subpart—

Books, documents, and records means all writings, recordings, transcriptions and tapes of any description necessary to verify the nature and extent of the costs of the services provided by the subcontractor.

Common ownership means that an individual or individuals possess significant ownership or equity in the subcontractor and the entity providing the services under the contract.

Contract for services means a contract through which a provider obtains the performance of an act or acts, as distinguished from supplies or equipment. It includes any contract for both goods and services to the extent the value or cost of the service component is $10,000 or more within a 12-month period.

Control means that an individual or an organization has the power, directly or indirectly, significantly to influence or direct the actions of policies of an organization.

Provider means a hospital, skilled nursing facility, home health agency, hospice or comprehensive outpatient rehabilitation facility, or a related organization (as defined in § 413.17 of this chapter) of any of these providers.

Related to the subcontractor means that the subcontractor is, to a significant extent, associated or affiliated with, owns, or is owned by, or has control of or is controlled by, the organization furnishing the services, facilities, or supplies.

Subcontractor means any entity, including an individual or individuals, that contracts with a provider to supply a service, either to the provider or directly to a beneficiary, for which Medicare reimburses the provider the cost of the service. This includes organizations related to the subcontractor that have a contract with the subcontractor for which the cost or value is $10,000 or more in a 12-month period.

[47 FR 58267, Dec. 30, 1982, as amended at 49 FR 13703, Apr. 6, 1984; 51 FR 34833, Sept. 30, 1986]

§ 420.302 Requirement for access clause in contracts.

(a) *Applicability.* This subpart applies to contracts—

(1) Between a provider and a subcontractor and, where subject to section 1861(v)(l)(I)(ii) of the Act, between a subcontractor and an organization related to the subcontractor;

(2) Entered into or renewed after December 5, 1980; and

(3) For services the cost or value of which is $10,000 or more over a 12-month period, including contracts for both goods and services in which the service component is worth $10,000 or more over a 12-month period.

(b) *Requirement.* Any contract meeting the conditions of paragraph (a) of this section must include a clause that allows the Comptroller General of the United States, HHS, and their duly authorized representatives access to the subcontractor's contract, books, documents, and records until the expiration of four years after the services are furnished under the contract or subcontract. The access must be provided for in accordance with the provisions of this subpart. The clause must also allow similar access by HHS, the Comptroller General, and their duly authorized representatives to contracts subject to section 1861(v)(l)(I)(ii) of the Act between a subcontractor and organizations related to the subcontractor and to books, documents, and records.

(c) *Prohibition against Medicare reimbursement.* If a contract subject to the requirements of this subpart does not contain the clause required by paragraph (b) of this section, CMS will not reimburse the provider for the cost of the services furnished under the contract and will recoup any payments previously made for services under the contract. However, in order to avoid nonreimbursement or recoupment, providers will have until July 30, 1983, to amend those contracts entered into or renewed after December 5, 1980, and before January 31, 1983, that do not conform to the requirements of paragraph (b) of this section.

[47 FR 58267, Dec. 30, 1982, as amended at 49 FR 13703, Apr. 6, 1984]

§ 420.303 HHS criteria for requesting books, documents, and records.

HHS will generally request books, documents, and records from a subcontractor only if one of the following situations exists and the question cannot satisfactorily and efficiently be resolved without access to the books, documents, and records:

(a) HHS has reason to believe that the costs claimed for services of the subcontractor are excessive or inappropriate.

(b) There is insufficient information to judge the appropriateness of the costs.

(c) There is a written accusation with suitable evidence against the provider

or subcontractor of kickbacks, bribes, rebates, or other illegal activities.

(d) There is evidence of a possible nondisclosure of the existence of a related organization.

§ 420.304 Procedures for obtaining access to books, documents, and records.

(a) *Contents of the request.* Requests for access will be in writing and contain the following elements:

(1) Reasonable identification of the books, documents, and records to which access is being requested.

(2) Identification of the contract or subcontract in which costs are being questioned as excessive or inappropriate.

(3) The reason that the appropriateness of the costs or value of the services of the subcontractor in question cannot be adequately or efficiently determined without access to the subcontractor's books and records.

(4) The authority in the statute and regulations for the access requested.

(5) To the extent possible, the identification of those individuals who will be visiting the subcontractor to obtain access to the books, documents, and records.

(6) The time and date of the scheduled visit.

(7) The name of the duly authorized representative of HHS to contact if there are any questions.

(b) *Subcontractor response to a request for access to books, documents, and records.* (1) The subcontractor will have 30 days from the date of a written request for access to books, documents, and records to make them available in accordance with the request.

(2) If the subcontractor believes the request is inadequate because it does not fully meet one or more of the required elements in paragraph (a) of this section, the subcontractor must advise the requesting organization of the additional information needed.

(i) The subcontractor must notify the requesting organization within 20 days of the date of the request that it was improperly completed.

(ii) The subcontractor must make the books, documents, and records available within 20 days after the date of the requesting organization's response.

(3) If the subcontractor believes, for good cause, that the requested books, documents, and records cannot be made available as requested with the 30-day period under paragraph (b)(1) of this section, the subcontractor may request an extension of time within which to comply with the request from the requesting organization. The requesting organization may, at its discretion, grant the request for an extension, in whole or in part, for good cause shown.

(4) The subcontractor must make the books, documents, and records available during its regular business hours for inspection, audit, and reproduction.

(5) If HHS asks the subcontractor to reproduce books, documents, and records, HHS will pay the reasonable cost of reproduction. However, if the subcontractor reproduces books, documents, and records as a means of making them available, the subcontractor must bear the cost of the reproduction and no Medicare reimbursement will be made for that purpose.

(6) HHS reserves the right to examine the originals of any requested contracts, books, documents, and records, if they exist.

(c) *Refusal by subcontractor to furnish access to records.* If CMS determines that the books, documents, and records are necessary for the reimbursement determination and the subcontractor refuses to make them available, HHS may initiate legal action against the subcontractor.

Subpart E—Rewards for Information Relating to Medicare Fraud and Abuse, and Establishment of a Program to Collect Suggestions for Improving Medicare Program Efficiency and to Reward Suggesters for Monetary Savings

SOURCE: 63 FR 31128, June 8, 1998, unless otherwise noted.

§ 420.400 Basis and scope.

This subpart implements sections 203(b) and (c) of Public Law 104–191, which require the establishment of programs to encourage individuals to report suspected cases of fraud and abuse

and submit suggestions on methods to improve the efficiency of the Medicare program. Sections 203(b) and (c) of Public Law 104–191 also provide the authority for CMS to reward individuals for reporting fraud and abuse and for submitting suggestions that could improve the efficiency of the Medicare program. This subpart sets forth procedures for rewarding individuals.

[64 FR 66401, Nov. 26, 1999]

§ 420.405 Rewards for information relating to Medicare fraud and abuse.

(a) *General rule.* CMS pays a monetary reward for information that leads to the recovery of at least $100 of Medicare funds from individuals and entities that are engaging in, or have engaged in, acts or omissions that constitute grounds for the imposition of a sanction under section 1128, section 1128A, or section 1128B of the Act or that have otherwise engaged in sanctionable fraud and abuse against the Medicare program. The determination of whether an individual meets the criteria for an award, and the amount of the award, is at the discretion of CMS. CMS pays rewards only if a reward is not otherwise provided for by law. When CMS applies the criteria specified in paragraphs (b), (c), and (e) of this section to determine the eligibility and the amount of the reward, it notifies the beneficiary as specified in paragraph (d) of this section.

(b) *Information eligible for reward.* (1) In order for an individual to be eligible to receive a reward, the information he or she supplied must relate to the activities of a specific individual or entity and must specify the time period of the alleged activities.

(2) CMS does not give a reward for information relating to an individual or entity that, at the time the information is provided, is already the subject of a review or investigation by CMS or its contractors, or the OIG, the Department of Justice, the Federal Bureau of Investigation, or any other Federal, State, or local law enforcement agency.

(c) *Persons eligible to receive a reward—*(1) *General rule.* Any person (other than one excluded under paragraph (c)(2) of this section) is eligible to receive a reward under this section if the person submits the information in the manner set forth in paragraph (f) of this section.

(2) *Excluded individuals.* (i) An individual who was, or is an immediate family member of, an officer or employee of HHS or its contractors, the SSA, the OIG, a State Medicaid Agency, or the Department of Justice, the Federal Bureau of Investigation, or any other Federal, State, or local law enforcement agency at the time he or she came into possession of, or divulged, information leading to a recovery of Medicare funds is not eligible to receive a reward under this section.

(ii) Any other Federal or State employee or contractor or an HHS grantee is not eligible for a reward under this section if the information submitted came to his or her knowledge in the course of his or her official duties.

(iii) An individual who illegally obtained the information he or she submitted is excluded from receiving a reward under this section.

(iv) An individual who participated in the sanctionable offense with respect to which payment would be made is excluded from receiving a reward under this section.

(d) *Notification of eligibility*—(1) *General rule.* After all Medicare funds have been recovered and CMS has determined a participant eligible to receive a reward under the provisions of this section, it notifies the informant of his or her eligibility, by mail, at the most recent address supplied by the individual. It is the individual's responsibility to ensure that the reward program has been notified of any change in his or her address or other relevant personal information (for example, change of name, phone number).

(2) *Special circumstances.* (i) If the individual has relocated to an unknown address, the individual or his or her legal representative may claim the reward by contacting CMS within 1 year from the date on which CMS first attempted to notify the individual about a reward. CMS does not consider the individual or his or her legal representative eligible for a reward more than 1 year after the date on which it first attempted to give notice. CMS does not pay interest on rewards that are not immediately claimed.

(ii) If the individual has become incapacitated or has died, an executor, administrator, or other legal representative may claim the reward on behalf of the individual or the individual's estate. The claimant must submit certified copies of the letters testamentary, letters of administration, or other similar evidence to show his or her authority to claim the reward. The claim must be filed within 1 year from the date on which CMS first gave or attempted to give notice of the reward.

(e) *Amount and payment of reward.* (1) In determining whether it will pay a reward and, if so, the amount of the reward, CMS takes into account all relevant factors, including the significance of the information furnished in relation to the ultimate resolution of the case and the recovery of Medicare funds.

(2) The amount of a reward represents what CMS considers to be adequate compensation in the particular case, not to exceed 10 percent of the overpayments recovered in the case or $1,000, whichever is less.

(3) If more than one person is eligible to receive a reward in a particular case, CMS allocates the total reward amount (not to exceed 10 percent of the overpayments recovered in that case or $1,000, whichever is less) among the participants.

(4) CMS bases rewards only on recovered Medicare payments and not on amounts collected as penalties or fines.

(5) CMS makes payments as promptly as the circumstances of the case permit, but not until it has collected all Medicare overpayments, fines, and penalties.

(6) No person may make any offer or promise or otherwise bind CMS or HHS with respect to the payment of any reward under this section or the amount of the reward.

(f) *Submission of information.* (1) An individual may submit information on persons or entities engaging in, or that have engaged in, fraud and abuse against the Medicare program to the Office of the Inspector General, or to the Medicare intermediary or carrier that has jurisdiction over the suspected fraudulent provider or supplier.

(2) A participant interested in receiving a reward must provide his or her name, address, telephone number, and any other requested identifying information so that he or she may be contacted, if necessary, for additional information and, when applicable, for the payment of a reward upon resolution of the case.

(g) *Confidentiality.* CMS does not reveal a participant's identity to any person, except as required by law.

(h) *Finding of ineligibility after reward is accepted.* If, after a reward is accepted, CMS finds that the awardee was ineligible to receive the reward, the Government is not liable for the reward and the awardee must refund all monies received.

§ 420.410 Establishment of a program to collect suggestions for improving Medicare program efficiency and to reward suggesters for monetary savings.

(a) *Definitions.* As used in this section, the following definitions apply:

Payment means a monetary award given to a suggester in recognition of, and as a reward for, a suggestion adopted by CMS that improves the efficiency of, and results in monetary savings to, the Medicare program.

Savings means the monetary value of the net benefits the Medicare program derives from implementing the suggestion.

Suggester means an individual, a group of individuals, or a legal entity such as a corporation, partnership, or professional association, not otherwise excluded under § 420.410(d), who submits a suggestion under this section.

Suggestion means an original idea submitted in writing.

Suggestion program means the specific procedures and requirements established by CMS for receiving suggestions from the suggester on methods to improve the efficiency of the Medicare program, evaluating the suggestions and, if appropriate, paying a reward to the suggester for adopted suggestions that result in improved efficiency and produce monetary savings to the Medicare program.

(b) *General rule.* CMS may make payment for adopted suggestions that increase the efficiency of the Medicare program and result in monetary savings. CMS only makes payment for

suggestions in instances in which a reward is not otherwise provided by law. The determination to adopt a suggestion, to reward the suggester, and the method of calculating a reward are at the sole discretion of CMS.

(c) *Eligibility.* Except as specified in paragraph (d) of this section, any individual, group of individuals or legal entity, such as a corporation, partnership or professional association, is eligible to submit a suggestion and be considered for a reward under this suggestion program if the suggestion is submitted to CMS in the manner set forth in paragraph (e) of this section.

(d) *Exclusions.* Medicare contractors, their officers and employees, individuals who work for Federal agencies under a contract, employees of Federally-sponsored research and demonstration projects, Federal officers and employees, and immediate family members of these individuals, are excluded from receiving payment under the suggestion program. If, after the suggester receives a reward payment, CMS determines that the suggester was ineligible to receive the reward, CMS is not liable for the reward payment and the suggester must refund all monies received.

(e) *Requirements for submitting suggestions*—(1) To be considered, the suggestion must be in writing, mailed to CMS, and must include the following information:

(i) A description of an existing problem or need;

(ii) A suggested method for solving the problem or filling the need; and

(iii) If known, an estimate of the savings potential that could result from implementing the suggestion.

(2) Suggestions must be mailed to: Centers for Medicare & Medicaid Services Suggestion Program, 7500 Security Blvd., Baltimore, Maryland 21244–1850.

(3) Any suggesters interested in receiving a reward must provide CMS with the following information: An individual suggester must provide his or her name, a group of suggesters must provide the names of all the group members, and a legal entity must provide its name and the name of its representative. All suggesters must provide an address, telephone number, and any other identifying information that CMS needs to contact the suggester for additional information and, where applicable, to mail the reward.

(f) *Evaluation process*—(1) *Relevant factors.* CMS evaluates all suggestions on the basis of the following factors:

(i) Originality of suggestion.

(ii) An estimate of potential monetary savings to the Medicare program.

(iii) The extent to which Medicare program efficiency would be improved if CMS adopts the suggestion.

(iv) Accuracy of the information reflected in the suggestion.

(v) Feasibility of implementation.

(vi) Nature and complexity of the suggestion.

(vii) Any other factors that appear to be relevant.

(2) *Evaluation time limit.* CMS concludes the evaluation process in a reasonable amount of time, not to exceed 2 years from the receipt date, taking into consideration the complexity of the suggestion, the number of possible implementation strategies, and CMS's current workload.

(g) *Basis for reward payment*—(1) *General rule.* If CMS determines that it is appropriate to make a reward payment for a suggestion adopted in whole or in part, that results in improved efficiency and monetary savings to the Medicare program, the payment is based on—

(i) The actual first-year net savings to the Medicare program, or

(ii) The average annual net savings to the Medicare program expected to be realized over a period of not more than 3 years if—

(A) An improvement is expected to yield monetary savings for more than 1 year and implementation involves substantial costs; or

(B) Monetary savings are negligible in the first year but are expected to substantially increase in subsequent years.

(2) *Reward payment amount.* CMS determines the amount of a reward payment using the following formula:

(i) Net savings from $1,000 to $10,000—10 percent of the savings, with a minimum award amount of $100;

(ii) Net savings of $10,001 to $100,000—$1,000 for the first $10,000 of savings, plus 3 percent of the net savings over $10,000;

(iii) Net savings of more than $100,000—$3,700 for the first $100,000 of savings, plus 0.5 percent of savings over $100,000, with a maximum award amount of $25,000.

(h) *Adoption of suggestion and issuance of reward payment*—(1) *Adoption.* Upon completing its evaluation, CMS decides whether to adopt a suggestion. If CMS receives the same or an overlapping suggestion from two or more unrelated parties, CMS will consider a reward only for the suggestion CMS received first, if the suggestion or overlapping part of the suggestion are identical, and CMS has adopted that part. If the suggestions are not identical, CMS will consider rewarding the suggestion received first, if it is feasible and CMS is able to adopt and implement the suggestion. If the first suggestion cannot be implemented, CMS may consider rewarding the suggestion received next, even if it is similar, provided CMS can adopt and implement the suggestion.

(2) *Issuance of reward payment.* After the reward payment amount is determined, as described in paragraph (g) of this section, CMS mails payment to the suggester (or to the legal representatives referenced in paragraph (k) of this section) only after the suggestion has been in operation for 1 year.

(i) *Group suggestions.* When CMS deems that a reward payment is appropriate for a suggestion submitted by a group of individuals, CMS pays an equal share of the reward to each of the individuals identified in the group. If an organization such as a corporation, partnership, or professional association submits a suggestion, CMS makes a single reward payment to that organization.

(j) *Change in name or address.* It is the suggester's responsibility to notify CMS of any change of address or other relevant information. If the suggester fails to update CMS on any change in this information, and the reward payment mailed to the suggester is returned to CMS, the suggester must claim the reward payment by contacting CMS within 1 year from the date CMS first mailed the reward payment to the suggester. CMS does not pay interest on rewards that, for any reason, are delayed or are not immediately claimed.

(k) *Incapacitated or deceased suggester.* If the suggester is incapacitated or has died, an executor, administrator, or other legal representative may claim the reward on behalf of the suggester or the suggester's estate. The claimant must submit certified copies of the letters testamentary, letters of administration, or other similar evidence to CMS showing his or her authority to claim the reward. The claim must be filed within 1 year from the date on which CMS first attempted to pay the reward to the individual who submitted the suggestion.

(l) *Maintenance of records*—(1) CMS retains records related to the administration of the suggestion program in accordance with 36 CFR part 1228 (the regulations for the National Archives and Records Administration).

(2) CMS does not disclose information submitted under the suggestion program, except as required by law.

[64 FR 66401, Nov. 26, 1999]

PART 421—MEDICARE CONTRACTING

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AUTHORITY: 42 U.S.C. 1302 and 1395hh.

SOURCE: 45 FR 42179, June 23, 1980, unless otherwise noted.

Subpart A—Scope, Definitions, and General Provisions

§ 421.1 Basis, applicability, and scope.

(a) *Basis.* This part is based on the provisions of the following sections of the Act:

Section 1124—Requirements for disclosure of certain information.

Sections 1816 and 1842—Provisions relating to the administration of Parts A and B.

Section 1893—Requirements for protecting the integrity of the Medicare program.

(b) *Applicability.* The provisions of this part apply to agreements with Part A (Hospital Insurance) fiscal intermediaries that received awards under sections 1816 or 1842 of the Act prior to October 1, 2005, contracts with Part B (Supplementary Medical Insurance) carriers that received awards under sections 1816 or 1842 of the Act prior to October 1, 2005, and contracts with Medicare integrity program contractors that perform program integrity functions.

(c) *Scope.* The scope of this part—

(1) Specifies that CMS may perform certain functions directly or by contract.

(2) Specifies criteria and standards CMS uses in evaluating the performance of fiscal intermediaries' successor entities and in assigning or reassigning a provider or providers to particular fiscal intermediaries.

(3) Provides the opportunity for a hearing for fiscal intermediaries and carriers affected by certain adverse actions.

(4) Provides adversely affected fiscal intermediaries an opportunity for judicial review of certain hearing decisions.

(5) Sets forth requirements related to contracts with Medicare integrity program contractors.

[72 FR 48886, Aug. 24, 2007]

§ 421.3 Definitions.

As used in this part—

Intermediary means an entity that has a contract with CMS (under statutory provisions in effect prior to October 1, 2005) to determine and make Medicare payments for Part A or Part B benefits payable on a cost basis (or under the prospective payment system for hospitals) and to perform other related functions. For purposes of applying the performance criteria in § 421.120 and the performance standards in § 421.122 and any adverse action resulting from that application, the term ''intermediary'' also means a Blue Cross plan that has entered into a subcontract approved by CMS with the Blue Cross and Blue Shield Association to perform intermediary functions.

[71 FR 68228, Nov. 24, 2006]

§ 421.5 General provisions.

(a) *Competitive bidding not required for carriers.* CMS may enter into contracts with carriers, or with intermediaries to

act as carriers in certain circumstances, without regard to section 3709 of the U.S. Revised Statutes or any other provision of law that requires competitive bidding.

(b) *Indemnification of intermediaries and carriers.* Intermediaries and carriers act on behalf of CMS in carrying out certain administrative responsibilities that the law imposes. Accordingly, their agreements and contracts contain clauses providing for indemnification with respect to actions taken on behalf of CMS and CMS is the real party of interest in any litigation involving the administration of the program.

(c) *Use of intermediaries to perform carrier functions.* CMS may contract with an intermediary to perform carrier functions with respect to services for which Part B payment is made to a provider.

(d) *Nonrenewal of agreement or contract.* Notwithstanding any of the provisions of this part, CMS has the authority not to renew an agreement or contract when its term expires.

(e) *Intermediary availability in an area.* For more effective and efficient administration of the program, CMS retains the right to expand or diminish the geographical area in which an intermediary is available to serve providers.

(f) *Provision for automatic renewal.* Agreements and contracts under this part may contain automatic renewal clauses for continuation from term to term unless either party gives notice, within timeframes specified in the agreement or contract, of its intention not to renew.

[45 FR 42179, June 23, 1980, as amended at 54 FR 4026, Jan. 27, 1989]

Subpart B—Intermediaries

§ 421.100 Intermediary functions.

An agreement between CMS and an intermediary specifies the functions to be performed by the intermediary.

(a) *Mandatory functions.* The contract must include the following functions:

(1) Determining the amount of payments to be made to providers for covered services furnished to Medicare beneficiaries.

(2) Making the payments.

(b) *Additional functions.* The contract may include any or all of the following functions:

(1) Any or all of the program integrity functions described in § 421.304, provided the intermediary is continuing those functions under an agreement entered into under section 1816 of the Act that was in effect on August 21, 1996, and they do not duplicate work being performed under a Medicare integrity program contract.

(2) Undertaking to adjust incorrect payments and recover overpayments when it is determined that an overpayment was made.

(3) Furnishing to CMS timely information and reports that CMS requests in order to carry out its responsibilities in the administration of the Medicare program.

(4) Establishing and maintaining procedures as approved by CMS for the redetermination of payment determinations.

(5) Maintaining records and making available to CMS the records necessary for verification of payments and for other related purposes.

(6) Upon inquiry, assisting individuals for matters pertaining to an intermediary agreement.

(7) Serving as a channel of communication to and from CMS of information, instructions, and other material as necessary for the effective and efficient performance of an intermediary agreement.

(8) Undertaking other functions as mutually agreed to by CMS and the intermediary.

(c) *Dual intermediary responsibilities.* Regarding the responsibility for service to provider-based HHAs and provider-based hospices, where the HHA or the hospice and its parent provider will be served by different intermediaries, the designated regional intermediary will process bills, make coverage determinations, and make payments to the HHAs and the hospices. The intermediary or Medicare integrity program contractor serving the parent provider will perform all fiscal functions, including audits and settlement of the Medicare cost reports and the HHA and hospice supplement worksheets.

[72 FR 48886, Aug. 24, 2007]

§421.103 Payment to providers.

Providers are assigned to intermediaries in accordance with §421.104. As the Medicare Administrative Contractors (MACs) are implemented, providers are reassigned from intermediaries to MACs in accordance with §412.404 of this chapter.

[71 FR 68228, Nov. 24, 2006]

§421.104 Assignment of providers of services to intermediaries during transition to Medicare Administrative Contractors (MACs).

(a) Beginning October 1, 2005, CMS assigns providers of services and other entities that may bill Part A benefits to intermediaries in a manner that will best support the transition to Medicare Administrative Contractors (MACs) under section 1874A of the Act in accordance with subpart E of this part.

(b) These providers of services and other entities must continue to bill the intermediary that they were billing prior to October 1, 2005, until one of the following events occurs:

(1) The intermediary's agreement with CMS ends, and the provider or entity is directed by CMS to bill another CMS contractor.

(2) The provider or entity is assigned to a MAC that has begun to administer claims within the geographic locale of the provider or entity.

(3) CMS directs the provider or entity to begin billing another CMS contractor in order to support the implementation of MACs under section 1874A of the Act and subpart E of this part.

(c) New providers of services and new entities will be assigned to the intermediary serving their geographic locale if no MAC has begun to administer Medicare claims in the locale. These providers or entities must continue to bill the intermediary until one of the events in paragraph (b) of this section occurs.

(d) Providers or entities will only be granted exceptions to the provisions of paragraphs (b) or (c) of this section if CMS deems the exception to be in the compelling interest of the Medicare program.

(e) CMS will notify the provider or entity, the outgoing intermediary, and the newly assigned intermediary of assignment or reassignment decisions.

[71 FR 68228, Nov. 24, 2006]

§421.110 Requirements for approval of an agreement.

Before entering into or renewing an intermediary agreement, CMS will—

(a) Determine that to do so is consistent with the effective and efficient administration of the Medicare program;

(b) Review the performance of the intermediary as measured by the criteria (§421.120) and standards (§421.122); and

(c) Determine that the intermediary or prospective intermediary—

(1) Is willing and able to assist providers in the application of safeguards against unnecessary utilization of services;

(2) Meets all solvency and financial responsibility requirements imposed by the statutes and regulatory authorities of the State or States in which it, or any subcontractor performing some or all of its functions, would serve;

(3) Has the overall resources and experience to administer its responsibilities under the Medicare program and has an existing operational, statistical, and recordkeeping capacity to carry out the additional program responsibilities it proposes to assume. CMS will presume that an intermediary or prospective intermediary meets this requirement if it has at least 5 years experience in paying for or reimbursing the cost of health services;

(4) Will serve a sufficient number of providers to permit a finding of effective and efficient administration. Under this criterion no intermediary or prospective intermediary shall be found to be not efficient or effective solely on the grounds that it serves only providers located in a single State;

(5) Has acted in good faith to achieve effective cooperation with the providers it will service and with the physicians and medical societies in the area;

(6) Has established a record of integrity and satisfactory service to the public; and

(7) Has an affirmative equal employment opportunity program that complies with the fair employment provisions of the Civil Rights Act of 1964 and Executive Order 11246, as amended.

§ 421.112 Considerations relating to the effective and efficient administration of the program.

(a) In order to accomplish the most effective and efficient administration of the Medicare program, the Secretary may make determinations with respect to the termination of an intermediary agreement, and CMS may make determinations with respect to renewal of an intermediary agreement under § 421.110.

(b) When taking the actions specified in paragraph (a) of this section, the Secretary or CMS will consider the performance of the individual intermediary in its Medicare operations using the factors contained in the performance criteria specified in § 421.120 and the performance standards specified in § 421.122.

(c) In addition, when taking the actions listed in paragraph (a) of this section, the Secretary or CMS may consider factors relating to—

(1) Consistency in the administration of program policy;

(2) Development of intermediary expertise in difficult areas of program administration;

(3) Individual capacity of available intermediaries to serve providers as it is affected by such considerations as—

(i) Program emphasis on the number or type of providers to be served; or

(ii) Changes in data processing technology;

(4) Overdependence of the program on the capacity of an intermediary to an extent that services could be interrupted;

(5) Economy in the delivery of intermediary services;

(6) Timeliness in the delivery of intermediary services;

(7) Duplication in the availability of intermediaries;

(8) Conflict of interest between an intermediary and provider; and

(9) Any additional pertinent factors.

[45 FR 42179, June 23, 1980, as amended at 59 FR 682, Jan. 6, 1994; 71 FR 68229, Nov. 24, 2006]

§ 421.114 Assignment and reassignment of providers by CMS.

CMS may assign or reassign any provider to any intermediary if it determines that the assignment or reassignment will be in the best interests of the Medicare program.

[71 FR 68229, Nov. 24, 2006]

§ 421.120 Performance criteria.

(a) *Application of performance criteria.* As part of the intermediary evaluations authorized by section 1816(f) of the Act, CMS periodically assesses the performance of intermediaries in their Medicare operations using performance criteria. The criteria measure and evaluate intermediary performance of functional responsibilities such as—

(1) Correct coverage and payment determinations;

(2) Responsiveness to beneficiary concerns; and

(3) Proper management of administrative funds.

(b) *Basis for criteria.* CMS will base the performance criteria on—

(1) Nationwide intermediary experience;

(2) Changes in intermediary operations due to fiscal constraints; and

(3) HFCA's objectives in achieving better performance.

(c) *Publication of criteria.* The development and revision of criteria for evaluating intermediary performance is a continuing process. Therefore, before the beginning of each evaluation period, CMS will publish the performance criteria as a notice in the FEDERAL REGISTER.

[48 FR 7178, Feb. 18, 1983]

§ 421.122 Performance standards.

(a) *Development of standards.* In addition to the performance criteria (§ 421.120), CMS develops detailed performance standards for use in evaluating intermediary performance which may be based on historical performance, application of acceptable statistical measures of variation to nationwide intermediary experience during a base period, or changing program emphases or requirements. These standards are also developed considering intermediary experience and evaluate

the specific requirements of each functional responsibility or criterion.

(b) *Factors beyond intermediary's control.* To identify measurable factors that significantly affect an intermediary's performance, but that are not within the intermediary's control, CMS will—

(1) Study the performance of intermediaries during the base period, and

(2) Consider the noncontrollable factors in developing performance standards.

(c) *Publication of standards.* The development and revision of standards for evaluating intermediary performance is a continuing process. Therefore, before the beginning of each evaluation period, which usually coincides with the Federal fiscal year period of October 1–September 30, CMS publishes the performance standards as part of the FEDERAL REGISTER notice describing the performance criteria issued under §421.120(c). CMS may not necessarily publish the criteria and standards every year. CMS interprets the statutory phrase ''before the beginning of each evaluation period'' as allowing publication of the criteria and standards after the Federal fiscal year begins, as long as the evaluation period of the intermediaries for the new criteria and standards begins after the publication of the notice.

[59 FR 682, Jan. 6, 1994]

§421.124 Intermediary's failure to perform efficiently and effectively.

(a) Failure by an intermediary to meet, or to demonstrate the capacity to meet, the criteria or standards specified in §§421.120 and 421.122 may be grounds for adverse action by the Secretary or by CMS, such as reassignment of providers, offer of a short-term agreement, termination of a contract, or non-renewal of a contract. If an intermediary meets all criteria and standards in its overall performance, but does not meet them with respect to a specific provider or class of providers, CMS may reassign that provider or class of providers to another intermediary in accordance with §421.114.

(b) In addition, notwithstanding whether an intermediary meets the criteria and standards, if the cost incurred by the intermediary to meet its contractual requirements exceeds the amount which CMS finds to be reasonable and adequate to meet the cost which must be incurred by an efficiently and economically operated intermediary, those high costs may also be grounds for adverse action.

[59 FR 682, Jan. 6, 1994]

§421.126 Termination of agreements.

(a) *Termination by intermediary.* An intermediary may terminate its agreement at any time by—

(1) Giving written notice of its intention to CMS and to the providers it services at least 180 days before its intended termination date; and

(2) Giving public notice of its intention by publishing a statement of the effective date of termination at least 60 days before that date. Publication must be in a newspaper of general circulation in each community served by the intermediary.

(b) *Termination by the Secretary, and right of appeal.* (1) The Secretary may terminate an agreement if—

(i) The intermediary fails to comply with the requirements of this subpart;

(ii) The intermediary fails to meet the criteria or standards specified in §§421.120 and 421.122; or

(iii) CMS has reassigned, under §421.114 or §421.116, all of the providers assigned to the intermediary.

(2) If the Secretary decides to terminate an agreement, he or she will offer the intermediary an opportunity for a hearing, in accordance with §421.128.

(3) If the intermediary does not request a hearing, or if the hearing decision affirms the Secretary's decision, the Secretary will provide reasonable notice of the effective date of termination to—

(i) The intermediary;

(ii) The providers served by the intermediary; and

(iii) The general public.

(4) The providers served by the intermediary will be given the opportunity to nominate another intermediary, in accordance with §421.104.

§ 421.128 Intermediary's opportunity for hearing and right to judicial review.

(a) *Basis for appeal.* An intermediary adversely affected by any of the following actions shall be granted an opportunity for a hearing:

(1) Assignment or reassignment of providers to another intermediary.

(2) Designation of a national or regional intermediary to serve a class of providers.

(3) Termination of the agreement.

(b) *Request for hearing.* The intermediary shall file the request with CMS within 20 days from the date on the notice of intended action.

(c) *Hearing procedures.* The hearing officer shall be a representative of the Secretary and not otherwise a party to the initial administrative decision. The intermediary may be represented by counsel and may present evidence and examine witnesses. A complete recording of the proceedings at the hearing will be made and transcribed.

(d) *Judicial review.* An adverse hearing decision concerning action under paragraph (a)(1) or (a)(2) of this section is subject to judicial review in accordance with 5 U.S.C. chapter 7.

(e) As specified in § 421.118, contracts awarded under the experimental authority of CMS are not subject to the provisions of this section.

(f) *Exception.* An intermediary adversely affected by the designation of a regional intermediary or an alternative regional intermediary for HHAs, or an intermediary for hospices, under § 421.117 of this subpart is not entitled to a hearing or judicial review concerning adverse effects caused by the designation of an intermediary.

[45 FR 42179, June 23, 1980, as amended at 47 FR 38540, Sept. 1, 1982; 49 FR 3660, Jan. 30, 1984; 53 FR 17945, May 19, 1988]

Subpart C—Carriers

§ 421.200 Carrier functions.

A contract between CMS and a carrier specifies the functions to be performed by the carrier. The contract may include any or all of the following functions:

(a) Any or all of the program integrity functions described in § 421.304 provided the following conditions are met:

(1) The carrier is continuing those functions under a contract entered into under section 1842 of the Act that was in effect on August 21, 1996.

(2) The functions do not duplicate work being performed under a Medicare integrity program contract, except that the function related to developing and maintaining a list of DME may be performed under both a carrier contract and a Medicare integrity program contract.

(b) Receiving, disbursing, and accounting for funds in making payments for services furnished to eligible individuals within the jurisdiction of the carrier.

(c) Determining the amount of payment for services furnished to an eligible individual.

(d) Undertaking to adjust incorrect payments and recover overpayments when it is determined that an overpayment was made.

(e) Furnishing to CMS timely information and reports that CMS requests in order to carry out its responsibilities in the administration of the Medicare program.

(f) Maintaining records and making available to CMS the records necessary for verification of payments and for other related purposes.

(g) Establishing and maintaining procedures under which an individual enrolled under Part B is granted an opportunity for a redetermination.

(h) Upon inquiry, assisting individuals with matters pertaining to a carrier contract.

(i) Serving as a channel of communication to and from CMS of information, instructions, and other material as necessary for the effective and efficient performance of a carrier contract.

(j) Undertaking other functions as mutually agreed to by CMS and the carrier.

[72 FR 48886, Aug. 24, 2007]

§ 421.201 Performance criteria and standards.

(a) *Application of performance criteria and standards.* As part of the carrier evaluations mandated by section 1842(b)(2) of the Act, CMS periodically assesses the performance of carriers in

their Medicare operations using performance criteria and standards.

(1) The criteria measure and evaluate carrier performance of functional responsibilities such as—

(i) Accurate and timely payment determinations;

(ii) Responsiveness to beneficiary, physician, and supplier concerns; and

(iii) Proper management of administrative funds.

(2) The standards evaluate the specific requirements of each functional responsibility or criterion.

(b) *Basis for criteria and standards.* CMS bases the performance criteria and standards on—

(1) Nationwide carrier experience;

(2) Changes in carrier operations due to fiscal constraints; and

(3) CMS's objectives in achieving better performance.

(c) *Publication of criteria and standards.* Before the beginning of each evaluation period, which usually coincides with the Federal fiscal year period of October 1–September 30, CMS publishes the performance criteria and standards as a notice in the FEDERAL REGISTER. CMS may not necessarily publish the criteria and standards every year. CMS interprets the statutory phrase ''before the beginning of each evaluation period'' as allowing publication of the criteria and standards after the Federal fiscal year begins, as long as the evaluation period of the carriers for the new criteria and standards begins after the publication of the notice.

[59 FR 682, Jan. 6, 1994]

§ 421.202 Requirements and conditions.

Before entering into or renewing a carrier contract, CMS determines that the carrier—

(a) Has the capacity to perform its contractual responsibilities effectively and efficiently;

(b) Has the financial responsibility and legal authority necessary to carry out its responsibilities; and

(c) Will be able to meet any other requirements CMS considers pertinent, and, if designated a regional DMEPOS carrier, any special requirements for regional carriers under § 421.210 of this subpart.

[45 FR 42179, June 23, 1980, as amended at 57 FR 27307, June 18, 1992]

§ 421.203 Carrier's failure to perform efficiently and effectively.

(a) Failure by a carrier to meet, or demonstrate the capacity to meet, the criteria and standards specified in § 421.201 may be grounds for adverse action by the Secretary, such as contract termination or non-renewal.

(b) Notwithstanding whether or not a carrier meets the criteria and standards specified in § 421.201, if the cost incurred by the carrier to meet its contractual requirements exceeds the amount that CMS finds to be reasonable and adequate to meet the cost which must be incurred by an efficiently and economically operated carrier, those high costs may also be grounds for adverse action.

[59 FR 682, Jan. 6, 1994]

§ 421.205 Termination by the Secretary.

(a) *Cause for termination.* The Secretary may terminate a contract with a carrier at any time if he or she determines that the carrier has failed substantially to carry out any material terms of the contract or has performed its function in a manner inconsistent with the effective and efficient administration of the Medicare Part B program.

(b) *Notice and opportunity for hearing.* Upon notification of the Secretary's intent to terminate the contract, the carrier may request a hearing within 20 days after the date on the notice of intent to terminate.

(c) *Hearing procedures.* The hearing procedures will be those specified in § 421.128(c).

§ 421.210 Designations of regional carriers to process claims for durable medical equipment, prosthetics, orthotics and supplies.

(a) *Basis.* This section is based on sections 1834(a)(12) and 1834(h) of the Act, which authorize the Secretary to designate one carrier for one or more entire regions to process claims for durable medical equipment, prosthetic devices, prosthetics, orthotics, and other

supplies (DMEPOS). This authority has been delegated to CMS.

(b) *Types of claims.* Claims for the following, except for items incident to a physician's professional service as defined in § 410.26, incident to a physician's service in a rural health clinic as defined in § 405.2413, or bundled into payment to a provider, ambulatory surgical center, or other facility, are processed by the designated carrier for its designated region and not by other carriers—

(1) Durable medical equipment (and related supplies) as defined in section 1861(n) of the Act;

(2) Prosthetic devices (and related supplies) as described in section 1861(s)(8) of the Act, (including intraocular lenses and parenteral and enteral nutrients, supplies, and equipment, when furnished under the prosthetic device benefit);

(3) Orthotics and prosthetics (and related supplies) as described in section 1861(s)(9);

(4) Home dialysis supplies and equipment as described in section 1861(s)(2)(F);

(5) Surgical dressings and other devices as described in section 1861(s)(5);

(6) Immunosuppressive drugs as described in section 1861(s)(2)(J); and

(7) Other items or services which are designated by CMS.

(c) *Region designation.* (1) The boundaries of the initial four regions for processing claims described in paragraph (b) of this section contain the following States and territories:

(i) Region A: Maine, New Hampshire, Vermont, Massachusetts, Connecticut, Rhode Island, New York, New Jersey, Pennsylvania, and Delaware.

(ii) Region B: Maryland, the District of Columbia, Virginia, West Virginia, Ohio, Michigan, Indiana, Illinois, Wisconsin, and Minnesota.

(iii) Region C: North Carolina, South Carolina, Kentucky, Tennessee, Georgia, Florida, Alabama, Mississippi, Louisiana, Texas, Arkansas, Oklahoma, New Mexico, Colorado, Puerto Rico, and the Virgin Islands.

(iv) Region D: Alaska, Hawaii, American Samoa, Guam, the Northern Mariana Islands, California, Nevada, Arizona, Washington, Oregon, Montana, Idaho, Utah, Wyoming, North Dakota, South Dakota, Nebraska, Kansas, Iowa, and Missouri.

(2) CMS has the option to modify the number and boundaries of the regions established in paragraph (c)(1) of this section based on appropriate criteria and considerations, including the effect of the change on beneficiaries and DMEPOS suppliers. To announce changes, CMS publishes a notice in the FEDERAL REGISTER that delineates the regional boundary or boundaries changed, the States and territories affected, and supporting criteria or considerations.

(d) *Criteria for designating regional carriers.* CMS designates regional carriers to achieve a greater degree of effectiveness and efficiency in the administration of the Medicare program. In making this designation, CMS will award regional carrier contracts in accordance with applicable law and will consider some or all of the following criteria—

(1) Timeliness of claim processing;

(2) Cost per claim;

(3) Claim processing quality;

(4) Experience in claim processing, and in establishing local medical review policy; and

(5) Other criteria that CMS believes to be pertinent.

(e) *Carrier designation.* (1) Each carrier designated a regional carrier must process claims for items listed in paragraph (b) of this section for beneficiaries whose permanent residence is within that carrier's region as designated under paragraph (c) of this section. When processing the claims, the carrier must use the payment rates applicable for the State of residence of the beneficiary, including a qualified Railroad Retirement beneficiary. A beneficiary's permanent residence is the address at which he or she intends to spend 6 months or more of the calendar year.

(2) CMS notifies affected Medicare beneficiaries and suppliers when it designates a regional carrier (in accordance with paragraph (d) of this section) to process DMEPOS claims (as defined in paragraph (b) of this section) for all Medicare beneficiaries residing in their respective regions (as designated under paragraph (c) of this section).

(3) CMS may contract for the performance of National Supplier Clearinghouse functions through a contract amendment to one of the DME regional carrier contracts or through a contract amendment to any Medicare carrier contract under § 421.200.

(4) CMS periodically recompetes the contracts for the DME regional carriers. CMS also periodically recompetes the National Supplier Clearinghouse function.

(f) *Collecting information of ownership.* Carriers designated as regional claims processors must obtain from each supplier of items listed in paragraph (b) of this section information concerning ownership and control as required by section 1124A of the Act and part 420 of this chapter, and certifications that supplier standards are met as required by part 424 of this chapter.

[57 FR 27307, June 18, 1992, as amended at 58 FR 60796, Nov. 18, 1993; 70 FR 9239, Feb. 25, 2005]

§ 421.212 Railroad Retirement Board contracts.

In accordance with this subpart C, the Railroad Retirement Board contracts with DMEPOS regional carriers designated by CMS, as set forth in § 421.210(e)(2), for processing claims for Medicare-eligible Railroad Retirement beneficiaries, for the same contract period as the contracts entered into between CMS and the DMEPOS regional carriers.

[58 FR 60797, Nov. 18, 1993]

§ 421.214 Advance payments to suppliers furnishing items or services under Part B.

(a) *Scope and applicability.* This section provides for the following:

(1) Sets forth requirements and procedures for the issuance and recovery of advance payments to suppliers of Part B services and the rights and responsibilities of suppliers under the payment and recovery process.

(2) Does not limit CMS's right to recover unadjusted advance payment balances.

(3) Does not affect suppliers' appeal rights under part 405, subpart H of this chapter relating to substantive determinations on suppliers' claims.

(4) Does not apply to claims for Part B services furnished by suppliers that have in effect provider agreements under section 1866 of the Act and part 489 of this chapter, and are paid by intermediaries.

(b) *Definition.* As used in this section, *advance payment* means a conditional partial payment made by the contractor in response to a claim that it is unable to process within established time limits except as provided in paragraph (j) of this section.

(c) *When advance payments may be made.* Unless otherwise qualified under paragraph (j) of this section, an advance payment may be made if all of the following conditions are met:

(1) The carrier is unable to process the claim timely.

(2) CMS determines that the prompt payment interest provision specified in section 1842(c) of the Act is insufficient to make a claimant whole.

(3) CMS approves, in writing to the carrier, the making of an advance payment by the carrier.

(d) *When advance payments are not made.* Advance payments are not made to any supplier that meets any of the following conditions:

(1) Is delinquent in repaying a Medicare overpayment.

(2) Has been advised of being under active medical review or program integrity investigation.

(3) Has not submitted any claims.

(4) Has not accepted claims' assignments within the most recent 180-day period preceding the system malfunction.

(5) Is in bankruptcy.

(e) *Requirements for suppliers.* (1) Except as provided for in paragraph (g)(1) of this section, a supplier must request, in writing to the carrier, an advance payment for Part B services it furnished.

(2) A supplier must accept an advance payment as a conditional payment subject to adjustment, recoupment, or both, based on an eventual determination of the actual amount due on the claim and subject to the provisions of this section.

(f) *Requirements for carriers.* (1) A carrier must notify a supplier as soon as it is determined that payment will not be

made in a timely manner, and an advance payment option is to be offered to the supplier.

(i) Unless otherwise qualified under paragraph (j) of this section, a contractor must calculate an advance payment for a particular claim at no more than 80 percent of the anticipated payment for that claim based upon the historical assigned claims payment data as defined in paragraph (f)(1)(ii) of this section for claims paid to the supplier. For suppliers qualifying and approved for advance payments under paragraph (j) of this section, a contractor may calculate an advance payment for a particular claim at up to 100 percent of the anticipated payment for that claim based upon the historical assigned claims payment data as defined in paragraph (f)(1)(ii) of this section for claims paid to the supplier.

(ii) ''Historical data'' are defined as a representative 90-day assigned claims payment trend within the most recent 180-day experience before the system malfunction.

(iii) Based on this amount and the number of claims pending for the supplier, the carrier must determine and issue advance payments.

(iv) If historical data are not available or if backlogged claims cannot be identified, the carrier must determine and issue advance payments based on some other methodology approved by CMS.

(v) Advance payments can be made no more frequently than once every 2 weeks to a supplier.

(2) Generally, a supplier will not receive advance payments for more assigned claims than were paid, on a daily average, for the 90-day period before the system malfunction.

(3) A carrier must recover an advance payment by applying it against the amount due on the claim on which the advance was made. If the advance payment exceeds the Medicare payment amount, the carrier must apply the unadjusted balance of the advance payment against future Medicare payments due the supplier.

(4) In accordance with CMS instructions, a carrier must maintain a financial system of data in accordance with the Statement of Federal Financial Accounting Standards for tracking each advance payment and its recoupment.

(g) *Requirements for CMS.* (1) In accordance with the provisions of this section, CMS may determine that circumstances warrant the issuance of advance payments to all affected suppliers furnishing Part B services. CMS may waive the requirement in paragraph (e)(1) of this section as part of that determination.

(2) If adjusting Medicare payments fails to recover an advance payment, CMS may authorize the use of any other recoupment method available (for example, lump sum repayment or an extended repayment schedule) including, upon written notice from the carrier to the supplier, converting any unpaid balances of advance payments to overpayments. Overpayments are recovered in accordance with part 401, subpart F of this chapter concerning claims collection and compromise and part 405, subpart C of this chapter concerning recovery of overpayments.

(h) *Prompt payment interest.* An advance payment is a ''payment'' under section 1842(c)(2)(C) of the Act for purposes of meeting the time limit for the payment of clean claims, to the extent of the advance payment.

(i) *Notice, review, and appeal rights.* (1) The decision to advance payments and the determination of the amount of any advance payment are committed to CMS's discretion and are not subject to review or appeal.

(2) The carrier must notify the supplier receiving an advance payment about the amounts advanced and recouped and how any Medicare payment amounts have been adjusted.

(3) The supplier may request an administrative review from the carrier if it believes the carrier's reconciliation of the amounts advanced and recouped is incorrectly computed. If a review is requested, the carrier must provide a written explanation of the adjustments.

(4) The review and explanation described in paragraph (i)(3) of this section is separate from a supplier's right to appeal the amount and computation of benefits paid on the claim, as provided at part 405, subpart H of this chapter. The carrier's reconciliation of amounts advanced and recouped is not

an initial determination as defined at § 405.803 of this chapter, and any written explanation of a reconciliation is not subject to further administrative review.

(j) *Advanced payments in exceptional circumstances.* CMS may approve, in writing to the contractor, the making of advance payments during the period of a Public Health Emergency, as defined in § 400.200 of this chapter, or during the period under a Presidential Disaster Declaration, under the following exceptional conditions:

(1) The contractor is unable to process the claim timely, or is at risk of being untimely in processing the claim; or

(2) When the supplier has experienced a temporary delay in preparing and submitting bills to the contractor beyond its normal billing cycle.

[61 FR 49275, Sept. 19, 1996, as amended at 85 FR 19289, Apr. 6, 2020]

Subpart D—Medicare Integrity Program Contractors

SOURCE: 72 FR 48886, Aug. 24, 2007, unless otherwise noted.

§ 421.300 Basis, applicability, and scope.

(a) *Basis.* This subpart implements section 1893 of the Act, which requires CMS to protect the integrity of the Medicare program by entering into contracts with eligible entities to carry out Medicare integrity program functions. The provisions of this subpart are based on section 1893 of the Act (and, where applicable, section 1874A of the Act) and the acquisition regulations set forth at 48 CFR chapters 1 and 3.

(b) *Applicability.* This subpart applies to entities that seek to compete or receive award of a contract under section 1893 of the Act, including entities that perform functions under this subpart emanating from the processing of claims for individuals entitled to benefits as qualified railroad retirement beneficiaries.

(c) *Scope.* The scope of this subpart follows:

(1) Defines the types of entities eligible to become Medicare integrity program contractors.

(2) Identifies the program integrity functions a Medicare integrity program contractor performs.

(3) Describes procedures for awarding and renewing contracts.

(4) Establishes procedures for identifying, evaluating, and resolving organizational conflicts of interest.

(5) Prescribes responsibilities.

(6) Sets forth limitations on contractor liability.

§ 421.302 Eligibility requirements for Medicare integrity program contractors.

(a) CMS may enter into a contract with an entity to perform the functions described in § 421.304 if the entity meets the following conditions:

(1) Demonstrates the ability to perform the Medicare integrity program contractor functions described in § 421.304. For purposes of developing and periodically updating a list of DME under § 421.304(e), an entity is deemed to be eligible to enter into a contract under the Medicare integrity program to perform the function if the entity is a carrier with a contract in effect under section 1842 of the Act.

(2) Agrees to cooperate with the OIG, the DOJ, and other law enforcement agencies, as appropriate, including making referrals, in the investigation and deterrence of potential fraud and abuse of the Medicare program.

(3) Complies with conflict of interest provisions in 48 CFR chapters 1 and 3, and is not excluded under the conflict of interest provision at § 421.310.

(4) Maintains an appropriate written code of conduct and compliance policies that include, but are not limited to, an enforced policy on employee conflicts of interest.

(5) Meets other requirements that CMS establishes.

(b) A MAC as described in section 1874A of the Act may perform any or all of the functions described in § 421.304, except that the functions may not duplicate work being performed under a Medicare integrity program contract.

(c) If a MAC performs any or all functions described in § 421.304, CMS may

require the MAC to comply with any or all of the requirements of paragraph (a) of this section as a condition of its contract.

§ 421.304 Medicare integrity program contractor functions.

The contract between CMS and a Medicare integrity program contractor specifies the functions the contractor performs. The contract may include any or all of the following functions:

(a) Conducting medical reviews, utilization reviews, and reviews of potential fraud related to the activities of providers of services and other individuals and entities (including entities contracting with CMS under parts 417 and 422 of this chapter) furnishing services for which Medicare payment may be made either directly or indirectly.

(b) Auditing, settling and determining cost report payments for providers of services, or other individuals or entities (including entities contracting with CMS under parts 417 and 422 of this chapter), as necessary to help ensure proper Medicare payment.

(c) Determining whether a payment is authorized under title XVIII, as specified in section 1862(b) of the Act, and recovering mistaken and conditional payments under section 1862(b) of the Act.

(d) Educating providers, suppliers, beneficiaries, and other persons regarding payment integrity and benefit quality assurance issues.

(e) Developing, and periodically updating, a list of items of DME that are frequently subject to unnecessary utilization throughout the contractor's entire service area or a portion of the area, in accordance with section 1834(a)(15)(A) of the Act.

§ 421.306 Awarding of a contract.

(a) CMS awards and administers Medicare integrity program contracts in accordance with acquisition regulations set forth at 48 CFR chapters 1 and 3, this subpart, all other applicable laws, and all applicable regulations. These requirements for awarding Medicare integrity program contracts are used as follows:

(1) When entering into new contracts.

(2) When entering into contracts that may result in the elimination of responsibilities of an individual fiscal intermediary or carrier under section 1816(l) or section 1842(c) of the Act, respectively.

(3) At any other time CMS considers appropriate.

(b) CMS may award an entity a Medicare integrity program contract by transfer if all of the following conditions apply:

(1) Through approval of a novation agreement in accordance with the requirements of the Federal Acquisition Regulation (FAR), CMS recognizes the entity as the successor in interest to a fiscal intermediary agreement or carrier contract under which the fiscal intermediary or carrier was performing activities described in section 1893(b) of the Act on August 21, 1996.

(2) The fiscal intermediary or carrier continued to perform Medicare integrity program activities until transferring the resources to the entity.

(c) An entity is eligible to be awarded a Medicare integrity program contract only if it meets the eligibility requirements specified in § 421.302; 48 CFR chapters 1 and 3; and other applicable laws and regulations.

§ 421.308 Renewal of a contract.

(a) *General.* (1) CMS specifies an initial contract term in the Medicare integrity program contract.

(2) Contracts under this subpart may contain renewal clauses.

(3) CMS may, but is not required to, renew the Medicare integrity program contract, without regard to any provision of law requiring competition, as it determines to be appropriate, by giving the contractor notice, within timeframes specified in the contract, of its intent to do so.

(b) *Conditions for renewal of contract.* CMS may renew a Medicare integrity program contract if all of the following conditions are met:

(1) The Medicare integrity program contractor continues to meet the requirements established in this subpart.

(2) The Medicare integrity program contractor meets or exceeds the performance requirements established in its current contract.

(3) It is in the best interest of the government.

(c) *Nonrenewal of a contract.* If CMS does not renew a contract, the contract ends in accordance with its terms.

§ 421.310 Conflict of interest requirements.

Offerors for MIP contracts and MIP contractors are subject to the following:

(a) The conflict of interest standards and requirements of the Federal Acquisition Regulation (FAR) organizational conflict of interest guidance specified under 48 CFR subpart 9.5.

(b) The standards and requirements as are contained in each individual contract awarded to perform section 1893 of the Act functions.

§ 421.312 Conflict of interest resolution.

(a) *Review Board.* CMS may establish and convene a Conflicts of Interest Review Board to assist the contracting officer in resolving organizational conflicts of interest.

(b) *Resolution*—(1) *Pre-award conflicts.* Resolution of an organizational conflict of interest is a determination by the contracting officer that one of the following has occurred:

(i) The conflict is mitigated.

(ii) The conflict precludes award of a contract to the offeror.

(iii) It is in the best interest of the government to award a contract to the offeror (in accordance with 48 CFR subpart 9.503) even though a conflict of interest exists.

(2) *Post-award conflicts.* Resolution of an organizational conflict of interest is a determination by the contracting officer that one of the following has occurred:

(i) The conflict is mitigated.

(ii) The conflict requires that CMS modify an existing contract.

(iii) The conflict requires that CMS terminate or not renew an existing contract.

(iv) It is in the best interest of the government to continue the contract even though a conflict of interest exists.

§ 421.316 Limitation on Medicare integrity program contractor liability.

(a) A MIP contractor, a person or an entity employed by, or having a fiduciary relationship with, or who furnishes professional services to a MIP contractor is not in violation of any criminal law or civilly liable under any law of the United States or of any State (or political subdivision thereof) by reason of the performance of any duty, function, or activity required or authorized under this subpart or under a valid contract entered into under this subpart, provided due care was exercised in that performance and the contractor has a contract with CMS under this subpart.

(b) CMS pays a contractor, a person or an entity described in paragraph (a) of this section, or anyone who furnishes legal counsel or services to a contractor or person, a sum equal to the reasonable amount of the expenses, as determined by CMS, incurred in connection with the defense of a suit, action, or proceeding, if the following conditions are met:

(1) The suit, action, or proceeding was brought against the contractor, such person or entity by a third party and relates to the contractor's, person's or entity's performance of any duty, function, or activity under a contract entered into with CMS under this subpart.

(2) The funds are available.

(3) The expenses are otherwise allowable under the terms of the contract.

Subpart E—Medicare Administrative Contractors (MACs)

SOURCE: 71 FR 68229, Nov. 24, 2006, unless otherwise noted.

§ 421.400 Statutory basis and scope.

(a) *Statutory basis.* This subpart implements section 1874A of the Act, which provides for the transition of the claims processing functions and operations for both Medicare Part A and Part B intermediaries and carriers to Medicare Administrative Contractors (MACs). The transition will occur between October 1, 2005, and October 1, 2011. MACs will be fully operational in distinct, nonoverlapping geographic jurisdictions by October 1, 2011.

(b) *Scope.* This subpart specifies the requirements under which providers and suppliers will be assigned to MACs.

§ 421.401 Definitions.

For purposes of this subpart—

Appropriate MAC means a MAC that has a contract under section 1874A of the Act to perform a particular Medicare administrative function in relation to:

(1) A particular individual entitled to benefits under Part A or enrolled under Part B, or both;

(2) A specific provider of services or supplier; or

(3) A class of providers of services or suppliers.

Medicare Administrative Contractor (MAC) means an agency, organization, or other person with a contract under section 1874A of the Act.

§ 421.404 Assignment of providers and suppliers to MACs.

(a) *Definitions.* As used in this section—

Chain provider means a group of two or more providers under common ownership or control.

Common control exists when an individual, a group of individuals, or an organization has the power, directly or indirectly, to significantly influence or direct the actions or policies of the group of suppliers or eligible providers.

Common ownership exists when an individual, a group of individuals, or an organization possesses significant equity in the group of suppliers or eligible providers.

Durable medical equipment, prosthetics, orthotics, and supplies (DMEPOS) means the types of services specified in § 421.210(b).

Eligible provider means a hospital, skilled nursing facility, or critical access hospital that meets the definition of a provider under § 400.202 of this chapter.

Home office means the entity that provides centralized management and administrative services to the individual providers or suppliers under common ownership and common control, such as centralized accounting, purchasing, personnel services, management direction and control, and other similar services.

Ineligible provider means a provider under § 400.202 of this chapter that is not an eligible provider.

Medicare benefit category means a category of covered benefits under Part A or Part B of the Medicare program (for example, inpatient hospital services, post-hospital extended care services, and physicians'services).

Provider has the same meaning as specified under § 400.202 of this chapter.

Qualified chain provider means a chain provider comprised of—

(1) 10 or more eligible providers collectively totaling 500 or more certified beds; or

(2) 5 or more eligible providers collectively totaling 300 or more certified beds, with eligible providers in 3 or more contiguous States.

Supplier has the same meaning as specified in § 400.202 of this chapter.

(b) *Assignment of providers to MACs.* (1) Providers enroll with and receive Medicare payment and other Medicare services from the MAC contracted by CMS to administer claims for the Medicare benefit category applicable to the provider's covered services for the geographic locale in which the provider is physically located.

(2) Qualified chain providers may request and receive an exception from the requirement of paragraph (b)(1) of this section from CMS. Upon CMS'approval, a qualified chain provider may enroll with and bill on behalf of the eligible providers under its common ownership or common control to the MAC contracted by CMS to administer claims for the Medicare benefit category applicable to the eligible providers'covered services for the geographic locale in which the qualified chain provider's home office is physically located.

(3) As MAC contractors become available, qualified chain providers, granted approval by CMS to enroll with and bill a single intermediary on behalf of their eligible member providers prior to October 1, 2005, will be assigned at an appropriate time to the MAC contracted by CMS to administer claims for the applicable Medicare benefit category for the geographic locale in which the chain provider's home office is physically located. The qualified chain provider will not need to request an exception to the requirement of paragraph (b)(1) of this section in order for this assignment to take effect.

(4) CMS may grant an exception to the requirement of paragraph (b)(1) of this section to eligible providers that are not under the common ownership or common control of a qualified chain provider, as well as ineligible providers, only if CMS finds the exception will support the implementation of MACs or will serve some other compelling interest of the Medicare program.

(c) *Assignment of suppliers to MACs.* (1) Suppliers, including physicians and other practitioners, but excluding suppliers of DMEPOS, enroll with and receive Medicare payment and other Medicare services from the MAC contracted by CMS to administer claims for the Medicare benefit category applicable to the supplier's covered services for the geographic locale in which the supplier furnished such services.

(2) Suppliers of DMEPOS receive Medicare payment and other Medicare services from the MAC assigned to administer claims for DMEPOS for the regional area in which the beneficiary receiving the DMEPOS resides. The terms of §§ 421.210 and 421.212 continue to apply to suppliers of DMEPOS.

(3) CMS may allow a group of ESRD suppliers under common ownership and common control to enroll with the MAC contracted by CMS to administer ESRD claims for the geographic locale in which the group's home office is located only if—

(i) The group of ESRD suppliers requests such privileges; and

(ii) CMS finds the exception will support the implementation of MACs or will serve some other compelling interest of the Medicare program.

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Subpart A—General Provisions

SOURCE: 63 FR 35068, June 26, 1998, unless otherwise noted.

§ 422.1 Basis and scope.

(a) *Basis.* This part is based on the indicated provisions of the following:

(1) The following provisions of the Act:

(i) 1106—Disclosure of information in possession of agency.

(ii) 1128J(d)—Reporting and Returning of Overpayments.

(iii) 1851—Eligibility, election, and enrollment.

(iv) 1852—Benefits and beneficiary protections.

(v) 1853—Payments to Medicare Advantage (MA) organizations.

(vi) 1854—Premiums.

(vii) 1855—Organization, licensure, and solvency of MA organizations.

(viii) 1856—Standards.

(ix) 1857—Contract requirements.

(x) 1858—Special rules for MA Regional Plans.

(xi) 1859—Definitions; enrollment restriction for certain MA plans.

(2) 8 U.S.C. 1611—Aliens who are not qualified aliens ineligible for Federal public benefits.

(b) *Scope.* This part establishes standards and sets forth the requirements, limitations, and procedures for Medicare services furnished, or paid for, by Medicare Advantage organizations through Medicare Advantage plans.

[63 FR 35068, June 26, 1998, as amended at 70 FR 4714, Jan. 28, 2005; 80 FR 7958, Feb. 12, 2015; 81 FR 80556, Nov. 15, 2016]

§ 422.2 Definitions.

As used in this part—

Aligned enrollment refers to the enrollment in a dual eligible special needs plan of full-benefit dual eligible individuals whose Medicaid benefits are covered under a Medicaid managed care organization contract under section 1903(m) of the Act between the applicable State and: the dual eligible special needs plan's (D–SNP's) MA organization, the D–SNP's parent organization, or another entity that is owned and controlled by the D–SNP's parent organization. When State policy limits a D–SNP's membership to individuals with aligned enrollment, this condition is referred to as exclusively aligned enrollment.

Arrangement means a written agreement between an MA organization and a provider or provider network, under which—

(1) The provider or provider network agrees to furnish for a specific MA plan(s) specified services to the organization's MA enrollees;

(2) The organization retains responsibilities for the services; and

(3) Medicare payment to the organization discharges the enrollee's obligation to pay for the services.

Attestation process means a CMS-developed RADV audit-related process

that is part of the medical record review process that enables MA organizations undergoing RADV audit to submit CMS-generated attestations for eligible medical records with missing or illegible signatures or credentials. The purpose of the CMS-generated attestations is to cure signature and credential issues. CMS-generated attestations do not provide an opportunity for a provider or supplier to replace a medical record or for a provider or supplier to attest that a beneficiary has the medical condition

Balance billing generally refers to an amount billed by a provider that represents the difference between the amount the provider charges an individual for a service and the sum of the amount the individual's health insurer (for example, the original Medicare program) will pay for the service plus any cost-sharing by the individual.

Basic benefits means Part A and Part B benefits except—

(1) Hospice services; and

(2) Beginning in 2021, organ acquisitions for kidney transplants, including costs covered under section 1881(d) of the Act.

Benefits means health care services that are intended to maintain or improve the health status of enrollees, for which the MA organization incurs a cost or liability under an MA plan (not solely an administrative processing cost). Benefits are submitted and approved through the annual bidding process.

Chronic condition special needs plan (C–SNPs) means an SNP that restricts enrollment to MA eligible individuals who have one or more severe or disabling chronic conditions, as defined under this section, including restricting enrollment based on the multiple commonly co-morbid and clinically linked condition groupings specified in § 422.4(a)(1)(iv).

Coinsurance is a fixed percentage of the total amount paid for a health care service that can be charged to an MA enrollee on a per-service basis.

Copayment is a fixed amount that can be charged to an MA plan enrollee on a per-service basis.

Cost-sharing includes deductibles, coinsurance, and copayments.

Downstream entity means any party that enters into a written arrangement, acceptable to CMS, with persons or entities involved with the MA benefit, below the level of the arrangement between an MA organization (or applicant) and a first tier entity. These written arrangements continue down to the level of the ultimate provider of both health and administrative services.

Dual eligible special needs plan or D–SNP means a specialized MA plan for special needs individuals who are entitled to medical assistance under a State plan under title XIX of the Act that—

(1) Coordinates the delivery of Medicare and Medicaid services for individuals who are eligible for such services;

(2) May provide coverage of Medicaid services, including long-term services and supports and behavioral health services for individuals eligible for such services;

(3) Has a contract with the State Medicaid agency consistent with § 422.107 that meets the minimum requirements in paragraph (c) of such section; and

(4) Beginning January 1, 2021, satisfies one or more of the following criteria for the integration of Medicare and Medicaid benefits:

(i) Meets the additional requirement specified in § 422.107(d) in its contract with the State Medicaid agency.

(ii) Is a highly integrated dual eligible special needs plan.

(iii) Is a fully integrated dual eligible special needs plan.

Facility-based Institutional special needs plan (FI–SNP) means a type of I–SNP that—

(1) Restricts enrollment to MA eligible individuals who meet the definition of institutionalized;

(2) Must own or contract with at least one institution, specified in the definition of institutionalized in this section, for each county in the plan's service area; and

(3) Must own or have a contractual arrangement with each institutionalized facility serving enrollees in the plan.

First tier entity means any party that enters into a written arrangement, acceptable to CMS, with an MA organization or applicant to provide administrative services or health care services for a Medicare eligible individual under the MA program.

Fiscally sound operation means an operation which at least maintains a positive net worth (total assets exceed total liabilities).

Fully integrated dual eligible special needs plan means a dual eligible special needs plan—

(1) That provides dual eligible individuals access to Medicare and Medicaid benefits under a single entity that holds both an MA contract with CMS and a Medicaid managed care organization contract under section 1903(m) of the Act with the applicable State;

(2) Whose capitated contract with the State Medicaid agency requires coverage of the following benefits, to the extent Medicaid coverage of such benefits is available to individuals eligible to enroll in a fully integrated dual eligible special needs plan (FIDE SNP) in the State, except as approved by CMS under § 422.107(g) and (h):

(i) Primary care and acute care, and for plan year 2025 and subsequent years including Medicare cost-sharing as defined in section 1905(p)(3)(B), (C), and (D) of the Act, without regard to the limitation of that definition to qualified Medicare beneficiaries;

(ii) Long-term services and supports, including coverage of nursing facility services for a period of at least 180 days during the plan year;

(iii) For plan year 2025 and subsequent years, behavioral health services;

(iv) For plan year 2025 and subsequent years, home health services as defined in § 440.70 of this chapter; and

(v) For plan year 2025 and subsequent years, medical supplies, equipment, and appliances, as described in § 440.70(b)(3) of this chapter;

(3) That coordinates the delivery of covered Medicare and Medicaid services using aligned care management and specialty care network methods for high-risk beneficiaries;

(4) That employs policies and procedures approved by CMS and the State to coordinate or integrate beneficiary communication materials, enrollment, communications, grievance and appeals, and quality improvement;

(5) For plan year 2025 and subsequent years, that has exclusively aligned enrollment; and

(6) For plan year 2025 and subsequent years, whose capitated contract with the State Medicaid agency covers the entire service area for the dual eligible special needs plan.

Hierarchical condition categories (HCC) mean diagnosis groupings that predict average healthcare spending. HCCs consist of International Classification of Diseases, Clinical Modification (ICD–CM) diagnosis codes and represent the disease component of the enrollee risk score that are applied to MA payments.

Highly integrated dual eligible special needs plan means a dual eligible special needs plan offered by an MA organization that provides coverage of Medicaid benefits under a capitated contract that meets the following requirements—

(1) The capitated contract is between the State Medicaid agency and one of the following:

(i) The MA organization.

(ii) The MA organization's parent organization, or another entity that is owned and controlled by its parent organization.

(iii) A local nonprofit public benefit corporation of which the MA organization, MA organization's parent organization, or another entity that is owned and controlled by its parent organization is a founding member where the local nonprofit public benefit corporation is responsible for the delivery of physical, behavioral, and dental health services.

(2) The capitated contract requires coverage of the following benefits, to the extent Medicaid coverage of such benefits is available to individuals eligible to enroll in a highly integrated dual eligible special needs plan (HIDE SNP) in the State, except as approved by CMS under § 422.107(g) or (h):

(i) Long-term services and supports, including community-based long-term services and supports and some days of coverage of nursing facility services during the plan year; or

(ii) Behavioral health services; and

(3) For plan year 2025 and subsequent years, the capitated contract covers the entire service area for the dual eligible special needs plan.

Hybrid Institutional special needs plan (HI–SNP) means a type of I–SNP that—

(1) Restricts enrollment to both MA eligible individuals who meet the definition of institutionalized and MA eligible individuals who meet the definition of institutionalized-equivalent in this section; and

(2) Meet the standards specified in the definitions of FI–SNP and IE–SNP.

Institutional-equivalent special needs plan (IE–SNP) means a type of I–SNP that restricts enrollment to MA eligible individuals who meet the definition of institutionalized-equivalent in this section.

Institutional special needs plan (I–SNP) means a SNP that restricts enrollment to MA eligible individuals who meet the definition of institutionalized and institutionalized-equivalent in this section. I–SNPs include the following subtypes:

(1) IE–SNP.

(2) HI–SNP.

(3) FI–SNP.

Institutionalized means, for the purposes of defining a special needs individual and for the open enrollment period for institutionalized individuals at § 422.62(a)(4), an MA eligible individual who continuously resides or is expected to continuously reside for 90 days or longer in one of the following long-term care facility settings:

(1) Skilled nursing facility (SNF) as defined in section 1819 of the Act (Medicare).

(2) Nursing facility (NF) as defined in section 1919 of the Act (Medicaid).

(3) Intermediate care facility for individuals with intellectual and developmental disabilities as defined in section 1905(d) of the Act.

(4) Psychiatric hospital or unit as defined in section 1861(f) of the Act.

(5) Rehabilitation hospital or unit as defined in section 1886(d)(1)(B) of the Act.

(6) Long-term care hospital as defined in section 1886(d)(1)(B) of the Act.

(7) Hospital which has an agreement under section 1883 of the Act (a swing-bed hospital).

(8) Subject to CMS approval, a facility that is not listed in paragraphs (1) through (7) of this definition but meets both of the following:

(i) Furnishes similar long-term, healthcare services that are covered under Medicare Part A, Medicare Part B, or Medicaid; and

(ii) Whose residents have similar needs and healthcare status as residents of one or more facilities listed in paragraphs (1) through (7) of this definition.

Institutionalized-equivalent means for the purpose of defining a special needs individual, an MA eligible individual who is living in the community but requires an institutional level of care. The determination that the individual requires an institutional level of care (LOC) must be made by—

(1) The use of a State assessment tool from the State in which the individual resides; and

(2) An assessment conducted by an impartial entity and having the requisite knowledge and experience to accurately identify whether the beneficiary meets the institutional LOC criteria. In States and territories that do not have an existing institutional level of care assessment tool, the individual must be assessed using the same methodology that State uses to determine institutional level of care for Medicaid nursing home eligibility.

Licensed by the State as a risk-bearing entity means the entity is licensed or otherwise authorized by the State to assume risk for offering health insurance or health benefits coverage, such that the entity is authorized to accept prepaid capitation for providing, arranging, or paying for comprehensive health services under an MA contract.

MA stands for Medicare Advantage.

MA local area is defined in § 422.252.

MA local plan means an MA plan that is not an MA regional plan.

MA-Prescription drug (PD) plan means an MA plan that provides qualified prescription drug coverage under Part D of the Social Security Act.

MA regional plan means a coordinated care plan structured as a preferred provider organization (PPO) that serves one or more entire regions. An MA regional plan must have a network of contracting providers that have agreed

to a specific reimbursement for the plan's covered services and must pay for all covered services whether provided in or out of the network.

MA eligible individual means an individual who meets the requirements of § 422.50.

MA organization means a public or private entity organized and licensed by a State as a risk-bearing entity (with the exception of provider-sponsored organizations receiving waivers) that is certified by CMS as meeting the MA contract requirements.

MA plan means health benefits coverage offered under a policy or contract by an MA organization that includes a specific set of health benefits offered at a uniform premium and uniform level of cost-sharing to all Medicare beneficiaries residing in the service area of the MA plan (or in individual segments of a service area, under § 422.304(b)(2)).

MA plan enrollee is an MA eligible individual who has elected an MA plan offered by an MA organization.

Mandatory supplemental benefits means health care services not covered by Medicare that an MA enrollee must accept or purchase as part of an MA plan. The benefits may include reductions in cost sharing for benefits under the original Medicare fee for service program and are paid for in the form of premiums and cost sharing, or by an application of the beneficiary rebate rule in section 1854(b)(1)(C)(ii)(I) of the Act, or both.

MSA stands for medical savings account.

MSA trustee means a person or business with which an enrollee establishes an MA MSA. A trustee may be a bank, an insurance company, or any other entity that—

(1) Is approved by the Internal Revenue Service to be a trustee or custodian of an individual retirement account (IRA); and

(2) Meets the requirements of § 422.262(b).

National coverage determination (NCD) means a national policy determination regarding the coverage status of a particular service that CMS makes under section 1862(a)(1) of the Act, and publishes as a FEDERAL REGISTER notice or CMS ruling. (The term does not include coverage changes mandated by statute.)

Network-based plan—

(1) Means—

(i) A coordinated care plan as specified in § 422.4(a)(1)(iii);

(ii) A network-based MSA plan; or

(iii) A section 1876 reasonable cost plan; and

(2) Excludes an MA regional plan that meets access requirements substantially through the authority of § 422.112(a)(1)(ii) instead of written contracts.

Optional supplemental benefits are health services not covered by Medicare that are purchased at the option of the MA enrollee and paid for in full, directly by (or on behalf of) the Medicare enrollee, in the form of premiums or cost-sharing. These services may be grouped or offered individually.

Original Medicare means health insurance available under Medicare Part A and Part B through the traditional fee-for service payment system.

Parent organization means the legal entity that exercises a controlling interest, through the ownership of shares, the power to appoint voting board members, or other means, in a Part D sponsor or MA organization, directly or through a subsidiary or subsidiaries, and which is not itself a subsidiary of any other legal entity.

Point of service (POS) means a benefit option that an MA HMO plan can offer to its Medicare enrollees as a mandatory supplemental, or optional supplemental benefit. Under the POS benefit option, the HMO plan allows members the option of receiving specified services outside of the HMO plan's provider network. In return for this flexibility, members typically have higher cost-sharing requirements for services received and, when offered as a mandatory or optional supplemental benefit, may also be charged a premium for the POS benefit option.

Preclusion list means a CMS compiled list of individuals and entities that—

(1) Meet all of the following requirements:

(i) The individual or entity is currently revoked from Medicare for a reason other than that stated in § 424.535(a)(3) of this chapter.

(ii) The individual or entity is currently under a reenrollment bar under § 424.535(c).

(iii) CMS determines that the underlying conduct that led to the revocation is detrimental to the best interests of the Medicare program. In making this determination under this paragraph (1)(iii), CMS considers the following factors:

(A) The seriousness of the conduct underlying the individual's or entity's revocation.

(B) The degree to which the individual's or entity's conduct could affect the integrity of the Medicare program.

(C) Any other evidence that CMS deems relevant to its determination; or

(2) Meet both of the following requirements:

(i) The individual or entity has engaged in behavior, other than that described in § 424.535(a)(3) of this chapter, for which CMS could have revoked the individual or entity to the extent applicable had they been enrolled in Medicare.

(ii) CMS determines that the underlying conduct that would have led to the revocation is detrimental to the best interests of the Medicare program. In making this determination under this paragraph (2)(ii), CMS considers the following factors:

(A) The seriousness of the conduct involved.

(B) The degree to which the individual's or entity's conduct could affect the integrity of the Medicare program; and

(C) Any other evidence that CMS deems relevant to its determination; or

(3) The individual or entity, regardless of whether they are or were enrolled in Medicare, has been convicted of a felony under Federal or State law within the previous 10 years that CMS deems detrimental to the best interests of the Medicare program. Factors that CMS considers in making such a determination under this paragraph (3) are—

(i) The severity of the offense;

(ii) When the offense occurred; and

(iii) Any other information that CMS deems relevant to its determination.

Prescription drug plan (PDP). PDP has the definition set forth in § 423.4 of this chapter.

Prescription drug plan (PDP) sponsor. A prescription drug plan sponsor has the definition set forth in § 423.4 of this chapter.

Provider means—

(1) Any individual who is engaged in the delivery of health care services in a State and is licensed or certified by the State to engage in that activity in the State; and

(2) Any entity that is engaged in the delivery of health care services in a State and is licensed or certified to deliver those services if such licensing or certification is required by State law or regulation.

Provider network means the providers with which an MA organization contracts or makes arrangements to furnish covered health care services to Medicare enrollees under an MA coordinated care plan or network PFFS plan.

RADV appeal process means an administrative process that enables MA organizations that have undergone RADV audit to appeal the Secretary's medical record review determinations and the Secretary's calculation of an MA organization's RADV payment error.

Related entity means any entity that is related to the MA organization by common ownership or control and

(1) Performs some of the MA organization's management functions under contract or delegation;

(2) Furnishes services to Medicare enrollees under an oral or written agreement; or

(3) Leases real property or sells materials to the MA organization at a cost of more than $2,500 during a contract period.

Religious Fraternal benefit (RFB) society means an organization that—

(1) Is described in section 501(c)(8) of the Internal Revenue Code of 1986 and is exempt from taxation under section 501(a) of that Act; and

(2) Is affiliated with, carries out the tenets of, and shares a religious bond with, a church or convention or association of churches or an affiliated group of churches.

RFB plan means an MA plan that is offered by an RFB society.

Risk adjustment data validation (RADV) audit means a payment audit of a MA organization administered by the

Secretary that ensures the integrity and accuracy of risk adjustment payment data.

Senior housing facility plan means an MA coordinated care plan that—

(1) Restricts enrollment to individuals who reside in a continuing care retirement community as defined in § 422.133(b)(2);

(2) Provides primary care services onsite and has a ratio of accessible physicians to beneficiaries that CMS determines is adequate consistent with prevailing patterns of community health care referenced at § 422.112(a)(10);

(3) Provides transportation services for beneficiaries to specialty providers outside of the facility; and

(4) Was participating as of December 31, 2009 in a demonstration established by CMS for not less than 1 year.

Service area means a geographic area that for local MA plans is one or more counties, as defined in § 422.116, and for MA regional plans is a region approved by CMS within which an MA-eligible individual may enroll in a particular MA plan offered by an MA organization. Facilities in which individuals are incarcerated are not included in the service area of an MA plan. Each MA plan must be available to all MA-eligible individuals within the plan's service area. In deciding whether to approve an MA plan's proposed service area, CMS considers the following criteria:

(1) For local MA plans:

(i) Whether the area meets the ''county integrity rule'' that a service area generally consists of a full county or counties.

(ii) However, CMS may approve a service area that includes only a portion of a county if it determines that the ''partial county'' area is necessary, nondiscriminatory, and in the best interests of the beneficiaries. CMS may also consider the extent to which the proposed service area mirrors service areas of existing commercial health care plans or MA plans offered by the organization.

(2) For all MA coordinated care plans, whether the contracting provider network meets the access and availability standards set forth in § 422.112. Although not all contracting providers must be located within the plan's service area, CMS must determine that all services covered under the plan are accessible from the service area.

(3) For MA regional plans, whether the service area consists of the entire region.

Severe or disabling chronic condition means, for the purpose of defining a special needs individual, the following co-morbid and medically complex chronic conditions that are life-threatening or significantly limit overall health or function, has a high risk of hospitalization or other significant adverse health outcomes, and requires intensive care coordination, and that which is designated by the Secretary under sections 1859(b)(6)(B)(iii)(II) and 1859(f)(9)(A) of the Act:

(1) Chronic alcohol use disorder and other substance use disorders (SUDs).

(2) Autoimmune disorders:

(i) Polyarteritis nodosa.

(ii) Polymyalgia rheumatica.

(iii) Polymyositis.

(iv) Dermatomyositis.

(v) Rheumatoid arthritis.

(vi) Systemic lupus erythematosus.

(vii) Psoriatic arthritis.

(viii) Scleroderma.

(3) Cancer.

(4) Cardiovascular disorders:

(i) Cardiac arrhythmias.

(ii) Coronary artery disease.

(iii) Peripheral vascular disease.

(iv) Valvular heart disease.

(5) Chronic heart failure.

(6) Dementia.

(7) Diabetes mellitus.

(8) Overweight, obesity, and metabolic syndrome.

(9) Chronic gastrointestinal disease:

(i) Chronic liver disease.

(ii) Non-alcoholic fatty liver disease (NAFLD).

(iii) Hepatitis B.

(iv) Hepatitis C.

(v) Pancreatitis.

(vi) Irritable bowel syndrome.

(vii) Inflammatory bowel disease.

(10) Chronic kidney disease (CKD):

(i) CKD requiring dialysis/End-stage renal disease (ESRD).

(ii) CKD not requiring dialysis.

(11) Severe hematologic disorders:

(i) Aplastic anemia.

(ii) Hemophilia.

(iii) Immune thrombocytopenic purpura.

(iv) Myelodysplastic syndrome.
(v) Sickle-cell disease (excluding sickle-cell trait).
(vi) Chronic venous thromboembolic disorder.
(12) HIV/AIDS.
(13) Chronic lung disorders:
(i) Asthma, Chronic bronchitis.
(ii) Cystic Fibrosis.
(iii) Emphysema.
(iv) Pulmonary fibrosis.
(v) Pulmonary hypertension.
(vi) Chronic Obstructive Pulmonary Disease (COPD).
(14) Chronic and disabling mental health conditions:
(i) Bipolar disorders.
(ii) Major depressive disorders.
(iii) Paranoid disorder.
(iv) Schizophrenia.
(v) Schizoaffective disorder.
(vi) Post-traumatic stress disorder (PTSD).
(vii) Eating Disorders.
(viii) Anxiety disorders.
(15) Neurologic disorders:
(i) Amyotrophic lateral sclerosis (ALS).
(ii) Epilepsy.
(iii) Extensive paralysis (that is, hemiplegia, quadriplegia, paraplegia, monoplegia).
(iv) Huntington's disease.
(v) Multiple sclerosis.
(vi) Parkinson's disease.
(vii) Polyneuropathy.
(viii) Fibromyalgia.
(ix) Chronic fatigue syndrome.
(x) Spinal cord injuries.
(xi) Spinal stenosis.
(xii) Stroke-related neurologic deficit.
(16) Stroke.
(17) Post-organ transplantation care.
(18) Immunodeficiency and Immunosuppressive disorders.
(19) Conditions associated with cognitive impairment:
(i) Alzheimer's disease.
(ii) Intellectual disabilities and developmental disabilities.
(iii) Traumatic brain injuries.
(iv) Disabling mental illness associated with cognitive impairment.
(v) Mild cognitive impairment.
(20) Conditions with functional challenges and require similar services including the following:
(i) Spinal cord injuries.
(ii) Paralysis.
(iii) Limb loss.
(iv) Stroke.
(v) Arthritis.
(21) Chronic conditions that impair vision, hearing (deafness), taste, touch, and smell.
(22) Conditions that require continued therapy services in order for individuals to maintain or retain functioning.

Special needs individual means an MA eligible individual who is institutionalized or institutionalized-equivalent, as those terms are defined in this section, is entitled to medical assistance under a State plan under title XIX, or has a severe or disabling chronic condition(s) and would benefit from enrollment in a specialized MA plan.

Specialized MA Plans for Special Needs Individuals means an MA coordinated care plan that exclusively enrolls special needs individuals as set forth in § 422.4(a)(1)(iv) and that provides Part D benefits under part 423 of this chapter to all enrollees; and which has been designated by CMS as meeting the requirements of an MA SNP as determined on a case-by-case basis using criteria that include the appropriateness of the target population, the existence of clinical programs or special expertise to serve the target population, and whether the proposal discriminates against sicker members of the target population.

Step therapy means a utilization management policy for coverage of drugs that begins medication for a medical condition with the most preferred or cost effective drug therapy and progresses to other drug therapies if medically necessary.

[63 FR 35068, June 26, 1998, as amended at 65 FR 40314, June 29, 2000; 68 FR 50855, Aug. 22, 2003; 70 FR 4714, Jan. 28, 2005; 70 FR 52026, Sept. 1, 2005; 70 FR 76197, Dec. 23, 2005; 72 FR 68722, Dec. 5, 2007; 74 FR 1540, Jan. 12, 2009; 75 FR 19803, Apr. 15, 2010; 76 FR 21561, Apr. 15, 2011; 79 FR 29955, May 23, 2014; 83 FR 16722, Apr. 16, 2018; 84 FR 15827, Apr. 16, 2019; 84 FR 23879, May 23, 2019; 86 FR 6094, Jan. 19, 2021; 87 FR 27893, May 9, 2022; 89 FR 30812, Apr. 23, 2024; 90 FR 15909 Apr. 15, 2025]

§ 422.3 MA organizations' use of reinsurance.

(a) An MA organization may obtain insurance or make other arrangements

for the cost of providing basic benefits to an individual enrollee in either of the following ways—

(1) The MA organization must retain risk for at least the first $10,000 in costs per individual enrollee for providing basic benefits during a contract year; or

(2) If the MA organization uses insurance or makes other arrangements for sharing such costs proportionately on a per member per year first dollar basis, the MA organization must retain risk based on the following:

(i) The actuarially equivalent value of the retained risk is greater than or equal to the value of risk retained in paragraph (a)(1) of this section.

(ii) The MA organization makes a determination of actuarial equivalence based on reasonable actuarial methods. For example, a reasonable method for determining actuarial equivalence would be to equate the percentage of net claim costs that the MA organization would retain under paragraphs (a)(1) and (a)(2)(i) of this section.

(b) In evaluating compliance with section 1855(b) of the Act and with paragraph (a) of this section, CMS will consider a parent organization and any of its subsidiaries to be part of the MA organization.

(c) The type of payment arrangement used between an MA organization and contracting physicians, other health professionals or institutions for the financial risk specified in section 1855(b)(4) of the Act (that is, the financial risk on a prospective basis for the provision of basic benefit by those physicians or other health professionals or through those institutions) is not limited by paragraph (a) of this section.

[85 FR 33901, June 2, 2020]

§ 422.4 Types of MA plans.

(a) *General rule.* An MA plan may be a coordinated care plan, a combination of an MA MSA plan and a contribution into an MA MSA established in accordance with § 422.262, or an MA private fee-for-service plan.

(1) *A coordinated care plan.* A coordinated care plan is a plan that includes a network of providers that are under contract or arrangement with the organization to deliver the benefit package approved by CMS.

(i) The network is approved by CMS to ensure that all applicable requirements are met, including access and availability, service area, and quality.

(ii) Coordinated care plans may include mechanisms to control utilization, such as referrals from a gatekeeper for an enrollee to receive services within the plan, and financial arrangements that offer incentives to providers to furnish high quality and cost-effective care.

(iii) Coordinated care plans include plans offered by any of the following:

(A) Health maintenance organizations (HMOs);

(B) Provider-sponsored organizations (PSOs), subject to paragraph (a)(1)(vi) of this section.

(C) Regional or local preferred provider organizations (PPOs) as specified in paragraph (a)(1)(v) of this section.

(D) Other network plans (except PFFS plans).

(iv) A specialized MA plan for special needs individuals (SNP) includes any type of coordinated care plan that meets CMS's SNP requirements and exclusively enrolls special needs individuals as defined by § 422.2 of this subpart. All MA plans wishing to offer a SNP will be required to be approved by the National Commission on Quality Assurance (NCQA) effective January 1, 2012. This approval process applies to existing SNPs as well as new SNPs joining the program. All SNPs must submit their model of care (MOC) to CMS for NCQA evaluation and approval as per CMS guidance.

(A) A C–SNP may focus on one severe or disabling chronic condition, as defined in § 422.2, or on a grouping of severe or disabling chronic conditions.

(B) Upon CMS approval, an MA organization may offer a C–SNP that focuses on multiple commonly co-morbid and clinically linked conditions from the following list of groupings:

(*1*) Diabetes mellitus and chronic heart failure.

(*2*) Chronic heart failure and cardiovascular disorders.

(*3*) Diabetes mellitus and cardiovascular disorders.

(*4*) Diabetes mellitus, chronic heart failure, and cardiovascular disorders.

(*5*) Stroke and cardiovascular disorders.

(*6*) Anxiety associated with COPD.

(*7*) Chronic kidney disease (CKD) and post-(renal) organ transplantation.

(*8*) Substance use disorders (SUD) and chronic mental health disorders.

(v) A PPO plan is a plan that—

(A) Has a network of providers that have agreed to a contractually specified reimbursement for covered benefits with the organization offering the plan;

(B) Provides for reimbursement for all covered benefits regardless of whether the benefits are provided within the network of providers;

(C) Only for purposes of quality assurance requirements in § 422.152(e), is offered by an organization that is not licensed or organized under State law as an HMO; and

(D) Does not permit prior notification for out-of-network services—that is, a reduction in the plan's standard cost-sharing levels when the out-of-network provider from whom an enrollee is receiving plan-covered services voluntarily notifies the plan prior to furnishing those services, or the enrollee voluntarily notifies the PPO plan prior to receiving plan-covered services from an out-of-network provider.

(vi) In accordance with § 422.370, CMS does not waive the State licensure requirement for organizations seeking to offer a PSO.

(2) *A combination of an MA MSA plan and a contribution into the MA MSA established in accordance with § 422.262.* (i) *MA MSA plan* means a plan that—

(A) Pays at least for the services described in § 422.101, after the enrollee has incurred countable expenses (as specified in the plan) equal in amount to the annual deductible specified in § 422.103(d);

(B) Does not permit prior notification—that is, a reduction in the plan's standard cost-sharing levels when the provider from whom an enrollee is receiving plan-covered services voluntarily notifies the plan prior to furnishing those services, or the enrollee voluntarily notifies the MSA plan prior to receiving plan-covered services from a provider; and

(C) Meets all other applicable requirements of this part.

(ii) *MA MSA* means a trust or custodial account—

(A) That is established in conjunction with an MSA plan for the purpose of paying the qualified expenses of the account holder; and

(B) Into which no deposits are made other than contributions by CMS under the MA program, or a trustee-to-trustee transfer or rollover from another MA MSA of the same account holder, in accordance with the requirements of sections 138 and 220 of the Internal Revenue Code.

(3) *MA private fee-for-service plan.* An MA private fee-for-service plan is an MA plan that—

(i) Pays providers of services at a rate determined by the plan on a fee-for-service basis without placing the provider at financial risk;

(ii) Subject to paragraphs (a)(3)(ii)(A) and (B) of this section, does not vary the rates for a provider based on the utilization of that provider's services; and

(A) May vary the rates for a provider based on the specialty of the provider, the location of the provider, or other factors related to the provider that are not related to utilization and do not violate § 422.205 of this part.

(B) May increase the rates for a provider based on increased utilization of specified preventive or screening services.

(iii) Does not restrict enrollees' choices among providers that are lawfully authorized to provide services and agree to accept the plan's terms and conditions of payment.

(iv) Does not permit prior notification—that is, a reduction in the plan's standard cost-sharing levels when the provider from whom an enrollee is receiving plan-covered services voluntarily notifies the plan prior to furnishing those services, or the enrollee voluntarily notifies the PFFS plan prior to receiving plan-covered services from a provider.

(b) *Multiple plans.* Under its contract, an MA organization may offer multiple plans, regardless of type, provided that the MA organization is licensed or approved under State law to provide those types of plans (or, in the case of a PSO plan, has received from CMS a

waiver of the State licensing requirement). If an MA organization has received a waiver for the licensing requirement to offer a PSO plan, that waiver does not apply to the licensing requirement for any other type of MA plan.

(c) *Rule for MA Plans' Part D coverage.* (1) Coordinated care plans. In order to offer an MA coordinated care plan in an area, the MA organization offering the coordinated care plan must offer qualified Part D coverage meeting the requirements in § 423.104 of this chapter in that plan or in another MA plan in the same area.

(2) *MSAs.* MA organizations offering MSA plans are not permitted to offer prescription drug coverage, other than that required under Parts A and B of Title XVIII of the Act.

(3) *Private Fee-For-Service.* MA organizations offering private fee-for-service plans can choose to offer qualified Part D coverage meeting the requirements in § 423.104 in that plan.

[63 FR 35068, June 26, 1998, as amended at 65 FR 40315, June 29, 2000; 70 FR 4714, Jan. 28, 2005; 70 FR 52026, Sept. 1, 2005; 73 FR 54248, Sept. 18, 2008; 74 FR 1541, Jan. 12, 2009; 75 FR 19804, Apr. 15, 2010; 76 FR 21561, Apr. 15, 2011; 89 FR 30814, Apr. 23, 2024]

§ 422.6 Cost-sharing in enrollment-related costs.

(a) *Basis and scope.* This section implements that portion of section 1857 of the Act that pertains to cost-sharing in enrollment-related costs. It sets forth the procedures that CMS follows to determine the aggregate annual ''user fee'' to be contributed by MA organizations and PDP sponsors under Medicare Part D and to assess the required user fees for each MA plan offered by MA organizations and PDP sponsors.

(b) *Purpose of assessment.* Section 1857(e)(2) of the Act authorizes CMS to charge and collect from each MA plan offered by an MA organization its pro rata share of fees for administering section 1851 of the Act (relating to dissemination of enrollment information), and section 4360 of the Omnibus Budget Reconciliation Act of 1990 (relating to the health insurance counseling and assistance program) and section 1860D–1(c) of the Act (relating to dissemination of enrollment information for the drug benefit).

(c) *Applicability.* The fee assessment also applies to those demonstrations for which enrollment is effected or coordinated under section 1851 of the Act.

(d) *Collection of fees*—(1) *Timing of collection.* CMS collects the fees over 9 consecutive months beginning with January of each fiscal year.

(2) *Amount to be collected.* The aggregate amount of fees for a fiscal year is the lesser of—

(i) The estimated costs to be incurred by CMS in that fiscal year to carry out the activities described in paragraph (b) of this section; or

(ii) For fiscal year 2006 and each succeeding year, the applicable portion (as defined in paragraph (e) of this section) of $200 million.''

(e) *Applicable portion.* In this section, the term ''applicable portion'' with respect to an MA plan means, for a fiscal year, CMS's estimate of Medicare Part C and D expenditures for those MA organizations as a percentage of all expenditures under title XVIII and with respect to PDP sponsors, the applicable portion is CMS's estimate of Medicare Part D prescription drug expenditures for those PDP sponsors as a percentage of all expenditures under title XVIII.

(f) *Assessment methodology.* (1) The amount of the applicable portion of the user fee each MA organization and PDP sponsor must pay is assessed as a percentage of the total Medicare payments to each organization. CMS determines the annual assessment percentage rate separately for MA organizations and for PDPs using the following formula:

(i) The assessment formula for MA organizations (including MA-PD plans):

C divided by A times B where—

A is the total estimated January payments to all MA organizations subject to the assessment;

B is the 9-month (January through September) assessment period; and

C is the total fiscal year MA organization user fee assessment amount determined in accordance with paragraph (d)(2) of this section.

(ii) The assessment formula for PDPs: C divided by A times B where—

A is the total estimated January payments to all PDP sponsors subject to

the assessment; B is the 9-month (January through September) assessment period; and C is the total fiscal year PDP sponsor's user fee assessment amount determined in accordance with paragraph (d)(2) of this section.

(2) CMS determines each MA organization's and PDP sponsor's pro rata share of the annual fee on the basis of the organization's calculated monthly payment amount during the 9 consecutive months beginning with January. CMS calculates each organization's monthly pro rata share by multiplying the established percentage rate by the total monthly calculated Medicare payment amount to the organization as recorded in CMS's payment system on the first day of the month.

(3) CMS deducts the organization's fee from the amount of Federal funds otherwise payable to the MA organization or PDP sponsor for that month.

(4) If assessments reach the amount authorized for the year before the end of September, CMS discontinues assessment.

(5) If there are delays in determining the amount of the annual aggregate fees specified in paragraph (d)(2) of this section, or the fee percentage rate specified in paragraph (f)(2), CMS may adjust the assessment time period and the fee percentage amount.

[65 FR 40315, June 29, 2000. Redesignated and amended at 70 FR 4715, Jan. 28, 2005; 70 FR 52026, Sept. 1, 2005]

Subpart B—Eligibility, Election, and Enrollment

SOURCE: 63 FR 35071, June 26, 1998, unless otherwise noted.

§ 422.50 Eligibility to elect an MA plan.

For this subpart, all references to an MA plan include MA-PD and both MA local and MA regional plans, as defined in § 422.2 unless specifically noted otherwise.

(a) An individual is eligible to elect an MA plan if he or she meets all of the following:;

(1) Is entitled to Medicare under Part A and enrolled in Part B (except that an individual entitled only to Part B and who was enrolled in an HMO or CMP with a risk contract under part 417 of this chapter on December 31, 1998 may continue to be enrolled in the MA organization as an MA plan enrollee).

(2) For coverage before January 1, 2021, has not been medically determined to have end-stage renal disease, except that—

(i) An individual who develops end-stage renal disease while enrolled in an MA plan or in a health plan offered by the MA organization is eligible to elect an MA plan offered by that organization;

(ii) An individual with end-stage renal disease whose enrollment in an MA plan was terminated or discontinued after December 31, 1998, because CMS or the MA organization terminated the MA organization's contract for the plan or discontinued the plan in the area in which the individual resides, is eligible to elect another MA plan. If the plan so elected is later terminated or discontinued in the area in which the individual resides, he or she may elect another MA plan; and

(iii) An individual with end-stage renal disease may elect an MA special needs plan as defined in § 422.2, as long as that plan has opted to enroll ESRD individuals.

(3) Meets either of the following residency requirements:

(i) Resides in the service area of the MA plan.

(ii) Resides outside of the service area of the MA plan and is enrolled in a health plan offered by the MA organization during the month immediately preceding the month in which the individual is entitled to both Medicare Part A and Part B, provided that an MA organization chooses to offer this option and that CMS determines that all applicable MA access requirements of § 422.112 are met for that individual through the MA plan's established provider network. The MA organization must furnish the same benefits to these enrollees as to enrollees who reside in the service area;

(4) Has been a member of an Employer Group Health Plan (EGHP) that includes the elected MA plan, even if the individual lives outside of the MA plan service area, provided that an MA organization chooses to offer this option and that CMS determines that all applicable MA access requirements at

§ 422.112 are met for that individual through the MA plan's established provider network. The MA organization must furnish the same benefits to all enrollees, regardless of whether they reside in the service area.

(5) Completes and signs an election form or completes another CMS-approved election method offered by the MA organization and provides information required for enrollment.

(6) Agrees to abide by the rules of the MA organization after they are disclosed to him or her in connection with the election process.

(7) Is a United States citizen or is lawfully present in the United States as determined in 8 CFR 1.3.

(b) An MA eligible individual may not be enrolled in more than one MA plan at any given time.

[63 FR 35071, June 26, 1998; 63 FR 52611, Oct. 1, 1998, as amended at 65 FR 40316, June 29, 2000; 68 FR 50855, Aug. 22, 2003; 70 FR 4715, Jan. 28, 2005; 70 FR 52026, Sept. 1, 2005; 80 FR 7958, Feb. 12, 2015; 85 FR 33901, June 2, 2020]

§ 422.52 Eligibility to elect an MA plan for special needs individuals.

(a) *General rule.* In order to elect a specialized MA plan for a special needs individual (Special Needs MA plan, or SNP), the individual must meet the eligibility requirements specified in this section.

(b) *Basic eligibility requirements.* Except as provided in paragraph (c) of this section, to be eligible to elect an SNP, an individual must:

(1) Meet the definition of a special needs individual, as defined at § 422.2;

(2) Meet the eligibility requirements for that specific SNP, including any additional eligibility requirements established in the State Medicaid agency contract (as described at § 422.107(a)) for dual eligible special needs plans; and

(3) Be eligible to elect an MA plan under § 422.50.

(c) *Exception to § 422.50.* For plan years beginning before January 1, 2021, CMS may waive § 422.50(a)(2) concerning the exclusion of persons with ESRD.

(d) *Deeming continued eligibility.* If an SNP determines that the enrollee no longer meets the eligibility criteria, but can reasonably be expected to again meet that criteria within a 6-month period, the enrollee is deemed to continue to be eligible for the MA plan for a period of not less than 30 days but not to exceed 6 months.

(e) *Restricting enrollment.* An SNP must restrict future enrollment to only special needs individuals as established under § 422.2.

(f) Establishing eligibility for enrollment. (1) For enrollments into an SNP that exclusively enrolls individuals that have severe or disabling chronic conditions (C–SNP), the organization must contact the applicant's current health care provider, who is a physician as defined in section 1861(r)(1) of the Act, physician assistant as defined in section 1861(aa)(5)(A) of the Act and who meets the qualifications specified in § 410.74(c) of this chapter, or a nurse practitioner as defined in section 1861(aa)(5)(A) of the Act and who meets the qualifications specified in § 410.75(b)(1)(i) and (ii) of this chapter to confirm that the applicant has the qualifying condition(s). The organization must obtain this information in one of the following two ways described in paragraph (f)(1)(i) or (ii) of this section:

(i) Contact the current health care provider or current health care provider's office and obtain verification of the applicant's condition(s) prior to enrollment in a form and manner authorized by CMS.

(ii) Through an assessment with the enrollee using a pre-enrollment qualification assessment tool (PQAT) where the assessment and the information gathered are verified (as described in paragraph (f)(1)(iii) of this section) before the end of the first month of enrollment in the C–SNP. Use of a PQAT requires the following:

(A) The PQAT must do all of the following:

(*1*) Include clinically appropriate questions relevant to the chronic condition(s) on which the C–SNP focuses.

(*2*) Gather sufficient reliable evidence of having the applicable condition using the applicant's past medical history, current signs or symptoms, and current medications.

(*3*) Include the date and time of the assessment completion if done face-to-face with the applicant, or the receipt

date if the C–SNP receives the completed PQAT by mail or by electronic means (if available).

(*4*) Include a signature line for and, once completed, be signed by the current health care provider specified in paragraph (f)(1) of this section to confirm the individual's eligibility for C–SNP enrollment.

(B) The C–SNP conducts a post-enrollment confirmation of each enrollee's information and eligibility by having the completed PQAT reviewed and signed by the enrollee's current health care provider as specified in paragraph (f)(1) of this section.

(C) The C–SNP must include the information gathered in the PQAT and used in this verification process in its records related to or about the enrollee that are subject to the confidentiality requirements in § 422.118.

(D)(*1*) The C–SNP tracks the total number of enrollees and the number and percent by condition whose post-enrollment verification matches the pre-enrollment assessment.

(*2*) Data and supporting documentation are made available upon request by CMS.

(E) If the organization does not obtain verification of the enrollees' required chronic condition(s) by the end of the first month of enrollment in the C–SNP, the organization must—

(*1*) Disenroll the enrollee as of the end of the second month of enrollment; and

(*2*) Send the enrollee notice of the disenrollment within the first 7 calendar days of the second month of enrollment.

(F) The organization must maintain the enrollment of the individual if verification of the required condition(s) is obtained at any point before the end of the second month of enrollment.

(iii) Prior to enrollment, the PQAT must be completed by the enrollee, completed by the enrollee's current health care provider, or administered with the enrollee by a provider employed or contracted by the plan. The PQAT must be signed by the enrollee's current health care provider as verification and confirmation that the enrollee has the severe or disabling chronic condition required to be eligible for the C–SNP, which may be done post-enrollment.

(2) [Reserved]

(g) *Special eligibility rule for certain C–SNPs.* For C–SNPs that use a group of multiple severe or disabling chronic conditions as described in § 422.4(a)(1)(iv) of this chapter, special needs individuals need only have one of the qualifying severe or disabling chronic conditions in order to be eligible to enroll.

[70 FR 4716, Jan. 28, 2005, as amended at 74 FR 1541, Jan. 12, 2009; 85 FR 33901, June 2, 2020; 89 FR 30814, Apr. 23, 2024]

§ 422.53 Eligibility to elect an MA plan for senior housing facility residents.

(a) *Basic eligibility requirements.* To be eligible to elect an MA senior housing facility plan, the individual must meet both of the following:

(1) Be a resident of an MA senior housing facility defined in § 422.2.

(2) Be eligible to elect an MA plan under § 422.50.

(b) *Restricting enrollment.* An MA senior housing facility plan must restrict enrollment to only those individuals who reside in a continuing care retirement community as defined at § 422.133(b)(2).

(c) *Establishing eligibility for enrollment.* An MA senior housing facility plan must verify the eligibility of each individual enrolling in its plan using a CMS approved process.

[76 FR 21561, Apr. 15, 2011]

§ 422.54 Continuation of enrollment for MA local plans.

(a) *Definition. Continuation area* means an additional area (outside the service area) within which the MA organization offering a local plan furnishes or arranges to furnish services to its continuation-of-enrollment enrollees. Enrollees must reside in a continuation area on a permanent basis. A continuation area does not expand the service area of any MA local plan.

(b) *Basic rule.* An MA organization may offer a continuation of enrollment option to MA local plan enrollees when they no longer reside in the service area of a plan and permanently move into the geographic area designated by the MA organization as a continuation

area. The intent to no longer reside in an area and permanently live in another area is verified through documentation that establishes residency, such as a driver's license or voter registration card.

(c) *General requirements.* (1) An MA organization that wishes to offer a continuation of enrollment option must meet the following requirements:

(i) Obtain CMS's approval of the continuation area, the communication materials that describe the option, and the MA organization's assurances of access to services.

(ii) Describe the option(s) in the member materials it offers and make the option available to all MA local plan enrollees residing in the continuation area.

(2) An enrollee who moves out of the service area and into the geographic area designated as the continuation area has the choice of continuing enrollment or disenrolling from the MA local plan. The enrollee must make the choice of continuing enrollment in a manner specified by CMS. If no choice is made, the enrollee must be disenrolled from the plan.

(d) *Specific requirements*—(1) *Continuation of enrollment benefits.* The MA organization must, at a minimum, provide or arrange for the Medicare-covered benefits as described in § 422.101(a).

(2) *Reasonable access.* The MA organization must ensure reasonable access in the continuation area—

(i) Through contracts with providers, or through direct payment of claims that satisfy the requirements in § 422.100(b)(2), to other providers who meet the requirement in subpart E of this part; and

(ii) By ensuring that the access requirements of § 422.112 are met.

(3) *Reasonable cost sharing.* For services furnished in the continuation area, an enrollee's cost-sharing liability is limited to the cost-sharing amounts required in the MA local plan's service area (in which the enrollee no longer resides).

(4) *Protection of enrollee rights.* An MA organization that offers a continuation of enrollment option must convey all enrollee rights conferred under this rule, with the understanding that—

(i) The ultimate responsibility for all appeals and grievance requirements remain with the organization that is receiving payment from CMS; and

(ii) Organizations that require enrollees to give advance notice of intent to use the continuation of enrollment option, must stipulate the notification process in the communication materials.

(e) *Capitation payments.* CMS's capitation payments to all MA organizations, for all Medicare enrollees, are based on rates established on the basis of the enrollee's permanent residence, regardless of where he or she receives services.

[63 FR 35071, June 26, 1998; 63 FR 52611, Oct. 1, 1998, as amended at 65 FR 40316, June 29, 2000; 70 FR 4716, Jan. 28, 2005; 83 FR 16722, Apr. 16, 2018]

§ 422.56 Enrollment in an MA MSA plan.

(a) *General.* An individual is not eligible to elect an MA MSA plan unless the individual provides assurances that are satisfactory to CMS that he or she will reside in the United States for at least 183 days during the year for which the election is effective.

(b) *Individuals eligible for or covered under other health benefits program.* Unless otherwise provided by the Secretary, an individual who is enrolled in a Federal Employee Health Benefit plan under 5 U.S.C. chapter 89, or is eligible for health care benefits through the Veteran's Administration under 10 U.S.C. chapter 55 or the Department of Defense under 38 U.S.C. chapter 17, may not enroll in an MA MSA plan.

(c) *Individuals eligible for Medicare cost-sharing under Medicaid State plans.* An individual who is entitled to coverage of Medicare cost-sharing under a State plan under title XIX of the Act is not eligible to enroll in an MA MSA plan.

(d) *Other limitations.* An individual who receives health benefits that cover all or part of the annual deductible under the MA MSA plan may not enroll in an MA MSA plan. Examples of this type of coverage include, but are not limited to, primary health care coverage other than Medicare, current coverage under the Medicare hospice

benefit, supplemental insurance policies not specifically permitted under § 422.104, and retirement health benefits.

[63 FR 35071, June 26, 1998; 63 FR 52612, Oct. 1, 1998, as amended at 70 FR 4716, Jan. 28, 2005]

§ 422.57 Limited enrollment under MA RFB plans.

An RFB society that offers an MA RFB plan may offer that plan only to members of the church, or convention or group of churches with which the society is affiliated.

§ 422.60 Election process.

(a) *Acceptance of enrollees: General rule.* (1) Except for the limitations on enrollment in an MA MSA plan provided by § 422.62(d)(1) and except as specified in paragraphs (a)(2) and (3) of this section, each MA organization must accept without restriction (except for an MA RFB plan as provided by § 422.57) individuals who are eligible to elect an MA plan that the MA organization offers and who elect an MA plan during initial coverage election periods under § 422.62(a)(1), annual election periods under § 422.62(a)(2), and under the circumstances described in § 422.62(b)(1) through (b)(4).

(2) MA organizations must accept elections during the open enrollment periods specified in § 422.62(a)(3) and (4) if their MA plans are open to new enrollees.

(3) Dual eligible special needs plans must limit enrollments to those individuals who meet the eligibility requirements established in the state Medicaid agency contract, as specified at § 422.52(b)(2).

(b) *Capacity to accept new enrollees.* (1) MA organizations may submit information on enrollment capacity of plans.

(2) If CMS determines that an MA plan offered by an MA organization has a capacity limit, and the number of MA eligible individuals who elect to enroll in that plan exceeds the limit, the MA organization offering the plan may limit enrollment in the plan under this part, but only if it provides priority in acceptance as follows:

(i) First, for individuals who elected the plan prior to the CMS determination that capacity has been exceeded, elections will be processed in chronological order by date of receipt of their election forms.

(ii) Then for other individuals in a manner that does not discriminate on the basis of any factor related to health as described in § 422.110.

(3) CMS considers enrollment limit requests for an MA plan service area, or a portion of the plan service area, only if the health and safety of beneficiaries is at risk, such as if the provider network is not available to serve the enrollees in all or a portion of the service area.

(c) *Election forms and other election mechanisms.* (1) The election must comply with CMS instructions regarding content and format and be approved by CMS as described in § 422.2262. The election must be completed by the MA eligible individual (or the individual who will soon become eligible to elect an MA plan) and include authorization for disclosure and exchange of necessary information between the U.S. Department of Health and Human Services and its designees and the MA organization. Persons who assist beneficiaries in completing forms must sign the form, or through other approved mechanisms, indicate their relationship to the beneficiary.

(2) The MA organization must file and retain election forms for the period specified in CMS instructions.

(d) *When an election is considered to have been made.* An election in an MA plan is considered to have been made on the date the completed election is received by the MA organization.

(e) *Handling of elections.* The MA organization must have an effective system for receiving, controlling, and processing elections. The system must meet the following conditions and requirements:

(1) Each election is dated as of the day it is received in a manner acceptable to CMS.

(2) Elections are processed in chronological order, by date of receipt.

(3) The MA organization gives the beneficiary prompt notice of acceptance or denial in a format specified by CMS.

(4) If the MA plan is enrolled to capacity, it explains the procedures that will be followed when vacancies occur.

(5) Upon receipt of the election, or for an individual who was accepted for future enrollment from the date a vacancy occurs, the MA organization transmits, within the timeframes specified by CMS, the information necessary for CMS to add the beneficiary to its records as an enrollee of the MA organization.

(f) *Exception for employer group health plans.* (1) In cases in which an MA organization has both a Medicare contract and a contract with an employer group health plan, and in which the MA organization arranges for the employer to process elections for Medicare-entitled group members who wish to enroll under the Medicare contract, the effective date of the election may be retroactive. Consistent with § 422.308(f)(2), payment adjustments based on a retroactive effective date may be made for up to a 90-day period.

(2) In order to obtain the effective date described in paragraph (f)(1) of this section, the beneficiary must certify that, at the time of enrollment in the MA organization, he or she received the disclosure statement specified in § 422.111.

(3) Upon receipt of the election from the employer, the MA organization must submit the enrollment within timeframes specified by CMS.

(g) *Passive enrollment by CMS*—(1) *Circumstances in which CMS may implement passive enrollment.* CMS may implement passive enrollment procedures in any of the following situations:

(i) Immediate terminations as provided in § 422.510(b)(2)(i)(B).

(ii) CMS determines that remaining enrolled in a plan poses potential harm to the members.

(iii) CMS determines, after consulting with the State Medicaid agency that contracts with the dual eligible special needs plan that is described in paragraph (g)(2)(i) of this section and meets the requirements of paragraph (g)(2) of this section, that the passive enrollment will promote integrated care and continuity of care for a full-benefit dual eligible beneficiary (as defined in § 423.772 of this chapter and entitled to Medicare Part A and enrolled in Part B under title XVIII) who is currently enrolled in an integrated dual eligible special needs plan.

(2) *MA plans that may receive passive enrollments.* CMS may implement passive enrollment described in paragraph (g)(1)(iii) of this section only into MA–PD plans that meet all the following requirements:

(i) Operate as a fully integrated dual eligible special needs plan or highly integrated dual eligible special needs plan.

(ii) Have substantially similar provider and facility networks and Medicare- and Medicaid-covered benefits as the plan (or plans) from which the beneficiaries are passively enrolled.

(iii) Have an overall quality rating from the most recently issued ratings, under the rating system described in §§ 422.160 through 422.166, of at least 3 stars or is a low enrollment contract or new MA plan as defined in § 422.252.

(iv) Not have any prohibition on new enrollment imposed by CMS.

(v) Have limits on premiums and cost-sharing appropriate to full-benefit dual eligible beneficiaries.

(vi) Have the operational capacity to passively enroll beneficiaries and agree to receive the enrollments.

(3) *Passive enrollment procedures.* Individuals will be considered to have elected the plan selected by CMS unless they—

(i) Decline the plan selected by CMS, in a form and manner determined by CMS, or

(ii) Request enrollment in another plan.

(4) *Beneficiary notification.* The MA organization that receives the passive enrollment must provide to the enrollee:

(i) In the case of a passive enrollment described in paragraphs (g)(1)(i) and (ii) of this section, a notice that describes the costs and benefits of the plan and the process for accessing care under the plan and clearly explains the beneficiary's ability to decline the enrollment or choose another plan. This notice must be provided to all potential passively-enrolled enrollees, in a form and manner determined by CMS, prior to the enrollment effective date (or as soon as possible after the effective date if prior notice is not practical).

(ii) In the case of a passive enrollment described in paragraph (g)(1)(iii)

of this section, two notices that describe the costs and benefits of the plan and the process for accessing care under the plan and clearly explain the beneficiary's ability to decline the enrollment or choose another plan.

(A) The first notice described in paragraph (g)(4)(ii) of this section must be provided, in a form and manner determined by CMS, no fewer than 60 calendar days prior to the enrollment effective date.

(B) The second notice described in paragraph (g)(4)(ii) of this section must be provided, in a form and manner determined by CMS, no fewer than 30 days prior to the enrollment effective date.

(5) *Special election period.* In the case of a passive enrollment described in this paragraph, individuals will be provided with a special enrollment period described in at § 423.38(c)(10) of this chapter.

(h) *Notification of reinstatement based on beneficiary cancellation of new enrollment.* When an individual is disenrolled from an MA plan due to the election of a new plan, the MA organization must reinstate the individual's enrollment in that plan if the individual cancels the election in the new plan within timeframes established by CMS. The MA organization offering the plan from which the individual was disenrolled must send the member notification of the reinstatement within 10 calendar days of receiving confirmation of the individual's reinstatement.

(i) *Authorized representatives.* As used in this subpart, an authorized representative is an individual who is the legal representative or otherwise legally able to act on behalf of an enrollee, as the law of the State in which the beneficiary resides may allow, in order to execute an enrollment or disenrollment request.

(1) The authorized representative would constitute the ''beneficiary'' or the ''enrollee'' for the purpose of making an election.

(2) Authorized representatives may include court-appointed legal guardians, persons having durable power of attorney for health care decisions, or individuals authorized to make health care decisions under state surrogate consent laws, provided they have the authority to act for the beneficiary in this capacity.

[63 FR 35071, June 26, 1998; 63 FR 52612, Oct. 1, 1998, as amended at 63 FR 54526, Oct. 9, 1998; 64 FR 7980, Feb. 17, 1999; 65 FR 40316, June 29, 2000; 70 FR 4716, Jan. 28, 2005; 70 FR 52026, Sept. 1, 2005; 74 FR 1541, Jan. 12, 2009; 77 FR 22166, Apr. 12, 2012; 83 FR 16722, Apr. 16, 2018; 84 FR 15828, Apr. 16, 2019; 89 FR 30814, Apr. 23, 2024]

§ 422.62 Election of coverage under an MA plan.

(a) *General: Coverage election periods*—(1) *Initial coverage election period for MA.* The initial coverage election period is the period during which a newly MA-eligible individual may make an initial election. This period begins 3 months before the month the individual is first entitled to both Part A and Part B and ends on the later of—

(i) The last day of the second month after the month in which they are first entitled to Part A and enrolled in Part B; or

(ii) If after May 15, 2006, the last day of the individual's Part B initial enrollment period.

(2) *Annual coordinated election period.* (i) For 2002 through 2010, except for 2006, the annual coordinated election period for the following calendar year is November 15 through December 31.

(ii) For 2006, the annual coordinated election period begins on November 15, 2005 and ends on May 15, 2006.

(iii) Beginning in 2011, the annual coordinated election period for the following calendar year is October 15 through December 7.

(iv) During the annual coordinated election period, an individual eligible to enroll in an MA plan may change his or her election from an MA plan to Original Medicare or to a different MA plan, or from Original Medicare to an MA plan. If an individual changes his or her election to Original Medicare, he or she may also elect a PDP.

(3) *Open enrollment period for individuals enrolled in MA*—(i) *For 2019 and subsequent years.* Except as provided in paragraphs (a)(3)(ii) and (iii) and (a)(4) of this section, an individual who is enrolled in an MA plan may make an election once during the first 3 months of the year to enroll in another MA plan or disenroll to obtain Original Medicare. An individual who chooses to

exercise this election may also make a coordinating election to enroll in or disenroll from Part D, as specified in § 423.38(e) of this chapter.

(ii) *Newly eligible MA individual.* For 2019 and subsequent years, a newly MA eligible individual who is enrolled in a MA plan may change his or her election once during the period that begins the month the individual is entitled to both Part A and Part B and ends on the last day of the third month of the entitlement. An individual who chooses to exercise this election may also make a coordinating election to enroll in or disenroll from Part D, as specified in § 423.38(e) of this chapter.

(iii) *Single election limitation.* The limitation to one election or change in paragraphs (a)(3)(i) and (ii) of this section does not apply to elections or changes made during the annual coordinated election period specified in paragraph (a)(2) of this section, or during a special election period specified in paragraph (b) of this section.

(4) *Open enrollment period for institutionalized individuals.* After 2005, an individual who is eligible to elect an MA plan and who is institutionalized, as defined in § 422.2, is not limited (except as provided for in paragraph (d) of this section for MA MSA plans) in the number of elections or changes he or she may make.

(i) Subject to the MA plan being open to enrollees as provided under § 422.60(a)(2), an MA eligible institutionalized individual may at any time elect an MA plan or change his or her election from an MA plan to Original Medicare, to a different MA plan, or from Original Medicare to an MA plan.

(ii) The open enrollment period for institutionalized individuals ends on the last day of the second month after the month the individual ceases to reside in one of the long-term care facility settings described in the definition of ''institutionalized'' in § 422.2.

(5) *Annual 45-day period for disenrollment from MA plans to Original Medicare.* Through 2018, at any time from January 1 through February 14, an individual who is enrolled in an MA plan may elect Original Medicare once during this 45-day period. An individual who chooses to exercise this election may also make a coordinating election to enroll in a PDP as specified in § 423.38(d) of this chapter.

(b) *Special election periods (SEPs).* An individual may at any time (that is, not limited to the annual coordinated election period) discontinue the election of an MA plan offered by an MA organization and change his or her election from an MA plan to original Medicare or to a different MA plan under any of the following circumstances:

(1) CMS or the organization has terminated the organization's contract for the plan, discontinued the plan in the area in which the individual resides, or the organization has notified the individual of the impending termination of the plan, or the impending discontinuation of the plan in the area in which the individual resides.

(2) The individual is not eligible to remain enrolled in the plan because of a change in his or her place of residence to a location out of the service area or continuation area or other change in circumstances as determined by CMS but not including terminations resulting from a failure to make timely payment of an MA monthly or supplemental beneficiary premium, or from disruptive behavior. Also eligible for this SEP are individuals who, as a result of a change in permanent residence, have new MA plan options available to them.

(3) The individual demonstrates to CMS that—

(i) The organization offering the plan substantially violated a material provision of its contract under this part in relation to the individual, including, but not limited to the following:

(A) Failure to provide the beneficiary on a timely basis medically necessary services for which benefits are available under the plan.

(B) Failure to provide medical services in accordance with applicable quality standards; or

(ii) The organization (or its agent, representative, or plan provider) materially misrepresented the plan's provisions in communications as outlined in subpart V of this part.

(4) The individual is making an MA enrollment request into or out of an employer sponsored MA plan, is disenrolling from an MA plan to take

employer sponsored coverage of any kind, or is disenrolling from employer sponsored coverage (including COBRA coverage) to elect an MA plan. This SEP is available to individuals who have (or are enrolling in) an employer or union sponsored MA plan and ends 2 months after the month the employer or union coverage of any type ends. The individual may choose an effective date that is not earlier than the first of the month following the month in which the election is made and no later than up to 3 months after the month in which the election is made.

(5) The individual is enrolled in an MA plan offered by an MA organization that has been sanctioned by CMS and elects to disenroll from that plan in connection with the matter(s) that gave rise to that sanction.

(i) Consistent with disclosure requirements at § 422.111(g), CMS may require the MA organization to notify current enrollees that if the enrollees believe they are affected by the matter(s) that gave rise to the sanction, the enrollees are eligible for a SEP to elect another MA plan or disenroll to original Medicare and enroll in a PDP.

(ii) The SEP starts with the imposition of the sanction and ends when the sanction ends or when the individual makes an election, whichever occurs first.

(6)(i) The individual is enrolled in a section 1876 cost contract that is not renewing its contract for the area in which the enrollee resides.

(ii) This SEP begins December 8 of the then-current contract year and ends on the last day of February of the following year.

(7) The individual is disenrolling from an MA plan to enroll in a Program of All-inclusive Care for the Elderly (PACE) organization or is enrolling in an MA plan after disenrolling from a PACE organization.

(i) An individual who disenrolls from PACE has a SEP for 2 months after the effective date of PACE disenrollment to elect an MA plan.

(ii) An individual who disenrolls from an MA plan has a SEP for 2 months after the effective date of MA disenrollment to elect a PACE plan.

(8) The individual terminated a Medigap policy upon enrolling for the first time in an MA plan and is still in a ''trial period'' and eligible for ''guaranteed issue'' of a Medigap policy, as outlined in section 1882(s)(3)(B)(v) of the Act.

(i) This SEP allows an eligible individual to make a one-time election to disenroll from his or her first MA plan to join original Medicare at any time of the year.

(ii) This SEP begins upon enrollment in the MA plan and ends after 12 months of enrollment or when the individual disenrolls from the MA plan, whichever is earlier.

(9) Until December 31, 2020, the individual became entitled to Medicare based on ESRD for a retroactive effective date (whether due to an administrative delay or otherwise) and was not provided the opportunity to elect an MA plan during his or her Initial Coverage Election Period (ICEP).

(i) The individual may prospectively elect an MA plan offered by an MA organization, provided—

(A) The individual was enrolled in a health plan offered by the same MA organization the month before their entitlement to Parts A and B;

(B) The individual developed ESRD while a member of that health plan; and

(C) The individual is still enrolled in that health plan.

(ii) This SEP begins the month the individual receives the notice of the Medicare entitlement determination and continues for 2 additional calendar months after the month the notice is received.

(10) The individual became entitled to Medicare for a retroactive effective date (whether due to an administrative delay or otherwise) and was not provided the opportunity to elect an MA plan during their initial coverage election period (ICEP). This SEP begins the month the individual receives the notice of the retroactive Medicare entitlement determination and continues for 2 additional calendar months after the month the notice is received. The effective date would be the first of the month following the month in which the election is made but would not be earlier than the first day of the month

in which the notice of the Medicare entitlement determination is received by the individual.

(11)(i) The individual enrolled in an MA special needs plan (SNP) and is no longer eligible for the SNP because he or she no longer meets the applicable special needs status.

(ii) This SEP begins the month the individual's special needs status changes and ends when the individual makes an enrollment request or 3 calendar months after the effective date of involuntary disenrollment from the SNP, whichever is earlier.

(12) The individual belongs to a qualified State Pharmaceutical Assistance Program (SPAP) and is requesting enrollment in an MA–PD plan.

(i) The individual may make one MA election per year.

(ii) This SEP is available while the individual is enrolled in the SPAP and, upon loss of eligibility for SPAP benefits, for an additional 2 calendar months after either the month of the loss of eligibility or notification of the loss, whichever is later.

(13)(i) The individual has severe or disabling chronic conditions and is eligible to enroll into a Chronic Care SNP designed to serve individuals with those conditions. The SEP is for an enrollment election that is consistent with the individual's eligibility for a Chronic Care SNP. Individuals enrolled in a Chronic Care SNP who have a severe or disabling chronic condition which is not a focus of their current SNP are eligible for this SEP to request enrollment in a Chronic Care SNP that focuses on this other condition. Individuals who are found after enrollment not to have the qualifying condition necessary to be eligible for the Chronic Care SNP are eligible for a SEP to enroll in a different MA plan.

(ii) This SEP is available while the individual has the qualifying condition and ends upon enrollment in the Chronic Care SNP. This SEP begins when the MA organization notifies the individual of the lack of eligibility and extends through the end of that month and the following 2 calendar months. The SEP ends when the individual makes an enrollment election or on the last day of the second of the 2 calendar months following notification of the lack of eligibility, whichever occurs first.

(14) The individual is enrolled in an MA–PD plan and requests to disenroll from that plan to enroll in or maintain other creditable prescription drug coverage.

(i) This SEP is available while the individual is enrolled in an MA–PD plan. The effective date of disenrollment from the MA plan is the first day of the month following the month a disenrollment request is received by the MA organization.

(ii) Permissible enrollment changes during this SEP are to disenroll from an MA–PD plan and elect original Medicare or to elect an MA-only plan, resulting in disenrollment from the MA–PD plan.

(15) The individual is requesting enrollment in an MA plan offered by an MA organization with a Star Rating of 5 Stars. An individual may use this SEP only once for the contract year in which the MA plan was assigned a 5-star overall performance rating, beginning the December 8th before that contract year through November 30th of that contract year.

(16) The individual is a non-U.S. citizen who becomes lawfully present in the United States.

(i) This SEP begins the month the individual attains lawful presence status and ends the earlier of when the individual makes an enrollment election or 2 calendar months after the month the individual attains lawful presence status.

(ii) [Reserved]

(17) The individual was adversely affected by having requested, but not received, required notices or information in an accessible format, as outlined in section 504 of the Rehabilitation Act of 1973 within the same timeframe that the MA organization or CMS provided the same information to individuals who did not request an accessible format.

(i) The SEP begins at the end of the election period during which the individual was seeking to make an enrollment election and the length is at least as long as the time it takes for the information to be provided to the individual in an accessible format.

(ii) MA organizations may determine eligibility for this SEP when the criterion is met, ensuring adequate documentation of the situation, including records indicating the date of the individual's request, the amount of time taken to provide accessible versions of the requested materials and the amount of time it takes for the same information to be provided to an individual who does not request an accessible format.

(18) Individuals affected by an emergency or major disaster declared by a Federal, State or local government entity are eligible for an SEP to make an MA enrollment or disenrollment election. The SEP starts as of the date the declaration is made, the incident start date or, if different, the start date identified in the declaration, whichever is earlier. The SEP ends 2 full calendar months following the end date identified in the declaration or, if different, the date the end of the incident is announced, the date the incident automatically ends under applicable state or local law, or, if the incident end date is not otherwise identified, the incident end date specified in paragraph (b)(18)(i) of this section.

(i) If the incident end date of an emergency or major disaster is not otherwise identified, the incident end date is 1 year after the SEP start date; or, if applicable, the date of a renewal or extension of the emergency or disaster declaration, whichever is later. The maximum length of this SEP, if the incident end date is not otherwise identified, is 14 full calendar months after the SEP start date or, if applicable, the date of a renewal or extension of the emergency or disaster declaration.

(ii) (A) Resides, or resided at the start of the SEP eligibility period described in this paragraph (b)(18), in an area for which a federal, state or local government entity has declared an emergency or major disaster; or

(B) Does not reside in an affected area but relies on help making healthcare decisions from one or more individuals who reside in an affected area; and

(iii) Was eligible for another election period at the time of the SEP eligibility period described in this paragraph (b)(18); and

(iv) Did not make an election during that other election period due to the emergency or major disaster.

(19) The individual experiences an involuntary loss of creditable prescription drug coverage, including a reduction in the level of coverage so that it is no longer creditable and excluding any loss or reduction of creditable coverage that is due to a failure to pay premiums.

(i) The individual is eligible to request enrollment in an MA–PD plan.

(ii) The SEP begins when the individual is notified of the loss of creditable coverage and ends 2 calendar months after the later of the loss (or reduction) or the individual's receipt of the notice.

(iii) The effective date of this SEP is the first of the month after the enrollment election is made or, at the individual's request, may be up to 3 months prospective.

(20) The individual was not adequately informed of a loss of creditable prescription drug coverage, or that they never had creditable coverage. CMS determines eligibility for this SEP on a case-by-case basis, based on its determination that an entity offering prescription drug coverage failed to provide accurate and timely disclosure of the loss of creditable prescription drug coverage or whether the prescription drug coverage offered is creditable.

(i) The individual is eligible for one enrollment in, or disenrollment from, an MA–PD plan.

(ii) This SEP begins the month of CMS' determination and continues for 2 additional calendar months following the determination.

(21) The individual's enrollment or non-enrollment in an MA–PD plan is erroneous due to an action, inaction, or error by a Federal employee.

(i) The individual is permitted enrollment in, or disenrollment from, the MA–PD plan, as determined by CMS.

(ii) This SEP begins the month of CMS approval of this SEP on the basis that the individual's enrollment was erroneous due to an action, inaction, or error by a Federal employee and continues for 2 additional calendar months following this approval.

(22) The individual is eligible for an additional Part D Initial Election Period, such as an individual currently entitled to Medicare due to a disability and who is attaining age 65.

(i) The individual is eligible to make an MA election to coordinate with the additional Part D Initial Election Period.

(ii) The SEP may be used to disenroll from an MA plan, with or without Part D benefits, to enroll in original Medicare, or to enroll in an MA plan that does not include Part D benefits, regardless of whether the individual uses the Part D Initial Election Period to enroll in a PDP.

(iii) The SEP begins and ends concurrently with the additional Part D Initial Election Period.

(23) Individuals affected by a significant change in plan provider network are eligible for a SEP that permits disenrollment from the MA plan that has changed its network to another MA plan or to original Medicare. This SEP can be used only once per significant change in the provider network.

(i) The SEP begins the month the individual is notified of eligibility for the SEP and extends an additional 2 calendar months thereafter.

(ii) An enrollee is affected by a significant network change when the enrollee is assigned to, currently receiving care from, or has received care within the past 3 months from a provider or facility being terminated from the provider network.

(iii) When instructed by CMS, the MA plan that has significantly changed its network must issue a notice, in the form and manner directed by CMS, that notifies enrollees who are eligible for this SEP of their eligibility for the SEP and how to use the SEP.

(24) The individual is enrolled in a plan offered by an MA organization that has been placed into receivership by a state or territorial regulatory authority. The SEP begins the month the receivership is effective and continues until it is no longer in effect or until the enrollee makes an election, whichever occurs first. When instructed by CMS, the MA plan that has been placed under receivership must notify its enrollees, in the form and manner directed by CMS, of the enrollees' eligibility for this SEP and how to use the SEP.

(25) The individual is enrolled in a plan that has been identified with the low performing icon in accordance with § 422.166(h)(1)(ii). This SEP exists while the individual is enrolled in the low performing MA plan.

(26) The individual enrolls in Medicare premium-Part A or Part B using an exceptional condition SEP, as described in 42 CFR 406.27 and 407.23. The SEP begins when the individual submits their application for premium-Part A and Part B, or Part B only, if the individual is already entitled to Part A (or is enrolling in premium-free Part A within the timeframe for use of this SEP), and continues for the first 2 months beyond the premium-Part A and/or Part B entitlement date. The MA plan enrollment is effective the first of the month following the month the MA plan receives the enrollment request.

(27) The individual meets such other exceptional conditions as CMS may provide.

(c) *Special election period for individual age 65.* Effective January 1, 2002, an MA eligible individual who elects an MA plan during the initial enrollment period, as defined under section 1837(d) of the Act, that surrounds his or her 65th birthday (this period begins 3 months before and ends 3 months after the month of the individual's 65th birthday) may discontinue the election of that plan and elect coverage under original Medicare at any time during the 12-month period that begins on the effective date of enrollment in the MA plan.

(d) *Special rules for MA MSA plans*—(1) *Enrollment.* An individual may enroll in an MA MSA plan only during an initial coverage election period or annual coordinated election period described in paragraphs (a)(1) and (a)(2) of this section.

(2) *Disenrollment.* (i) Except as provided in paragraph (d)(2)(ii) of this section, an individual may disenroll from an MA MSA plan only during—

(A) An annual election period; or

(B) The special election period described in paragraph (b) of this section.

(ii) *Exception.* An individual who elects an MA MSA plan during an annual election period and has never before elected an MA MSA plan may revoke that election, no later than December 15 of that same year, by submitting to the organization that offers the MA MSA plan a signed and dated request in the form and manner prescribed by CMS or by filing the appropriate disenrollment form through other mechanisms as determined by CMS.

[63 FR 35071, June 26, 1998; 63 FR 52612, Oct. 1, 1998, as amended at 65 FR 40317, June 29, 2000; 70 FR 4717, Jan. 28, 2005; 76 FR 21561, Apr. 15, 2011; 83 FR 16722, Apr. 16, 2018; 85 FR 33901, June 2, 2020; 88 FR 22328, Apr. 12, 2023; 88 FR 50044, Aug. 1, 2023; 89 FR 30815, Apr. 23, 2024]

§ 422.64 Information about the MA program.

Each MA organization must provide, on an annual basis, and in a format and using standard terminology that may be specified by CMS, the information necessary to enable CMS to provide to current and potential beneficiaries the information they need to make informed decisions with respect to the available choices for Medicare coverage.

[65 FR 40317, June 29, 2000]

§ 422.66 Coordination of enrollment and disenrollment through MA organizations.

(a) *Enrollment.* An individual who wishes to elect an MA plan offered by an MA organization may make or change his or her election during the election periods specified in § 422.62 by filing the appropriate election form with the organization or through other mechanisms as determined by CMS.

(b) *Disenrollment*—(1) *Basic rule.* An individual who wishes to disenroll from an MA plan may change his or her election during the election periods specified in § 422.62 in either of the following manners:

(i) Elect a different MA plan by filing the appropriate election with the MA organization.

(ii) Submit a request for disenrollment to the MA organization in the form and manner prescribed by CMS or file the appropriate disenrollment request through other mechanisms as determined by CMS.

(2) *When a disenrollment request is considered to have been made.* A disenrollment request is considered to have been made on the date the disenrollment request is received by the MA organization.

(3) *Responsibilities of the MA organization.* The MA organization must—

(i) Submit a disenrollment notice to CMS within timeframes specified by CMS;

(ii) Provide enrollee with notice of disenrollment in a format specified by CMS; and

(iii) In the case of a plan where lock-in applies, include in the notice a statement explaining that he or she—

(A) Remains enrolled until the effective date of disenrollment; and

(B) Until that date, neither the MA organization nor CMS pays for services not provided or arranged for by the MA plan in which the enrollee is enrolled; and

(iv) File and retain disenrollment requests for the period specified in CMS instructions.

(v) In the case of an incomplete disenrollment request—

(A) Document its efforts to obtain information to complete the disenrollment request;

(B) Notify the individual (in writing or verbally) within 10 calendar days of receipt of the disenrollment request.

(C) The organization must deny the request if any additional information needed to make the disenrollment request ''complete'' is not received within the following timeframes:

(*1*) For disenrollment requests received during the AEP, by December 7, or within 21 calendar days of the request for additional information, whichever is later.

(*2*) For disenrollment requests received during all other election periods, by the end of the month in which the disenrollment request was initially received, or within 21 calendar days of the request for additional information, whichever is later.

(4) *Effect of failure to submit disenrollment notice to CMS promptly.* If the MA organization fails to submit

the correct and complete notice required in paragraph (b)(3)(i) of this section, the MA organization must reimburse CMS for any capitation payments received after the month in which payment would have ceased if the requirement had been met timely.

(5) *Retroactive disenrollment.* CMS may grant retroactive disenrollment in the following cases:

(i) There never was a legally valid enrollment.

(ii) A valid request for disenrollment was properly made but not processed or acted upon.

(6) *When a disenrollment request is considered incomplete.* A disenrollment request is considered to be incomplete if the required but missing information is not received by the MA organization within the timeframe specified in paragraph (b)(3)(v)(C) of this section.

(c) *Election by default: Initial coverage election period*—(1) *Basic rule.* Subject to paragraph (c)(2) of this section, an individual who fails to make an election during the initial coverage election period is deemed to have elected original Medicare.

(2) *Default enrollment into MA dual eligible special needs plan*—(i) *Conditions for default enrollment.* During an individual's initial coverage election period, an individual may be deemed to have elected a MA special needs plan for individuals entitled to medical assistance under a State plan under Title XIX (including a fully integrated dual eligible special needs plan as defined in § 422.2) offered by the organization provided all the following conditions are met:

(A) At the time of the deemed election, the individual remains enrolled in an affiliated Medicaid managed care plan. For purposes of this section, an affiliated Medicaid managed care plan is one that is offered by the MA organization that offers the dual eligible MA special needs plan or is offered by an entity that shares a parent organization with such MA organization;

(B) The state has approved the use of the default enrollment process in the contract described in § 422.107 and provides the information that is necessary for the MA organization to identify individuals who are in their initial coverage election period;

(C) The MA organization offering the MA special needs plan has issued the notice described in paragraph (c)(2)(iv) of this section to the individual;

(D) Prior to the effective date described in paragraph (c)(2)(iii) of this section, the individual does not decline the default enrollment and does not elect to receive coverage other than through the MA organization;

(E) CMS has approved the MA organization to use default enrollment under paragraph (c)(2)(ii) of this section;

(F) The MA organization has a minimum overall quality rating from the most recently issued ratings, under the rating system described in §§ 422.160 through 422.166, of at least 3 stars or is a low enrollment contract or new MA plan as defined in § 422.252; and

(G) The MA organization does not have any prohibition on new enrollment imposed by CMS.

(ii) *CMS approval of default enrollment.* An MA organization must obtain approval from CMS before implementing any default enrollment as described in this section. CMS approval will be for a period not to exceed five years, although CMS may suspend or rescind approval prior to the expiration of this period if CMS determines the MA organization is not in compliance with the requirements of this section.

(iii) *Effective date of default enrollment.* Default enrollment in the dual eligible MA special needs plan is effective the month in which the individual is first entitled to both Part A and Part B.

(iv) *Notice requirement for default enrollments.* In addition to the information described in § 422.111 and no fewer than 60 calendar days prior to the enrollment effective date described in paragraph (c)(2)(iii) of this section, the MA organization must provide to each individual who qualifies for deemed enrollment under paragraph (c)(2) of this section a notice that includes the following:

(A) Information on the differences in premium, benefits and cost sharing between the individual's current Medicaid managed care plan and the dual eligible MA special needs plan and the process for accessing care under the MA plan;

(B) The individual's ability to decline the enrollment, up to and including the day prior to the enrollment effective date, and either enroll in Original Medicare or choose another MA plan; and

(C) A general description of alternative Medicare health and drug coverage options available to an individual in his or her Initial Coverage Election Period.

(d) *Conversion of enrollment (seamless continuation of coverage)*—(1) *Basic rule.* An MA plan offered by an MA organization must accept any individual (regardless of whether the individual has end-stage renal disease) who requests enrollment during his or her Initial Coverage Election Period while enrolled in a health plan offered by the MA organization during the month immediately preceding the MA plan enrollment effective date, and who meets the eligibility requirements at § 422.50.

(2) *Reserved vacancies.* Subject to CMS's approval, an MA organization may set aside a reasonable number of vacancies in order to accommodate enrollment of conversions. Any set aside vacancies that are not filled within a reasonable time must be made available to other MA eligible individuals.

(3) *Effective date of conversion.* If an individual chooses to remain enrolled with the MA organization as an MA enrollee, the individual's conversion to an MA enrollee is effective the month in which he or she is entitled to both Part A and Part B in accordance with the requirements in paragraph (d)(5) of this section.

(4) *Prohibition against disenrollment.* The MA organization may disenroll an individual who is converting under the provisions of paragraph (a) of this section only under the conditions specified in § 422.74.

(5) *Election.* An individual who requests seamless continuation of coverage as described in paragraph (d)(1) of this section may complete a simplified election, in a form and manner approved by CMS that meets the requirements in § 422.60(c)(1).

(6) *Submittal of information to CMS.* The MA organization must transmit the information necessary for CMS to add the individual to its records as specified in § 422.60(e)(6).

(e) *Maintenance of enrollment.* (1) An individual who has made an election under this section is considered to have continued to have made that election until either of the following, which ever occurs first:

(i) The individual changes the election under this section.

(ii) The elected MA plan is discontinued or no longer serves the area in which the individual resides, as provided under § 422.74(b)(3), or the organization does not offer or the individual does not elect the option of continuing enrollment, as provided under § 422.54.

(2) An individual enrolled in an MA plan that becomes an MA-PD plan on January 1, 2006, will be deemed to have elected to enroll in that MA-PD plan.

(3) An individual enrolled in an MA plan that, as of December 31, 2005, offers any prescription drug coverage will be deemed to have elected an MA-PD plan offered by the same organization as of January 1, 2006.

(4) An individual who has elected an MA plan that does not provide prescription drug coverage will not be deemed to have elected an MA-PD plan and will remain enrolled in the MA plan as provided in paragraph (e)(1) of this section.

(5) An individual enrolled in an MA-PD plan as of December 31 of a year is deemed to have elected to remain enrolled in that plan on January 1 of the following year.

(f) *Exception for employer group health plans.* (1) In cases when an MA organization has both a Medicare contract and a contract with an employer group health plan, and in which the MA organization arranges for the employer to process election forms for Medicare-entitled group members who wish to disenroll from the Medicare contract, the effective date of the election may be retroactive. Consistent with § 422.308(f)(2), payment adjustments based on a retroactive effective date may be made for up to a 90-day period.

(2) Upon receipt of the election from the employer, the MA organization must submit a disenrollment notice to

CMS within timeframes specified by CMS.

[63 FR 35071, June 26, 1998; 63 FR 52612, Oct. 1, 1998, as amended at 65 FR 40317, June 29, 2000; 70 FR 4718, Jan. 28, 2005; 70 FR 52026, Sept. 1, 2005; 83 FR 16722, Apr. 16, 2018; 89 FR 30815, Apr. 23, 2024]

§ 422.68 Effective dates of coverage and change of coverage.

(a) *Initial coverage election period.* An election made during an initial coverage election period as described in § 422.62(a)(1) is effective as follows:

(1) If made prior to the month of entitlement to both Part A and Part B, it is effective as of the first day of the month of entitlement to both Part A and Part B.

(2) If made during or after the month of entitlement to both Part A and Part B, it is effective the first day of the calendar month following the month in which the election is made.

(b) *Annual coordinated election periods.* For an election or change of election made during the annual coordinated election period as described in § 422.62(a)(2)(i), coverage is effective as of the first day of the following calendar year except that for the annual coordinated election period described in § 422.62(a)(2)(ii), elections made after December 31, 2005 through May 15, 2006 are effective as of the first day of the first calendar month following the month in which the election is made.

(c) *Open enrollment periods.* For an election, or change in election, made during an open enrollment period, as described in § 422.62(a)(3) through (5), coverage is effective as of the first day of the first calendar month following the month in which the election is made.

(d) *Special election periods.* For an election or change of election made during a special election period as described in § 422.62(b), the coverage or change in coverage is effective the first day of the calendar month following the month in which the election is made, unless otherwise noted.

(e) *Special election period for individual age 65.* For an election of coverage under original Medicare made during a special election period for an individual age 65 as described in § 422.62(c), coverage is effective as of the first day of the first calendar month following the month in which the election is made.

(f) *Annual 45-day period for disenrollment from MA plans to Original Medicare.* Through 2018, an election made from January 1 through February 14 to disenroll from an MA plan to Original Medicare, as described in § 422.62(a)(5), is effective the first day of the first month following the month in which the election is made.

(g) *Beneficiary choice of effective date.* If a beneficiary is eligible for more than one election period, resulting in more than one possible effective date, the MA organization must allow the beneficiary to choose the election period that results in the individual's desired effective date.

(1) To determine the beneficiary's choice of election period and effective date, the MA organization must attempt to contact the beneficiary and must document its attempts.

(2) If the MA organization is unable to obtain the beneficiary's desired enrollment effective date, the MA organization must assign an election period using the following ranking of election periods:

(i) ICEP/Part D IEP.

(ii) MA–OEP.

(iii) SEP.

(iv) AEP.

(v) OEPI.

(3) If the MA organization is unable to obtain the beneficiary's desired disenrollment effective date, the MA organization must assign an election period that results in the earliest disenrollment.

[63 FR 35071, June 26, 1998, as amended at 65 FR 40317, June 29, 2000; 67 FR 13288, Mar. 22, 2002; 70 FR 4718, Jan. 28, 2005; 76 FR 21562, Apr. 15, 2011; 83 FR 16724, Apr. 16, 2018; 85 FR 33903, June 2, 2020; 89 FR 30815, Apr. 23, 2024]

§ 422.74 Disenrollment by the MA organization.

(a) *General rule.* Except as provided in paragraphs (b) through (d) of this section, an MA organization may not—

(1) Disenroll an individual from any MA plan it offers; or

(2) Orally or in writing, or by any action or inaction, request or encourage an individual to disenroll.

(b) *Basis for disenrollment*—(1) *Optional disenrollment.* An MA organization may disenroll an individual from an MA plan it offers in any of the following circumstances:

(i) Any monthly basic and supplementary beneficiary premiums are not paid on a timely basis, subject to the grace period for late payment established under paragraph (d)(1) of this section.

(ii) The individual has engaged in disruptive behavior specified at paragraph (d)(2) of this section.

(iii) The individual provides fraudulent information on his or her election form or permits abuse of his or her enrollment card as specified in paragraph (d)(3) of this section.

(2) *Required disenrollment.* An MA organization must disenroll an individual from an MA plan it offers in any of the following circumstances:

(i) The individual no longer resides in the MA plan's service area as specified under paragraph (d)(4) of this section, is no longer eligible under §422.50(a)(3)(ii), and optional continued enrollment has not been offered or elected under §422.54.

(ii) The individual loses entitlement to Part A or Part B benefits as described in paragraph (d)(5) of this section.

(iii) Death of the individual as described in paragraph (d)(6) of this section.

(iv) Individuals enrolled in a specialized MA plan for special needs individuals that exclusively serves and enrolls special needs individuals who no longer meet the special needs status of that plan (or deemed continued eligibility, if applicable).

(v) The individual is not lawfully present in the United States.

(vi) The individual no longer meets the MA MSA's eligibility criteria specified under §422.56 due to a mid-year change in eligibility.

(3) *Plan termination or reduction of area where plan is available*—(i) *General rule.* An MA organization that has its contract for an MA plan terminated, that terminates an MA plan, or that discontinues offering the plan in any portion of the area where the plan had previously been available, must disenroll affected enrollees in accordance with the procedures for disenrollment set forth at paragraph (d)(7) of this section, unless the exception in paragraph (b)(3)(ii) of this section applies.

(ii) *Exception.* When an MA organization discontinues offering an MA plan in a portion of its service area, the MA organization may elect to offer enrollees residing in all or portions of the affected area the option to continue enrollment in an MA plan offered by the organization, provided that there is no other MA plan offered in the affected area at the time of the organization's election. The organization may require an enrollee who chooses to continue enrollment to agree to receive the full range of basic benefits (excluding emergency and urgently needed care) exclusively through facilities designated by the organization within the plan service area.

(c) *Notice requirement.* If the disenrollment is for any of the reasons specified in paragraphs (b)(1), (b)(2)(i), (b)(2)(vi), or (b)(3) of this section (that is, other than death or loss of entitlement to Part A or Part B) the MA organization must give the individual a written notice of the disenrollment with an explanation of why the MA organization is planning to disenroll the individual. Notices for reasons specified in paragraphs (b)(1) through (b)(2)(i) and (b)(2)(vi) of this section must—

(1) Be provided to the individual before submission of the disenrollment to CMS; and

(2) Include an explanation of the individual's right to submit a grievance under the MA organization's grievance procedures.

(d) *Process for disenrollment.* (1) Except as specified in paragraph (d)(1)(iv) of this section, an MA organization may disenroll an individual from the MA plan for failure to pay basic and supplementary premiums under the following circumstances:

(i) The MA organization can demonstrate to CMS that it made reasonable efforts to collect the unpaid premium amount, including:

(A) Alerting the individual that the premiums are delinquent;

(B) Providing the individual with a grace period, that is, an opportunity to

pay past due premiums in full. The length of the grace period must—

(*1*) Be at least 2 whole calendar months; and

(*2*) Begin on the first day of the month for which the premium is unpaid or the first day of the month following the date on which premium payment is requested, whichever is later.

(C) Advising the individual that failure to pay the premiums by the end of the grace period will result in termination of MA coverage.

(ii) The MA organization provides the enrollee with notice of disenrollment that meets the requirements set forth in paragraph (c) of this section.

(iii) If the enrollee fails to pay the premium for optional supplemental benefits but pays the basic premium and any mandatory supplemental premium, the MA organization has the option to discontinue the optional supplemental benefits and retain the individual as an MA enrollee.

(iv) An MA organization may not disenroll an individual who had monthly premiums withheld per § 422.262(f)(1) and (g) of this part, or who is in premium withhold status, as defined by CMS.

(v) *Extension of grace period for good cause and reinstatement.* When an individual is disenrolled for failure to pay the plan premium, CMS (or a third party to which CMS has assigned this responsibility, such as an MA organization) may reinstate enrollment in the MA plan, without interruption of coverage, if the individual does all of the following:

(A) Submits a request for reinstatement for good cause within 60 calendar days of the disenrollment effective date;

(B) Has not previously requested reinstatement for good cause during the same 60-day period following the involuntary disenrollment;

(C) Shows good cause for failure to pay within the initial grace period;

(D) Pays all overdue premiums within 3 calendar months after the disenrollment date; and

(E) Establishes by a credible statement that failure to pay premiums within the initial grace period was due to circumstances for which the individual had no control, or which the individual could not reasonably have been expected to foresee.

(vi) *No extension of grace period.* A beneficiary's enrollment in the MA plan may not be reinstated if the only basis for such reinstatement is a change in the individual's circumstances subsequent to the involuntary disenrollment for non-payment of premiums.

(2) *Disruptive behavior*—(i) *Definition of disruptive behavior.* An MA plan enrollee is disruptive if his or her behavior substantially impairs the plan's ability to arrange for or provide services to the individual or other plan members. An individual cannot be considered disruptive if such behavior is related to the use of medical services or compliance (or noncompliance) with medical advice or treatment.

(ii) *Basis of disenrollment for disruptive behavior.* An organization may disenroll an individual whose behavior is disruptive as defined in 422.74(d)(2)(i) only after it meets the requirements described in this section and CMS has reviewed and approved the request.

(iii) *Effort to resolve the problem.* (A) The MA organization must—

(*1*) Make a serious effort to resolve the problems presented by the individual, including providing reasonable accommodations, as determined by CMS, for individuals with mental or cognitive conditions, including mental illness and developmental disabilities.

(*2*) Inform the individual of the right to use the organization's grievance procedures, through the notices described in paragraph (d)(2)(vii) of this section.

(B) The beneficiary has a right to submit any information or explanation that he or she may wish to the MA organization.

(iv) *Documentation.* The MA organization—

(A) Must document the enrollee's behavior, its own efforts to resolve any problems, as described in paragraph (d)(2)(iii) of this section, and any extenuating circumstances.

(B) May request from CMS the ability to decline future enrollment by the individual.

(C) Must submit to CMS—

(*1*) The information specified in paragraph (d)(2)(iv)(A) of this section;

(*2*) Any documentation received by the beneficiary;

(*3*) Dated copies of the notices required in paragraph (d)(2)(vii) of this section.

(v) *CMS review of the proposed disenrollment.* CMS will review the information submitted by the MA organization and any information submitted by the beneficiary (which the MA organization must forward to CMS) to determine if the MA organization has fulfilled the requirements to request disenrollment for disruptive behavior. If the organization has fulfilled the necessary requirements, CMS will review the information and make a decision to approve or deny the request for disenrollment, including conditions on future enrollment, within 20 working days. During the review, CMS will ensure that staff with appropriate clinical or medical expertise review the case before making the final decision. The MA organization will be required to provide a reasonable accommodation, as determined by CMS, for the individual in such exceptional circumstances that CMS deems necessary. CMS will notify the MA organization within 5 working days after making its decision.

(vi) *Effective date of disenrollment.* If CMS permits an MA organization to disenroll an individual for disruptive behavior, the termination is effective the first day of the calendar month after the month in which the MA organization gives the individual notice of the disenrollment that meets the requirements set forth in paragraph (c) of this section, unless otherwise determined by CMS.

(vii) *Required notices.* The MA organization must provide the individual two notices prior to submitting the request for disenrollment to CMS.

(A) The first notice, the advance notice, informs the member that continued disruptive behavior could lead to involuntary disenrollment and provides the individual an opportunity to cease the behavior in order to avoid the disenrollment action.

(*1*) If the disruptive behavior ceases after the member receives the advance notice and then later resumes, the organization must begin the process again.

(*2*) The organization must wait at least 30 days after sending the advance notice before sending the second notice, during which 30-day period the individual has the opportunity to cease their behavior.

(B) The second notice, the notice of intent to request CMS permission to disenroll the member, notifies the member that the MA organization requests CMS permission to involuntarily disenroll the member.

(*1*) This notice must be provided prior to submission of the request to CMS.

(*2*) These notices are in addition to the disenrollment submission notice required under § 422.74(c).

(3) *Individual commits fraud or permits abuse of enrollment card*—(i) *Basis for disenrollment.* An MA organization may disenroll the individual from an MA plan if the individual—

(A) Knowingly provides, on the election form, fraudulent information that materially affects the individual's eligibility to enroll in the MA plan; or

(B) Intentionally permits others to use his or her enrollment card to obtain services under the MA plan.

(ii) *Notice of disenrollment.* The MA organization must give the individual a written notice of the disenrollment that meets the requirements set forth in paragraph (c) of this section.

(iii) *Report to CMS.* The MA organization must report to CMS any disenrollment based on fraud or abuse by the individual.

(4) *Individual no longer resides in the MA plan's service area*—(i) *Basis for disenrollment.* Unless continuation of enrollment is elected under § 422.54, the MA organization must disenroll an individual, and must document the basis for such action, if the MA organization establishes, on the basis of a written statement from the individual or other evidence acceptable to CMS, that the individual has permanently moved—

(A) Out of the MA plan's service area or is incarcerated as specified in paragraph (d)(4)(v) of this section.

(B) From the residence in which the individual resided at the time of enrollment in the MA plan to an area outside the MA plan's service area, for those individuals who enrolled in the MA plan under the eligibility requirements at § 422.50(a)(3)(ii) or (a)(4).

(ii) *Special rule.* If the individual has not moved from the MA plan's service area (or residence, as described in paragraph (d)(4)(i)(B) of this section), but has left the service area (or residence) for more than 6 months, the MA organization must disenroll the individual from the plan, unless the exception in paragraph (d)(4)(iii) of this section applies.

(A) The individual is considered to be temporarily absent from the plan service area when one or more of the required materials and content referenced in § 422.2267(e), if provided by mail, is returned to the MA organization by the U.S. Postal Service as undeliverable and a forwarding address is not provided.

(B) [Reserved]

(iii) *Exception.* If the MA plan offers a visitor/traveler benefit when the individual is out of the service area but within the United States (as defined in § 400.200 of this chapter) for a period of consecutive days longer than 6 months but less than 12 months, the MA organization may elect to offer to the individual the option of remaining enrolled in the MA plan if—

(A) The individual is disenrolled on the first day of the 13th month after the individual left the service area (or residence, if paragraph (d)(4)(i)(B) of this section applies);

(B) The individual understands and accepts any restrictions imposed by the MA plan on obtaining these services while absent from the MA plan's service area for the extended period, consistent with paragraph (d)(4)(i)(C) of the section;

(C) The MA organization makes this visitor/traveler option available to all Medicare enrollees who are absent for an extended period from the MA plan's service area. MA organizations may limit this visitor/traveler option to enrollees who travel to certain areas, as defined by the MA organization, and who receive services from qualified providers who directly provide, arrange for, or pay for health care; and

(D) The MA organization furnishes all Medicare Parts A and B services and all mandatory and optional supplemental benefits at the same cost sharing levels as apply within the plan's service area; and

(E) The MA organization furnishes the services in paragraph (d)(4)(iii)(D) of this section consistent with Medicare access and availability requirements at § 422.112 of this part.

(F) The individual is considered to be temporarily absent from the plan service area when one or more of the required materials and content referenced in § 422.2267(e), if provided by mail, is returned to the MA organization by the U.S. Postal Service as undeliverable and a forwarding address is not provided.

(iv) *Notice of disenrollment.* The MA organization must give the individual a written notice of the disenrollment that meets the requirements set forth in paragraph (c) of this section within 10 calendar days of the plan's confirmation of the individual's residence outside of the plan service area or within the first 10 calendar days of the sixth month of an individual's temporary absence from the plan service area or, for individuals using a visitor/traveler benefit, within the first 10 calendar days of the last month of the allowable absence. If the plan learns of an individual's temporary absence from the plan service area after the expiration of the allowable period, the plan must send this notice within 10 calendar days of the plan learning of the absence.

(v) *Incarceration.* (A) The MA organization must disenroll an individual if the MA organization establishes, on the basis of evidence acceptable to CMS, that the individual is incarcerated and does not reside in the service area of the MA plan as specified at § 422.2 or when notified of the incarceration by CMS as specified in paragraph (d)(4)(v)(B) of this section.

(B) *Notification by CMS of incarceration.* When CMS notifies the MA organization of the disenrollment due to the individual being incarcerated and not residing in the service area of the MA plan as per § 422.2, disenrollment is effective the first of the month following the start of incarceration, unless otherwise specified by CMS.

(5) *Loss of entitlement to Part A or Part B benefits.* If an individual is no longer entitled to Part A or Part B benefits, CMS notifies the MA organization that the disenrollment is effective the first day of the calendar month following

the last month of entitlement to Part A or Part B benefits.

(6) *Death of the individual.* If the individual dies, disenrollment is effective the first day of the calendar month following the month of death.

(7) *Plan termination or area reduction.* (i) When an MA organization has its contract for an MA plan terminated, terminates an MA plan, or discontinues offering the plan in any portion of the area where the plan had previously been available, the MA organization must give each affected MA plan enrollee a written notice of the effective date of the plan termination or area reduction and a description of alternatives for obtaining benefits under the MA program.

(ii) The notice must be sent before the effective date of the plan termination or area reduction, and in the timeframes specified in § 422.506(a)(2).

(8) *Loss of special needs status.* If an enrollee loses special needs status and must be disenrolled under paragraph (b)(2)(iv) of this section, the SNP must provide the enrollee with a minimum of 30 days' advance notice of disenrollment, regardless of the date of loss of special needs status.

(i) The advance notice must be provided to the enrollee within 10 calendar days of the plan learning of the loss of special needs status and must afford the enrollee an opportunity to prove that they are still eligible to remain in the plan.

(ii) The advance notice must include all of the following:

(A) The disenrollment effective date.

(B) A description of eligibility for the SEP described in § 422.62(b)(11).

(C) If applicable all of the following:

(*1*) Information regarding the period of deemed continued eligibility authorized by § 422.52(d).

(*2*) The duration of the period of deemed continued eligibility.

(*3*) The consequences of not regaining special needs status within the period of deemed continued eligibility.

(iii) A final notice of involuntary disenrollment must be sent as follows:

(A) Within 3 business days following the disenrollment effective date, which is either—

(*1*) The last day of the period of deemed continued eligibility, if applicable; or

(*2*) A minimum of 30 days after providing the advance notice of disenrollment.

(B) Before submission of the disenrollment to CMS.

(iv) The final notice of involuntary disenrollment must include an explanation of the enrollee's right to file a grievance under the MA organization's grievance procedures that are required by § 422.564.

(9) *Enrollee is not lawfully present in the United States.* Disenrollment is effective the first day of the month following notice by CMS that the individual is ineligible in accordance with § 417.422(h) of this chapter.

(10) *Mid-year change in MSA eligibility.* If an individual is no longer eligible for an MA MSA plan due to a mid-year change in eligibility, disenrollment is effective the first day of the calendar month following the MA organization's notice to the individual that they are ineligible in accordance with § 422.74(b)(2)(vi) of this section.

(e) *Consequences of disenrollment*—(1) *Disenrollment for non-payment of premiums, disruptive behavior, fraud or abuse, loss of Part A or Part B or mid-year loss of MSA eligibility.* An individual who is disenrolled under paragraph (b)(1)(i) through (iii), (b)(2)(ii) or (b)(2)(vi) of this section is deemed to have elected original Medicare.

(2) *Disenrollment based on plan termination, area reduction, or individual moves out of area.* (i) An individual who is disenrolled under paragraph (b)(2)(i) or (b)(3) of this section has a special election period in which to make a new election as provided in § 422.62(b)(1) and (b)(2).

(ii) An individual who fails to make an election during the special election period is deemed to have elected original Medicare.

[63 FR 35071, June 26, 1998; 63 FR 52612, Oct. 1, 1998, as amended at 65 FR 40318, June 29, 2000; 68 FR 50855, Aug. 22, 2003; 70 FR 4718, Jan. 28, 2005; 74 FR 1541, Jan. 12, 2009; 75 FR 19804, Apr. 15, 2010; 76 FR 21562, Apr. 15, 2011; 79 FR 29955, May 23, 2014; 80 FR 7959, Feb. 12, 2015; 89 FR 30816, Apr. 23, 2024; 89 FR 63826, Aug. 6, 2024]

Subpart C—Benefits and Beneficiary Protections

SOURCE: 63 FR 35077, June 26, 1998, unless otherwise noted.

§ 422.100 General requirements.

(a) *Basic rule.* Subject to the conditions and limitations set forth in this subpart, an MA organization offering an MA plan must provide enrollees in that plan with coverage of the basic benefits described in paragraph (c)(1) of this section (except that additional telehealth benefits may be, but are not required to be, offered by the MA plan) and, to the extent applicable, supplemental benefits as described in paragraph (c)(2) of this section, by furnishing the benefits directly or through arrangements, or by paying for the benefits. CMS reviews these benefits subject to the requirements of this section and the requirements in subpart G of this part.

(b) *Services of noncontracting providers and suppliers.* (1) An MA organization must make timely and reasonable payment to or on behalf of the plan enrollee for the following services obtained from a provider or supplier that does not contract with the MA organization to provide services covered by the MA plan:

(i) Ambulance services dispatched through 911 or its local equivalent as provided in § 422.113.

(ii) Emergency and urgently needed services as provided in § 422.113.

(iii) Maintenance and post-stabilization care services as provided in § 422.113.

(iv) Renal dialysis services provided while the enrollee was temporarily outside the plan's service area.

(v) Services for which coverage has been denied by the MA organization and found (upon appeal under subpart M of this part) to be services the enrollee was entitled to have furnished, or paid for, by the MA organization.

(2) An MA plan (and an MA MSA plan, after the annual deductible in § 422.103(d) has been met) offered by an MA organization satisfies paragraph (a) of this section with respect to benefits for services furnished by a noncontracting provider if that MA plan provides payment in an amount the provider would have received under original Medicare (including balance billing permitted under Medicare Part A and Part B).

(c) *Types of benefits.* An MA plan includes at a minimum basic benefits, and also may include mandatory and optional supplemental benefits.

(1) Basic benefits are all items and services (other than hospice care or, beginning in 2021, coverage for organ acquisitions for kidney transplants) for which benefits are available under Parts A and B of Medicare, including additional telehealth benefits offered consistent with the requirements at § 422.135.

(2) Supplemental benefits are benefits offered under § 422.102.

(i) Supplemental benefits consist of—

(A) Mandatory supplemental benefits are services not covered by Medicare that an MA enrollee must purchase as part of an MA plan that are paid for in full, directly by (or on behalf of) Medicare enrollees, in the form of premiums or cost sharing.

(B) Optional supplemental benefits are health services not covered by Medicare that are purchased at the option of the MA enrollee and paid for in full, directly by (or on behalf of) the Medicare enrollee, in the form of premiums or cost sharing. These services may be grouped or offered individually.

(ii) Supplemental benefits must meet the following requirements:

(A) Except in the case of special supplemental benefit for the chronically ill (SSBCI) offered in accordance with § 422.102(f) that are not primarily health related, the benefits diagnose, prevent, or treat an illness or injury; compensate for physical impairments; act to ameliorate the functional/psychological impact of injuries or health conditions; or reduce avoidable emergency and health care utilization;

(B) The MA organization incurs a non-zero direct medical cost, except that in the case of a SSBCI that is not primarily health related that is offered in accordance with § 422.102, the MA organization may instead incur a non-zero direct non-administrative cost; and

(C) The benefits are not covered by Medicare (This specifically includes Medicare Parts A, B, and D).

(d) *Availability and structure of plans.* An MA organization offering an MA plan must offer it—

(1) To all Medicare beneficiaries residing in the service area of the MA plan;

(2)(i) At a uniform premium, with uniform benefits and level of cost-sharing throughout the plan's service area, or segment of service area as provided in § 422.262(c)(2).

(ii) MA plans may provide supplemental benefits (such as specific reductions in cost sharing or additional services or items) that are tied to disease state or health status in a manner that ensures that similarly situated individuals are treated uniformly; there must be some nexus between the health status or disease state and the specific benefit package designed for enrollees meeting that health status or disease state.

(e) *Multiple plans in one service area.* An MA organization may offer more than one MA plan in the same service area subject to the conditions and limitations set forth in this subpart for each MA plan.

(f) *CMS review and approval of MA benefits and associated cost sharing.* CMS reviews and approves MA benefits and associated cost sharing using written policy guidelines and requirements in this part and other CMS instructions to ensure all of the following:

(1) *Guidelines.* Medicare-covered services meet CMS fee-for-service guidelines.

(2) *Discrimination.* MA organizations are not designing benefits to discriminate against beneficiaries, promote discrimination, discourage enrollment or encourage disenrollment, steer subsets of Medicare beneficiaries to particular MA plans, or inhibit access to services.

(3) *Other requirements.* Benefit design meets other MA program requirements.

(4) *In-network MOOP limit.* Except as provided in paragraph (f)(5) of this section, MA local plans (as defined in § 422.2) must have an enrollee in-network maximum out-of-pocket (MOOP) amount for basic benefits that is no greater than the annual limit calculated by CMS using Medicare Fee-for-Service (FFS) data projections. With respect to a private fee-for-service (PFFS) plan, the in-network MOOP limits specified in this paragraph (f)(4) apply. MA organizations are responsible for tracking out-of-pocket spending accrued by the enrollee, and must alert enrollees and contracted providers when the plan's in-network MOOP amount is reached.

(i) *Medicare FFS data projections in CMS MOOP limit calculations.* For each year beginning on or after January 1, 2023, CMS calculates three MOOP limits using Medicare FFS data projections. For purposes of this paragraph (f)(4) and calculating actuarially equivalent copayments as described in paragraph (f)(7) of this section, the term *Medicare FFS data projections* means the projections of beneficiary out-of-pocket costs for the applicable contract year, based on recent Medicare FFS data, including data for beneficiaries with and without diagnoses of ESRD, that are consistent with generally accepted actuarial principles and practices as outlined in paragraph (f)(7)(i) of this section. The dollar ranges for the three MOOP limits are as follows:

(A) *Mandatory MOOP limit.* One dollar above the intermediate MOOP limit and up to and including the mandatory MOOP limit.

(B) *Intermediate MOOP limit.* One dollar above the lower MOOP limit and up to and including the intermediate MOOP limit.

(C) *Lower MOOP limit.* Between $0.00 and up to and including the lower MOOP limit.

(ii) *MOOP type.* An MA organization that establishes a plan's MOOP amount within the dollar range specified in paragraphs (f)(4)(i)(A) through (C) of this section has the corresponding mandatory, intermediate, or lower MOOP type for purposes of paragraphs (f) and (j) of this section and §§ 422.101(d) and 422.113(b)(2)(v).

(iii) *CMS rounding of MOOP limits.* Each MOOP limit CMS calculates is rounded to the nearest $50 increment and in cases where the MOOP limit is projected to be exactly in between two $50 increments, CMS rounds to the lower $50 increment.

(iv) *MOOP limits for 2023.* For 2023, CMS calculates the MOOP limits as follows, applying paragraph (f)(4)(vi)(A) of this section:

(A) *Mandatory MOOP limit.* $7,175 (the 95th percentile of projected contract year 2021 Medicare FFS beneficiary out-of-pocket spending for beneficiaries without diagnoses of ESRD) plus 70 percent of the ESRD cost differential unless: The resulting MOOP limit (after application of the rounding rules in paragraph (f)(4)(iii) of this section) reflects an increase greater than 10 percent compared to the mandatory MOOP limit from the prior year, in which case CMS caps the increase to the mandatory MOOP limit by 10 percent of the prior year's MOOP limit.

(B) *Intermediate MOOP limit.* The numeric midpoint between the mandatory and lower MOOP limits (calculated before application of the rounding rules in paragraph (f)(4)(iii) of this section and after application of the 10 percent cap on increases to the mandatory and lower MOOP limits from the prior year in paragraphs (f)(4)(iv)(A) and (C) of this section).

(C) *Lower MOOP limit.* $3,360 (the 85th percentile of projected contract year 2021 Medicare FFS beneficiary out-of-pocket spending for beneficiaries without diagnoses of ESRD) plus 70 percent of the ESRD cost differential unless: The resulting MOOP limit (after application of the rounding rules in paragraph (f)(4)(iii) of this section) reflects an increase greater than 10 percent compared to the voluntary MOOP limit from the prior year, in which case CMS caps the increase to the lower MOOP limit by 10 percent of the prior year's MOOP limit.

(v) *MOOP limits for 2024 and subsequent years.* For 2024 and subsequent years, CMS annually calculates the MOOP limits as follows, applying paragraph (f)(4)(vi)(B) of this section:

(A) *Mandatory and lower MOOP limits.* The prior year's MOOP limits are increased or decreased for the upcoming contract year to reflect the applicable percentiles (95th for the mandatory MOOP and 85th for the lower MOOP) of the Medicare FFS data projections unless: Either of the resulting MOOP limits reflect an increase greater than 10 percent compared to the same type of MOOP limit from the prior year, in which case CMS caps the increase to the applicable MOOP limit(s) by 10 percent of the prior year's MOOP limit annually until the MOOP limit(s) reflects the applicable percentile(s).

(B) *Intermediate MOOP limit.* Is either maintained at the prior year's limit or if either the mandatory or lower MOOP limit changes from the prior year, updated to the new numeric midpoint between the mandatory and lower MOOP limits (calculated before application of the rounding rules in paragraph (f)(4)(iii) of this section and after application of the 10-percent cap on increases to the mandatory and lower MOOP limits from the prior year in paragraph (f)(4)(v)(A) of this section).

(vi) *CMS calculation of the ESRD cost differential.* For purposes of the ESRD cost transition methodology to calculate annual MOOP limits contained in this section, the *ESRD cost differential* is the difference between, first, for the mandatory MOOP limit, $7,175 and for the lower MOOP limit, $3,360 and second, for the mandatory MOOP limit, the 95th percentile and, for the lower MOOP limit, the 85th percentile of the Medicare FFS data projections for each year between 2023 and 2024. CMS transitions to using the Medicare FFS data projections by factoring in a percentage of the ESRD cost differential on the following schedule:

(A) For 2023, CMS uses projected Medicare FFS beneficiary out-of-pocket spending for beneficiaries without diagnoses of ESRD plus 70 percent of the ESRD cost differential.

(B) For 2024 and subsequent years, CMS uses the Medicare FFS data projections.

(5) *Combined MOOP limit.* With respect to a local PPO plan, the MOOP limits specified under paragraph (f)(4) of this section apply only to use of in-network providers.

(i) *Combined and total catastrophic MOOP limits.* MA local PPO plans must establish a combined enrollee MOOP amount for basic benefits that are provided in-network and out-of-network that is no greater than the total catastrophic limit applicable to regional plans in § 422.101(d)(3).

(ii) *In-network and combined MOOP type.* The type of in-network MOOP limit dictates the type of combined MOOP limit the MA plan may use. MA PPO plans must have the same MOOP

type (lower, intermediate, or mandatory) for the in-network MOOP limit and combined limit on in-network and out-of-network out-of-pocket expenditures.

(iii) *MOOP limit attainment.* MA organizations are responsible for tracking out-of-pocket spending accrued by the enrollee and must alert enrollees and contracted providers when the combined MOOP amount is reached.

(6) *General cost sharing limits.* Cost sharing for basic benefits specified by CMS does not exceed levels annually determined by CMS to be discriminatory for such services. For each year beginning on or after January 1, 2023, a MA organization must establish cost sharing for basic benefits that complies with the cost sharing limits in this paragraph (f)(6), paragraph (j) of this section, and § 422.113(b)(2), which are in addition to any other limits and rules applicable to MA cost sharing, including the requirement in § 422.254(b)(4) that overall MA cost sharing for basic benefits be actuarially equivalent to Medicare FFS cost sharing. Cost sharing may be a coinsurance or copayment; a cost sharing limit is calculated for a plan benefit package service category or for a reasonable group of benefits covered under the plan. For purposes of cost sharing evaluation, the analysis is completed at the plan (or segment) level. An MA plan must not charge an enrollee a copayment for a basic benefit that is greater than the cost of the covered service(s).

(i) *The 50 percent cap on original Medicare benefits.* For in-network basic benefits that are not specifically addressed in this paragraph (f)(6), paragraph (j)(1) of this section, or § 422.113(b)(2), and for out-of-network basic benefits, MA plans must not establish a cost sharing amount that exceeds 50 percent coinsurance or an actuarially equivalent copayment value (calculated by CMS following the requirements in paragraph (f)(7) of this section or, if CMS does not calculate a copayment limit, based on the average Medicare FFS allowable amount for the plan service area or the estimated total MA plan financial liability for the service category or for a reasonable group of benefits in the PBP for that contract year). The rules in this paragraph (f)(6)(i) apply regardless of the type of MOOP limit established by the plan.

(ii) *Copayment rounding rules.* The following rounding rules apply in calculating copayment limits and in evaluating compliance with this paragraph (f)(6) and paragraphs (f)(7), (f)(8), and (j)(1) of this section:

(A) For service categories subject to paragraph (f)(6)(i) of this section, professional services subject to paragraph (f)(6)(iii) of this section, and benefits listed in paragraph (j)(1)(i) of this section, the final actuarially equivalent copayment value is rounded to the nearest whole $5.

(B) For inpatient hospital acute and psychiatric and skilled nursing facility cost sharing limits subject to paragraphs (f)(6)(iv) and (j)(1)(i)(C) of this section, the final actuarially equivalent copayment value is rounded to the nearest whole $1.

(C) When the actuarially equivalent copayment value is projected to be exactly between two increments, the final figure is rounded to the lower dollar amount.

(iii) *Cost sharing limits for professional services.* (A) For in-network basic benefits that are professional services, including primary care services, physician specialist services, partial hospitalization, and rehabilitation services, an MA plan must not establish cost sharing that exceeds the limits in this paragraph (f)(6)(iii) for the MOOP limit established by the MA plan.

(B) When calculating copayment limits for purposes of this paragraph, CMS calculates an actuarially equivalent value to the coinsurance limits in this paragraph (f)(6)(iii), subject to the requirements in paragraph (f)(7) of this section and the restrictions on increases to copayment limits in paragraph (f)(8) of this section. If CMS does not calculate a copayment limit for a professional service category, the MA plan must not establish a copayment that exceeds the actuarially equivalent value to the coinsurance limits in this paragraph (f)(6)(iii) based on the estimated total MA plan financial liability for that benefit for that contract year.

(C) For 2023, MA plans must not exceed the cost sharing limits for professional service categories, as follows:

(*1*) *Mandatory MOOP limit.* 45 percent coinsurance or an actuarially equivalent copayment value and the MA plan must not pay less than 55 percent of the estimated total MA plan financial liability for the benefit.

(*2*) *Intermediate MOOP limit.* 47 percent coinsurance or an actuarially equivalent copayment value and the MA plan must not pay less than 53 percent of the estimated total MA plan financial liability for the benefit.

(*3*) *Lower MOOP limit.* 50 percent coinsurance or an actuarially equivalent copayment value and the MA plan must not pay less than 50 percent of the estimated total MA plan financial liability.

(D) For 2024, MA plans must not exceed the cost sharing limits for professional service categories, as follows:

(*1*) *Mandatory MOOP limit.* 40 percent coinsurance or an actuarially equivalent copayment value and the MA plan must not pay less than 60 percent of the estimated total MA plan financial liability for the benefit.

(*2*) *Intermediate MOOP limit.* 45 percent coinsurance or an actuarially equivalent copayment value and the MA plan must not pay less than 55 percent of the estimated total MA plan financial liability for the benefit.

(*3*) *Lower MOOP limit.* 50 percent coinsurance or an actuarially equivalent copayment value and the MA plan must not pay less than 50 percent of the estimated total MA plan financial liability.

(E) For 2025, MA plans must not exceed the cost sharing limits for professional service categories, as follows:

(*1*) *Mandatory MOOP limit.* 35 percent coinsurance or an actuarially equivalent copayment value and the MA plan must not pay less than 65 percent of the estimated total MA plan financial liability for the benefit.

(*2*) *Intermediate MOOP limit.* 42 percent coinsurance or an actuarially equivalent copayment value and the MA plan must not pay less than 58 percent of the estimated total MA plan financial liability for the benefit.

(*3*) *Lower MOOP limit.* 50 percent coinsurance or an actuarially equivalent copayment value and the MA plan must not pay less than 50 percent of the estimated total MA plan financial liability.

(F) For 2026 and subsequent years, MA plans must not exceed the cost sharing limits for professional service categories, as follows:

(*1*) *Mandatory MOOP limit.* 30 percent coinsurance or an actuarially equivalent copayment value and the MA plan must not pay less than 70 percent of the estimated total MA plan financial liability for the benefit.

(*2*) *Intermediate MOOP limit.* 40 percent coinsurance or an actuarially equivalent copayment value and the MA plan must not pay less than 60 percent of the estimated total MA plan financial liability for the benefit.

(*3*) *Lower MOOP limit.* 50 percent coinsurance or an actuarially equivalent copayment value and the MA plan must not pay less than 50 percent of the estimated total MA plan financial liability.

(iv) *Inpatient hospital acute and psychiatric service category cost sharing limits.* (A) For in-network basic benefits that are inpatient hospital acute and psychiatric service categories, an MA plan must not establish cost sharing that exceeds the limits calculated by CMS under paragraph (f)(6)(iv) of this section and subject to paragraph (f)(7) of this section for the MOOP limit established by the MA plan.

(B) Cost sharing limits for inpatient hospital acute and psychiatric service categories are calculated for the following seven length-of-stay scenarios for a period for which cost sharing would apply under original Medicare: Inpatient hospital acute stay scenarios of 3 days, 6 days, 10 days, and 60 days and inpatient hospital psychiatric stay scenarios of 8 days, 15 days, and 60 days.

(C) CMS calculates the inpatient hospital acute and psychiatric service category cost sharing limits annually using projections of Medicare FFS out-of-pocket costs and utilization for the applicable year and length of stay scenario and factors in out-of-pocket costs incurred by beneficiaries with diagnoses of ESRD on the transition schedule described in paragraphs (f)(4)(vi)(A) through (B) of this section and may also use patient utilization information from MA encounter data.

(D) Provided that the total cost sharing for the inpatient benefit does not exceed the MA plan's MOOP limit or overall cost sharing for inpatient benefits in original Medicare on a per member per month actuarially equivalent basis, cost sharing applicable to inpatient hospital acute and psychiatric service categories is permitted up to the following limits (based on original Medicare cost sharing for a new benefit period):

(*1*) *Mandatory MOOP limit.* Cost sharing must not exceed 100 percent of estimated Medicare FFS cost sharing, including the projected Part A deductible and related Part B costs, for each length-of-stay scenario.

(*2*) *Intermediate MOOP limit.* Cost sharing must not exceed the numeric midpoint between the cost sharing limits established in paragraphs (f)(6)(iv)(D)(*1*) and (*3*) of this section for the same inpatient hospital length of stay scenario, before application of the rounding rules in paragraph (f)(6)(ii) of this section.

(*3*) *Lower MOOP limit.* Cost sharing must not exceed 125 percent of estimated Medicare FFS cost sharing, including the projected Part A deductible and related Part B costs, for each length of stay scenario other than the inpatient hospital acute 60-day length-of-stay for MA plans that establish a lower MOOP limit. For inpatient hospital acute 60-day length of stays, MA plans that establish a lower MOOP limit have the flexibility to establish cost sharing above 125 percent of estimated Medicare FFS cost sharing.

(7) *Using generally accepted actuarial principles and practices.* (i) *Application of generally accepted actuarial principles and practices.* The projections and calculations used in the methodologies described in paragraphs (f)(4), (f)(5), (f)(6), (f)(7)(ii), (f)(8), and (j) of this section and in § 422.101(d)(2) and (3) must be made using generally accepted actuarial principles and practices.

(A) In applying generally accepted actuarial principles and practices, actuarial judgment and discretion may be used, including taking into account information such as changes in legislation (such as changes in Medicare benefits), Medicare payment policy, trends over several years of data, and external variables (such as public health emergencies); selecting among different approaches (such as weighting for utilization and using average or median values); and in selecting data or data samples.

(B) MA organizations must use generally accepted actuarial principles and practices in complying with the regulations in paragraphs (f)(6) and (j) of this section.

(C) CMS applies generally accepted actuarial principles and practices in evaluating MA plan compliance with paragraphs (f)(6) and (j) of this section.

(ii) *CMS calculation of actuarially equivalent copayment limits.* As feasible and appropriate to carry out program purposes, CMS calculates copayment limits for basic benefits in accordance with paragraphs (f)(6)(i) and (iii) and (j)(1) of this section. Beginning January 1, 2023, unless specified otherwise in paragraphs (f)(6) and (j)(1) of this section, CMS calculates these copayment limits at an actuarially equivalent value to the cost sharing standard as follows:

(A) Using Medicare FFS data projections, as defined in paragraph (f)(4)(i) of this section, for the applicable year and service category.

(B) Using patient utilization information from MA encounter data, in addition to the Medicare FFS data projections (including cost and utilization data), if available and where appropriate to consider utilization differences between Medicare FFS beneficiaries and MA enrollees to reach a value that most closely reflects an actuarially equivalent copayment for the benefit and beneficiary population.

(C) Selecting a particular approach to calculate an actuarially equivalent copayment value in situations where there may be multiple or a range of actuarially equivalent copayment values for a service category in order to carry out program purposes, including: Setting copayment limits that most closely reflect an actuarially equivalent copayment for the benefit and beneficiary population, protecting against discriminatory cost sharing, and avoiding unnecessary fluctuations in cost sharing that may confuse beneficiaries.

(D) Applying the actuarially equivalent copayment transition in paragraph (f)(8) of this section.

(E) Applying rounding rules in paragraph (f)(6)(ii) of this section.

(iii) *CMS issuance of annual guidance.* CMS issues guidance that specifies the MOOP limits and cost sharing standards for the upcoming contract year (beginning with contract year 2024) that are set and calculated using the methodology and standards in paragraphs (f) and (j) of this section and §§ 422.101(d) and 422.113. This guidance is released prior to bid submission to allow sufficient time for MA organizations to prepare and submit plan bids. Unless a public comment period is impracticable, unnecessary, or contrary to the public interest, CMS provides a public notice and comment period on the projected MOOP limits and cost sharing standards for the upcoming contract year.

(8) *Annual cap on CMS increasing copayment limits during the actuarially equivalent copayment transition.* For 2023 through 2025, CMS sets a copayment limit for a service category subject to paragraph (f)(6)(iii) or (j)(1) of this section at an amount that is the lesser of an actuarially equivalent value to the applicable cost sharing standard (from paragraph (f)(6)(iii) or (j)(1) of this section) or the value resulting from the actuarially equivalent copayment transition in paragraph (f)(8)(ii) of this section for that service category.

(i) CMS *calculation of the actuarially equivalent copayment differential.* For purposes of this section, the actuarially equivalent copayment differential is as follows:

(A) For cost sharing at the mandatory and lower MOOP limits, the difference between, first, the copayment limit set for a plan benefit package service category based on the MOOP type for 2022 and second, the copayment value for the same service category that is actuarially equivalent to the coinsurance limits in paragraphs (f)(6)(iii) and (j)(1) of this section that apply in 2026 based on the MOOP type, using the Medicare FFS data projections that are updated each year to reflect the costs of the contract year for which the copayment limit will apply.

(B) For cost sharing at the intermediate MOOP limit, the difference between, first, the copayment limit set for a plan benefit package service category based on the mandatory MOOP type for 2022 and second, the copayment value for the same service category that is actuarially equivalent to the coinsurance limits in paragraphs (f)(6)(iii) and (j)(1) of this section that apply in 2026 for the intermediate MOOP type, using the Medicare FFS data projections that are updated each year to reflect the costs of the contract year for which the copayment limit will apply.

(ii) *CMS's actuarially equivalent copayment transition.* For service categories subject to the cost sharing standards in paragraphs (f)(6)(iii) and (j)(1) of this section, copayment limits calculated by CMS for 2023 through 2025 are capped at the amounts calculated under this paragraph, unless specified otherwise in paragraph (f)(8) of this section, rounded as provided in paragraph (f)(6)(ii) of this section:

(A) For 2023, CMS uses the copayment limits set for 2022 plus 25 percent of the actuarially equivalent copayment differential.

(B) For 2024, CMS uses the copayment limits set for 2022 plus 50 percent of the actuarially equivalent copayment differential.

(C) For 2025, CMS uses the copayment limits set for 2022 plus 75 percent of the actuarially equivalent copayment differential.

(D) For 2026 and subsequent years, CMS calculates service category copayment limits at the projected actuarially equivalent value to the cost sharing standards in paragraphs (f)(6)(iii)(F) and (j)(1) of this section and subject to paragraph (f)(7) of this section.

(9) *Bundled cost sharing.* Cost sharing (copayments and coinsurance) for basic benefits must reflect the enrollee's entire cost sharing responsibility, inclusive of professional, facility, or provider setting charges, by combining (or bundling) all applicable fees into the cost sharing amount for that particular service(s) and setting(s) and be clearly reflected as a single, total cost

sharing in appropriate materials distributed to beneficiaries for basic benefits.

(g) *Benefits affecting screening mammography, influenza vaccine, and pneumoccal vaccine.* (1) Enrollees of MA organizations may directly access (through self-referral) screening mammography and influenza vaccine.

(2) MA organizations may not impose cost-sharing for influenza vaccine and pneumococcal vaccine on their MA plan enrollees.

(h) *Requirements relating to Medicare conditions of participation.* Basic benefits must be furnished through providers meeting the requirements in § 422.204(b)(3).

(i) *Provider networks.* The MA plans offered by an MA organization may share a provider network as long as each MA plan independently meets the access and availability standards described at § 422.112, as determined by CMS.

(j) *Cost sharing and actuarial equivalence standards for basic benefits*—(1) *Specific benefits for which cost sharing may not exceed cost sharing under original Medicare.* (i) *General rule.* For each year beginning on or after January 1, 2023, in-network cost sharing established by an MA plan for the basic benefits listed in this paragraph may not exceed the cost sharing required under original Medicare. When an MA plan uses coinsurance, the coinsurance must not exceed the coinsurance charged in original Medicare. When an MA plan uses copayments, the copayment must not exceed the actuarially equivalent value calculated using the rules in paragraph (j)(1)(ii) of this section. The benefits listed in this paragraph are as follows:

(A) Chemotherapy administration services to include chemotherapy/radiation drugs and radiation therapy integral to the treatment regimen.

(B) Renal dialysis services as defined at section 1881(b)(14)(B) of the Act.

(C) Skilled nursing care, defined as services provided during a covered stay in a skilled nursing facility during the period for which cost sharing would apply under original Medicare, when the MA plan establishes the mandatory MOOP type; when the MA plan establishes the lower MOOP type, the cost sharing must not be greater than $20 per day for the first 20 days of a SNF stay; when the MA plan establishes the intermediate MOOP type, the cost sharing must not be greater than $10 per day for the first 20 days of a SNF stay.

(1) Regardless of the MOOP amount established by the MA plan, the per-day cost sharing for days 21 through 100 must not be greater than one eighth of the projected (or actual) Part A deductible amount.

(2) Total cost sharing for the overall SNF benefit must not be greater than the per member per month actuarially equivalent cost sharing for the SNF benefit in original Medicare.

(D) Home health services (as defined in section 1861(m) of the Act), when the MA plan establishes a mandatory or intermediate MOOP type; when the MA plan establishes the lower MOOP type, the cost sharing must not be greater than 20 percent coinsurance or an actuarially equivalent copayment.

(E) The following specific service categories of durable medical equipment (DME): Equipment, prosthetics, medical supplies, diabetes monitoring supplies, diabetic shoes or inserts when the MA plan establishes the mandatory MOOP limit. For all MOOP limits, total cost sharing for the overall DME benefit must not be greater than the per member per month actuarially equivalent cost sharing for the DME benefit in original Medicare.

(F) Other drugs covered under Part B of original Medicare (that is, Part B drugs not included in paragraph (j)(1)(i)(A) of this section).

(ii) *Rules for calculating copayment limits.* For 2023 and subsequent years, CMS calculates copayment limits for the basic benefits listed in paragraph (j)(1)(i) of this section subject to the requirements in paragraph (f)(7) of this section and the restrictions on increases to copayment limits in paragraph (f)(8) of this section. If CMS does not calculate a copayment limit for a benefit listed in paragraph (j)(1)(i) of this section, an MA plan must establish a copayment that does not exceed an actuarially equivalent value to the coinsurance required under original Medicare; such actuarially equivalent

value must be established in accordance with paragraph (f)(7)(i) of this section and based on the average Medicare FFS allowed amount in the plan's service area or the estimated total MA plan financial liability for that benefit for that contract year.

(2) *Actuarially equivalent cost sharing evaluation for all basic benefits and specific categories of basic benefits in the aggregate.* For each year beginning on or after January 1, 2023, an MA plan's total cost sharing for all basic benefits, excluding out of network benefits covered by a regional MA plan, must not exceed cost sharing for those benefits in original Medicare on a per member per month actuarially equivalent basis.

(i) MA plans must have cost sharing for the following specific benefit categories that does not exceed the cost sharing for those benefit categories in original Medicare on a per member per month actuarially equivalent basis:

(A) Inpatient hospital acute and psychiatric services, defined as services provided during a covered inpatient stay during the period for which cost sharing would apply under original Medicare.

(B) Durable medical equipment (DME).

(C) Drugs and biologics covered under Part B of original Medicare.

(D) Skilled nursing care, defined as services provided during a covered stay in a skilled nursing facility during the period for which cost sharing would apply under original Medicare.

(ii) CMS may extend flexibility for MA plans when evaluating compliance with the requirements in paragraph (j)(2)(i) of this section regarding actuarial equivalent cost sharing for all basic benefits and specific categories of basic benefits to the extent that it is actuarially justifiable provided that the MA plan's cost sharing is based on generally accepted actuarial principles and practices (consistent with paragraph (f)(7) of this section), supporting documentation included in the bid, and the MA plan's cost sharing for specific service categories otherwise satisfies applicable cost sharing standards.

(k) *Cost sharing for in-network preventive services.* MA organizations may not charge deductibles, copayments, or coinsurance for in-network Medicare-covered preventive services (as defined in § 410.152(l)).

(l) Coverage of DME. MA organizations—

(1) Must cover and ensure enrollees have access to all categories of DME covered under Part B; and

(2) May, within specific categories of DME, limit coverage to certain DME brands, items, and supplies of preferred manufacturers provided the MA organization ensures all of the following:

(i) Its contracts with DME suppliers ensure that enrollees have access to all DME brands, items, and supplies of preferred manufacturers.

(ii) Its enrollees have access to all medically-necessary DME brands, items, and supplies of non-preferred manufacturers.

(iii) At the enrollees' request, it provides for an appropriate transition process for new enrollees during the first 90 days of their coverage under its MA plan, during which time the MA organization will do the following:

(A) Ensure the provision of a transition supply of DME brands, items, and supplies of non-preferred manufacturers.

(B) Provide for the repair of DME brands, items, and supplies of non-preferred manufacturers.

(iv) It makes no negative changes to its DME brands, items, and supplies of preferred manufacturers during the plan year.

(v) It treats denials of DME brands, items, and supplies of non-preferred manufacturers as organization determinations subject to § 422.566.

(vi) It discloses DME coverage limitations and beneficiary appeal rights in the case of a denial of a DME brand, item, or supply of a non-preferred manufacturer as part of the description of benefits required under § 422.111(b)(2) and § 422.111(h).

(vii) It provides full coverage, without limitation on brand and manufacturer, to all DME categories or subcategories annually determined by CMS to require full coverage.

(m) *Special requirements during a disaster or emergency.* (1) When a disaster or emergency is declared as described in paragraph (m)(2) of this section and there is disruption of access to health care as described in paragraph (m)(6) of

this section, an MA organization offering an MA plan must, until the end date specified in paragraph (m)(3) of this section occurs, ensure access to covered benefits in the following manner:

(i) Cover Medicare Parts A and B services and supplemental Part C plan benefits furnished at non-contracted facilities subject to § 422.204(b)(3).

(ii) Waive, in full, requirements for gatekeeper referrals where applicable.

(iii) Provide the same cost-sharing for the enrollee as if the service or benefit had been furnished at a plan-contracted facility.

(iv) Make changes that benefit the enrollee effective immediately without the 30-day notification requirement at § 422.111(d)(3).

(2) *Declarations of disasters.* A declaration of a disaster or emergency will identify the geographic area affected by the event and may be made as one of the following:

(i) Presidential declaration of a disaster or emergency under the either of the following:

(A) Stafford Act.

(B) National Emergencies Act.

(ii) Secretarial declaration of a public health emergency under section 319 of the Public Health Service Act.

(iii) Declaration by the Governor of a State or Protectorate.

(3) *End of the special requirements for the disaster or emergency.* An MA organization must continue furnishing access to benefits as specified in paragraphs (m)(1)(i) through (iv) of this section for 30 days after the conditions described in paragraph (m)(3)(i) or (ii) of this section occur with respect to all applicable emergencies or after the condition described in paragraph (m)(3)(iii) of this section occurs, whichever is earlier:

(i) All sources that declared a disaster or emergency that include the service area declare an end.

(ii) No end date was identified as described in paragraph (m)(3)(i) of this section, and all applicable emergencies or disasters declared for the area have ended, including through expiration of the declaration or any renewal of such declaration.

(iii) There is no longer a disruption of access to health care as defined in paragraph (m)(6) of this section.

(4) *MA plans unable to operate.* An MA plan that cannot resume normal operations by the end of the disaster or emergency as described in paragraph (m)(3)(i) or (ii) of this section must notify CMS.

(5) *Disclosure.* In addition to other requirements of annual disclosure under § 422.111, an organization must do all of the following:

(i) Indicate the terms and conditions of payment during the disaster or emergency for non-contracted providers furnishing benefits to plan enrollees residing in the affected service area(s).

(ii) Annually notify enrollees of the information listed in paragraphs (m)(1) through (3) and (m)(5) of this section.

(iii) Provide the information described in paragraphs (m)(1), (2), and (3) and (m)(5)(i) of this section on its website.

(6) *Disruption of access to health care.* A disruption of access to health care for the purpose of paragraph (m) of this section is an interruption or interference in the service area (as defined at § 422.2) such that enrollees do not have the ability to access contracted providers or contracted providers do not have the ability to provide needed services to enrollees, resulting in MA plans failing to meet the normal prevailing patterns of community health care delivery in the service area under § 422.112(a).

(n) *Digital health education program.* MA organizations must establish procedures to identify and offer digital health education to enrollees with low digital health literacy to assist with accessing any medically necessary covered benefits that are furnished when the enrollee and the provider are not in the same location using electronic exchange, as defined in § 422.135.

(1) The MA organization must make information about its digital health literacy screening and digital health education programs available to CMS upon request. Requested information may include, but is not limited to, statistics on the number of enrollees identified with low digital health literacy and receiving digital health education,

manner(s) or method of digital health literacy screening and digital health education, financial impact of the programs on the MA organization, evaluations of effectiveness of digital health literacy interventions, and demonstration of compliance with the requirements of this section.

(2) [Reserved]

(o) *Cost sharing standards for D–SNP PPOs.* Beginning on or after January 1, 2026, an MA organization offering a local PPO plan or regional PPO plan that is a dual eligible special needs plan must establish cost sharing for out-of-network services that—

(1) Complies with the limits described in paragraph (f)(6) of this section with the exception that references to the MOOP amounts refer to the total catastrophic limits under § 422.101(d)(3) for local PPOs and MA regional plans; and

(2) Complies with the limits described in paragraph (j)(1) of this section with the exception that references to the MOOP amounts refer to the total catastrophic limits under § 422.101(d)(3) for local PPOs and MA regional plans and, for regional PPO dual eligible special needs plans, excluding paragraph (j)(1)(i)(C)(*2*) and the last sentence of paragraph (j)(1)(i)(E) of this section.

[65 FR 40319, June 29, 2000, as amended at 67 FR 13288, Mar. 22, 2002; 70 FR 4719, Jan. 28, 2005; 70 FR 52026, Sept. 1, 2005; 75 FR 19804, Apr. 15, 2010; 76 FR 21562, Apr. 15, 2011; 77 FR 22166, Apr. 12, 2012; 80 FR 7959, Feb. 12, 2015; 83 FR 16724, Apr. 16, 2018; 84 FR 15828, Apr. 16, 2019; 86 FR 6094, Jan. 19, 2021; 87 FR 22423, Apr. 14, 2022; 87 FR 27893, May 9, 2022; 88 FR 22328, Apr. 12, 2023; 89 FR 30817, Apr. 23, 2024]

§ 422.101 Requirements relating to basic benefits.

Except as specified in § 422.318 (for entitlement that begins or ends during a hospital stay) and § 422.320 (with respect to hospice care), each MA organization must meet the following requirements:

(a) Provide coverage of, by furnishing, arranging for, or making payment for, all services that are covered by Part A and Part B of Medicare (if the enrollee is entitled to benefits under both parts) or by Medicare Part B (if entitled only under Part B) and that are available to beneficiaries residing in the plan's service area. Services may be provided outside of the service area of the plan if the services are accessible and available to enrollees.

(b) Comply with—

(1) CMS's national coverage determinations;

(2) General coverage and benefit conditions included in Traditional Medicare laws, unless superseded by laws applicable to MA plans. This includes criteria for determining whether an item or service is a benefit available under Traditional Medicare. For example, this includes payment criteria for inpatient admissions at 42 CFR 412.3, services and procedures that the Secretary designates as requiring inpatient care under 42 CFR 419.22(n), and requirements for payment of Skilled Nursing Facility (SNF) Care, Home Health Services under 42 CFR part 409, and Inpatient Rehabilitation Facilities (IRF) at 42 CFR 412.622(a)(3).

(3) Written coverage decisions of local Medicare contractors with jurisdiction for claims in the geographic area in which services are covered under the MA plan. If an MA plan covers geographic areas encompassing more than one local coverage policy area, the MA organization offering such an MA plan may elect to apply to plan enrollees in all areas uniformly the coverage policy that is the most beneficial to MA enrollees. MA organizations that elect this option must notify CMS before selecting the area that has local coverage policies that are most beneficial to enrollees as follows:

(i) An MA organization electing to adopt a uniform local coverage policy for a plan or plans must notify CMS at least 60 days before the date specified in § 422.254(a)(1), which is 60 days before the date bid amounts are due for the subsequent year. Such notice must identify the plan or plans and service area or services areas to which the uniform local coverage policy or policies will apply, the competing local coverage policies involved, and a justification explaining why the selected local coverage policy or policies are most beneficial to MA enrollees.

(ii) CMS will review notices provided under paragraph (b)(3)(i) of this section, evaluate the selected local coverage policy or policies based on such factors as cost, access, geographic distribution of enrollees, and health status of enrollees, and notify the MA organization of its approval or denial of the selected uniform local coverage policy or policies.

(4) Instead of applying rules in paragraph (b)(3)(ii) of this section, and to the extent it exercises this option, an organization offering an MA regional plan in an MA region that covers more than one local coverage policy area must uniformly apply all of the local coverage policy determinations that apply in the selected local coverage policy area in that MA region to all parts of that same MA region. The selection of the single local coverage policy area's local coverage policy determinations to apply throughout the MA region is at the discretion of the MA regional plan and is not subject to CMS pre-approval.

(5) If an MA organization offering an MA local plan elects to exercise the option in paragraph (b)(3) of this section related to a local MA plan, or if an MA organization offering an MA regional plan elects to exercise the option in paragraph (b)(4) of this section related to an MA regional plan, then the MA organization must make information on the selected local coverage policy readily available, including through the Internet, to enrollees and health care providers.

(6) MA organizations may create publicly accessible internal coverage criteria that are based on current evidence in widely used treatment guidelines or clinical literature when coverage criteria are not fully established in applicable Medicare statutes, regulations, NCDs or LCDs. Current, widely-used treatment guidelines are those developed by organizations representing clinical medical specialties, and refers to guidelines for the treatment of specific diseases or conditions. Acceptable clinical literature includes large, randomized controlled trials or prospective cohort studies with clear results, published in a peer-reviewed journal, and specifically designed to answer the relevant clinical question, or large systematic reviews or meta-analyses summarizing the literature of the specific clinical question.

(i) *Coverage criteria not fully established.* Coverage criteria are not fully established when:

(A) additional, unspecified criteria are needed to interpret or supplement general provisions in order to determine medical necessity consistently. The MA organization must demonstrate that the additional criteria provide clinical benefits that are highly likely to outweigh any clinical harms, including from delayed or decreased access to items or services;

(B) NCDs or LCDs include flexibility that explicitly allows for coverage in circumstances beyond the specific indications that are listed in an NCD or LCD; or

(C) There is an absence of any applicable Medicare statutes, regulations, NCDs or LCDs setting forth coverage criteria.

(ii) *Publicly accessible.* For internal coverage policies, the MA organization must provide in a publicly accessible way the following:

(A) The internal coverage criteria in use and a summary of evidence that was considered during the development of the internal coverage criteria used to make medical necessity determinations;

(B) A list of the sources of such evidence; and

(C) An explanation of the rationale that supports the adoption of the coverage criteria used to make a medical necessity determination. When coverage criteria are not fully established as described in paragraph (6)(i)(A), the MA organization must identify the general provisions that are being supplemented or interpreted and explain how the additional criteria provide clinical benefits that are highly likely to outweigh any clinical harms, including from delayed or decreased access to items or services.

(c) Medical necessity determinations and special coverage provisions—(1) *Medical necessity determinations.* (i) MA organizations must make medical necessity determinations based on all of the following:

(A) Coverage and benefit criteria as specified at paragraphs (b) and (c) of

this section and may not deny coverage for basic benefits based on coverage criteria not specified in paragraph (b) or (c) of this section.

(B) Whether the provision of items or services is reasonable and necessary under section 1862(a)(1) of the Act.

(C) The enrollee's medical history (for example, diagnoses, conditions, functional status), physician recommendations, and clinical notes.

(D) Where appropriate, involvement of the organization's medical director as required at § 422.562(a)(4).

(ii) [Reserved]

(2) *Exception for qualifying hospital stay.* MA organizations may elect to furnish, as part of their Medicare covered benefits, coverage of posthospital SNF care as described in subparts C and D of this part, in the absence of the prior qualifying hospital stay that would otherwise be required for coverage of this care.

(d) *Special cost-sharing rules for MA regional plans.* In addition to the requirements in paragraph (a) through paragraph (c) of this section, MA regional plans must provide for the following:

(1) *Single deductible.* MA regional and local PPO plans, to the extent they apply a deductible as follows:

(i) Must have a single deductible related to all in-network and out-of-network Medicare Part A and Part B services.

(ii) May specify separate deductible amounts for specific in-network Medicare Part A and Part B services, to the extent these deductible amounts apply to the single deductible amount specified in paragraph (d)(1)(i) of this section.

(iii) May waive other plan-covered items and services from the single deductible described in paragraph (d)(1)(i) of this section.

(iv) Must waive all Medicare-covered preventive services (as defined in § 410.152(l)) from the single deductible described paragraph (d)(1)(i) of this section.

(2) *Catastrophic limit.* For each year beginning on or after January 1, 2023, MA regional plans must do the following:

(i) Establish a catastrophic enrollee MOOP amount for basic benefits that are furnished by in-network providers that is consistent with § 422.100(f)(4).

(ii) Have the same MOOP type (lower, intermediate, or mandatory) for the catastrophic (in-network MOOP) limit and total catastrophic (combined in-network and out-of-network expenditures) limit under paragraph (d)(3) of this section.

(3) *Total catastrophic limit.* For each year beginning on or after January 1, 2023, MA regional plans must establish a total catastrophic (combined in-network and out-of-network expenditures) enrollee MOOP amount for basic benefits that is consistent with this paragraph (d)(3).

(i) The total catastrophic limit may not be used to increase the catastrophic limit described in paragraph (d)(2) of this section.

(ii) CMS calculates the total catastrophic limits by multiplying the respective in-network MOOP limits (before the rounding rules in § 422.100(f)(4)(iii) are applied and after application of the 10 percent cap on increases to the mandatory and lower MOOP limits from the prior year in § 422.100(f)(4)(iv) and (v)) by 1.5 for the relevant year, then applying the rounding rules in § 422.100(f)(4)(iii). The dollar ranges for the three total catastrophic MOOP limits are as follows:

(A) *Mandatory MOOP limit.* One dollar above the in-network intermediate MOOP limit and up to and including the total catastrophic mandatory MOOP limit.

(B) *Intermediate MOOP limit.* One dollar above the in-network lower MOOP limit and up to and including the total catastrophic intermediate MOOP limit.

(C) *Lower MOOP limit.* Between $0.00 and up to and including the total catastrophic lower MOOP limit.

(iii) An MA organization must establish the total catastrophic MOOP amount (mandatory, intermediate, or lower) within the dollar range specified in paragraphs (d)(3)(ii)(A) through (C) of this section for purposes of paragraph (d) of this section and §§ 422.100(f)(6), (j)(1), and 422.113(b)(2)(v).

(4) *Tracking of deductible and catastrophic limits and notification.* MA regional plans are required to track the deductible (if any) and catastrophic limits in paragraphs (d)(1) through (3)

of this section based on accrued out-of-pocket beneficiary costs for original Medicare covered services, and are also required to notify members and health care providers when the deductible (if any) or a limit has been reached.

(e) *Other rules for MA regional plans.* (1) MA regional plans are required to provide reimbursement for all covered benefits, regardless of whether those benefits are provided within or outside of the network of contracted providers.

(2) In applying the actuarially equivalent level of cost-sharing with respect to MA bids related to benefits under the original Medicare program option as set forth at § 422.256(b)(3), only the catastrophic limit on out-of-pocket expenses for in-network benefits in paragraph (d)(2) of this section will be taken into account.

(f) *Special needs plan model of care.*

(1) MA organizations offering special needs plans (SNP) must implement an evidence-based model of care with appropriate networks of providers and specialists designed to meet the specialized needs of the plan's targeted enrollees. The MA organization must, with respect to each individual enrolled, do all of the following:

(i) Within 90 days (before or after) of the effective date of enrollment for all new enrollees, conduct a comprehensive initial health risk assessment (HRA).

(ii) Conduct a comprehensive annual HRA.

(iii) Use a comprehensive risk assessment tool that CMS may review during oversight activities that meet both of the following:

(A) Assesses the enrollee's physical, psychosocial, and functional needs.

(B) Includes one or more questions from a list of screening instruments specified by CMS in subregulatory guidance on each of the following domains:

(*1*) Housing stability.

(*2*) Food security.

(*3*) Access to transportation.

(iv) Must do all of the following:

(A) Make at least three attempts to reach the enrollee (not including any automated phone calls), unless an enrollee agrees or declines to participate in the HRA before three attempts are made, on different days at different times of day to reach the enrollee to schedule the comprehensive initial or annual HRA.

(B) If the enrollee has not responded, send a follow-up letter to conduct the initial or annual HRA.

(C) For any enrollees who are unable to be reached or decline to participate in the HRA, document the attempts to contact the enrollee and, if applicable, the enrollee's choice not to participate.

(v) For D–SNPs that are applicable integrated plans (as defined in § 422.561), conduct a comprehensive HRA that meets all requirements at paragraphs (f)(1)(i) through (iv) of this section and Medicaid requirements at § 438.208(b)(3) of this chapter, such that enrollees complete a single integrated assessment for Medicare and Medicaid, beginning no later than contract year 2027.

(vi) Ensure that the results from the comprehensive initial and annual HRA conducted for each enrollee are addressed in the enrollee's individualized care plan as required under paragraph (f)(1)(vii) of this section.

(vii) Within 90 days of conducting a comprehensive initial HRA or 90 days after the effective date of enrollment, whichever is later, develop a comprehensive individualized plan of care that meets all of the following:

(A) Is person-centered and based on the enrollee's preferences, including for delivery of services and benefits, and their needs identified in the HRA.

(B) Is developed through an interdisciplinary care team with the active participation of the enrollee (or the enrollee's representative, as applicable), as feasible.

(C) Identifies person-centered goals and objectives (as prioritized by the enrollee), including measurable outcomes as well as specific services and benefits to be provided.

(D) Is updated as warranted by changes in the health status or care transitions of enrollees.

(viii) For any enrollees who are unable to be reached or decline to participate in the development or updates to the comprehensive individualized plan of care, document the attempts to contact the enrollee or the enrollee's refusal to participate.

(ix) In the management of care, use an interdisciplinary team that includes a team of providers with demonstrated expertise and training, and, as applicable, training in a defined role appropriate to their licensure in treating individuals similar to the targeted population of the plan.

(x) Provide, on at least an annual basis, beginning within the first 12 months of enrollment, as feasible and with the enrollee's consent, for face-to-face encounters for the delivery of health care or care management or care coordination services and be between each enrollee and a member of the enrollee's interdisciplinary team or the plan's case management and coordination staff, or contracted plan healthcare providers. A face-for-face encounter must be either in person or through a visual, real-time, interactive telehealth encounter.

(2) MA organizations offering SNPs must also develop and implement the following model of care components to assure an effective care management structure:

(i) Target one of the three SNP populations defined in §422.2 of this part.

(ii) Have appropriate staff (employed, contracted, or non-contracted) trained on the SNP plan model of care to coordinate and/or deliver all services and benefits.

(iii) Coordinate the delivery of care across healthcare settings, providers, and services to assure continuity of care.

(iv) Coordinate the delivery of specialized benefits and services that meet the needs of the most vulnerable beneficiaries among the three target special needs populations as defined in §422.2 of this part, including frail/disabled beneficiaries and beneficiaries near the end of life.

(v) Coordinate communication among plan personnel, providers, and beneficiaries.

(vi) For I–SNPs, ensure that contracts with long-term care institutions (listed in the definition of the term institutionalized in §422.2) contain requirements allowing I–SNP clinical and care coordination staff access to enrollees of the I–SNP who are institutionalized.

(3)(i) All MA organizations wishing to offer or continue to offer a SNP will be required to be approved by the National Committee for Quality Assurance (NCQA) effective January 1, 2012 and subsequent years. All SNPs must submit their model of care (MOC) to CMS for NCQA evaluation and approval in accordance with CMS guidance.

(ii) As part of the evaluation and approval of the SNP model of care, NCQA must evaluate whether goals were fulfilled from the previous model of care.

(A) Plans must provide relevant information pertaining to the MOC's goals as well as appropriate data pertaining to the fulfillment the previous MOC's goals.

(B) Plans submitting an initial model of care must provide relevant information pertaining to the MOC's goals for review and approval.

(C) If the SNP model of care did not fulfill the previous MOC's goals, the plan must indicate in the MOC submission how it will achieve or revise the goals for the plan's next MOC.

(iii) Each element of the model of care of a plan must meet a minimum benchmark score of 50 percent and each MOC must meet an aggregate minimum benchmark of 70 percent, and a plan's model of care is only approved if each element of the model of care meets the minimum benchmark and the model of care meets the aggregate minimum benchmark.

(A) An MOC for a C–SNP that receives a passing score is approved for 1 year.

(B)(*1*) An MOC for an I–SNP or D–SNP that receives an aggregate minimum benchmark score of 85 percent or greater is approved for 3 years.

(*2*) An MOC for an I–SNP or D–SNP that receives a score of 75 percent to 84 percent is approved for 2 years.

(*3*) An MOC for an I–SNP or DSNP that receives a score of 70 percent to 74 percent is approved for 1 year.

(C) For an MOC that fails to meet a minimum element benchmark score of 50 percent or an MOC that fails to meet the aggregate minimum benchmark of 70 percent, the MA organization is permitted a one-time opportunity to resubmit the corrected MOC for reevaluation; and an MOC that is corrected

and resubmitted using this cure period is approved for only 1 year.

(iv) An MA organization sponsoring a SNP that seeks to revise the MOC before the end of the MOC approval period may submit changes to the MOC as off-cycle MOC submissions for review by NCQA as follows:

(A) C–SNPs, D–SNPs and I–SNPs must submit updates and corrections to their NCQA-approved MOC when CMS requires an off-cycle submission to ensure compliance with applicable law.

(B) D–SNPs and I–SNPs must submit updates and corrections to their NCQA approved MOC between June 1st and November 30th of each calendar year if the I–SNP or D–SNP wishes to make any of the following revisions:

(*1*) Substantial changes in policies or procedures pertinent to any of the following:

(*i*) The health risk assessment (HRA) process.

(*ii*) Revising processes to develop and update the Individualized Care Plan (ICP).

(*iii*) The integrated care team process.

(*iv*) Risk stratification methodology.

(*v*) Care transition protocols.

(*2*) Target population changes that warrant modifications to care management approaches.

(*3*) Changes in a SNP's plan benefit package between consecutive contract years that can considerably impact critical functions necessary to maintain member well-being and are related to SNP operations.

(*4*) Changes in level of authority or oversight for personnel conducting care coordination activities (for example, medical provider to non-medical provider, clinical vs. non-clinical personnel).

(*5*) Changes to quality metrics used to measure performance.

(C) NCQA only reviews off-cycle submissions after the start of the effective date of the current MOC unless CMS deems it necessary to ensure compliance with the applicable regulations.

(D) SNPs may not implement any changes to a MOC until NCQA has reviewed and approved the off-cycle MOC changes. NCQA does not rescore the MOC during the off-cycle review of changes to the MOC, but changes are reviewed and determined by NCQA to be either ''Acceptable'' or ''Non-acceptable.'' ''Acceptable'' means that the changes have been approved by NCQA and the MOC has been updated; ''Non-acceptable'' means the changes have been rejected by NCQA and the MOC has not been changed. If NCQA determines that off-cycle changes are unacceptable, the SNP must continue to implement the MOC as originally approved.

(E) Successful revision of the MOC under paragraph (f)(3)(iv)(B) of this section does not change the MOC's original period of approval.

(F) C–SNPs are only permitted to submit an off-cycle MOC submission when CMS requires an off-cycle submission to ensure compliance with applicable law.

(G) When a deficiency is identified in the off-cycle MOC revision(s) submitted by a SNP, the SNP has one opportunity to submit a corrected off-cycle revision between June 1st and November 30th of each calendar year.

[65 FR 40319, June 29, 2000, as amended at 68 FR 50856, Aug. 22, 2003; 70 FR 4720, Jan. 28, 2005; 70 FR 52026, Sept. 1, 2005; 70 FR 76197, Dec. 23, 2005; 73 FR 54248, Sept. 18, 2008; 74 FR 1541, Jan. 12, 2009; 76 FR 21562, Apr. 15, 2011; 76 FR 54634, Sept. 1, 2011; 77 FR 22167, Apr. 12, 2012; 83 FR 16724, Apr. 16, 2018; 86 FR 6094, Jan. 19, 2021; 86 FR 29528, June 2, 2021; 87 FR 22427, Apr. 14, 2022; 87 FR 27894, May 9, 2022; 88 FR 22328, Apr. 12, 2023; 89 FR 30817, Apr. 23, 2024; 89 FR 79451, Sept. 30, 2024; 90 FR 15909, Apr. 15, 2025]

§ 422.102 Supplemental benefits.

(a) *Mandatory supplemental benefits.* (1) Subject to CMS approval, an MA organization may require Medicare enrollees of an MA plan (other than an MSA plan) to accept or pay for services in addition to Medicare-covered services described in § 422.101.

(2) If the MA organization imposes mandatory supplemental benefits, it must impose them on all Medicare beneficiaries enrolled in the MA plan.

(3) CMS approves mandatory supplemental benefits if the benefits are designed in accordance with CMS' guidelines and requirements as stated in this part and other written instructions.

(4) Beginning in 2006, an MA plan may reduce cost sharing below the actuarial value specified in section 1854(e)(4)(A) of the Act for Part A and B benefits only as a mandatory supplemental benefit.

(5) An MA plan may reduce the cost sharing for items and services that are not basic benefits only as a mandatory supplemental benefit (reductions or payment of cost sharing for Part D drugs is not permissible as a Part C supplemental benefit).

(6) An MA plan may offer mandatory supplemental benefits in the following forms:

(i) Reductions in cost sharing through the use of reimbursement, through a debit card or other means, for cost sharing paid for covered benefits. Reimbursements must be limited to the specific plan year.

(ii) Use of a uniform dollar amount as a maximum plan allowance for a package of supplemental benefits, including reductions in cost sharing or coverage of specific items and services, available to enrollees on a uniform basis for enrollee use for any supplemental benefit in the package. Allowance must be limited to the specific plan year.

(b) *Optional supplemental benefits.* Except as provided in § 422.104 in the case of MSA plans, each MA organization may offer (for election by the enrollee and without regard to health status) services that are not included in the basic benefits as described in § 422.100(c) and any mandatory supplemental benefits described in paragraph (a) of this section. Optional supplemental benefits are purchased at the discretion of the enrollee and must be offered to all Medicare beneficiaries enrolled in the MA plan.

(c) *Payment for supplemental services.* All supplemental benefits are paid for in full, directly by (or on behalf of) the enrollee of the MA plan.

(d) *Supplemental benefits packaging.* MA organizations may offer enrollees a group of services as one optional supplemental benefit, offer services individually, or offer a combination of groups and individual services.

(e) *Supplemental benefits for certain dual eligible special needs plans.* Subject to CMS approval, fully integrated dual eligible special needs plans and highly integrated dual eligible special needs plans that meet minimum performance and quality-based standards may offer additional supplemental benefits, consistent with the requirements of this part, where CMS finds that the offering of such benefits could better integrate care for the dual eligible population provided that the special needs plan—

(1) Operated in the MA contract year prior to the MA contract year for which it is submitting its bid; and

(2) Offers its enrollees such benefits without cost-sharing or additional premium charges.

(f) *Special supplemental benefits for the chronically ill (SSBCI)*—(1) *Requirements*—(i) *Chronically-ill enrollee.* (A) A chronically ill enrollee is an individual enrolled in the MA plan who has one or more comorbid and medically complex chronic conditions that meet all of the following:

(*1*) Is life threatening or significantly limits the overall health or function of the enrollee;

(*2*) Has a high risk of hospitalization or other adverse health outcomes; and

(*3*) Requires intensive care coordination.

(B) CMS may publish a non-exhaustive list of conditions that are medically complex chronic conditions that are life threatening or significantly limit the overall health or function of an individual.

(ii) *SSBCI definition.* A special supplemental benefit for the chronically ill (SSBCI) is a supplemental benefit that has, with respect to a chronically ill enrollee, a reasonable expectation of improving or maintaining the health or overall function of the enrollee; an SSBCI that meets the standard in this paragraph (f)(1)(ii) may also include a benefit that is not primarily health related.

(iii) *Non-allowable SSBCI.* Examples of items or services that may not be offered as SSBCI include all of the following:

(A) Procedures that are solely cosmetic in nature and do not extend upon Traditional Medicare coverage (for example, cosmetic surgery, such as facelifts, or cosmetic treatments for facial lines, atrophy of collagen and fat, and bone loss due to aging).

(B) Hospital indemnity insurance.

(C) Funeral planning and expenses.
(D) Life insurance.
(E) Alcohol.
(F) Tobacco.
(G) Cannabis products.
(H) Broad membership programs inclusive of multiple unrelated services and discounts.
(I) Non-healthy food.

(2) *Offering SSBCI.* (i) An MA plan may offer SSBCI to a chronically ill enrollee only as a mandatory supplemental benefit.

(ii) Upon approval by CMS, an MA plan may offer SSBCI that are not uniform for all chronically ill enrollees in the plan.

(iii) An MA plan may consider social determinants of health as a factor to help identify chronically ill enrollees whose health or overall function could be improved or maintained with SSBCI. An MA plan may not use social determinants of health as the sole basis for determining eligibility for SSBCI.

(3) *MA organization responsibilities.* An MA organization that includes an item or service as SSBCI in its bid must be able to demonstrate through relevant acceptable evidence that the item or service has a reasonable expectation of improving or maintaining the health or overall function of a chronically ill enrollee. By the date on which an MA organization submits its bid, the MA organization must establish a written bibliography of relevant acceptable evidence concerning the impact that the item or service has on the health or overall function of its recipient. For each citation in the written bibliography, the MA organization must include a working hyperlink to or a document containing the entire source cited.

(i) Relevant acceptable evidence includes large, randomized controlled trials or prospective cohort studies with clear results, published in a peer-reviewed journal, and specifically designed to investigate whether the item or service impacts the health or overall function of a population, or large systematic reviews or meta-analyses summarizing the literature of the same.

(ii) An MA organization must include in its bibliography a comprehensive list of relevant acceptable evidence published within the 10 years prior to the June immediately preceding the coverage year during which the SSBCI will be offered, including any available negative evidence and literature.

(iii) If no evidence of the type described in paragraphs (f)(3)(i) and (ii) of this section exists for a given item or service, then MA organization may cite case studies, federal policies or reports, internal analyses, or any other investigation of the impact that the item or service has on the health or overall function of its recipient as relevant acceptable evidence in the MA organization's bibliography.

(iv) The MA organization must make its bibliography of relevant acceptable evidence available to CMS upon request.

(4) *Plan responsibilities.* An MA plan offering SSBCI must do all of the following:

(i) Have written policies for determining enrollee eligibility and must document its determination that an enrollee is a chronically ill enrollee based on the definition in paragraph (f)(1)(i) of this section.

(ii) Make information and documentation related to determining enrollee eligibility available to CMS upon request.

(iii)(A) Have and apply written policies based on objective criteria for determining a chronically ill enrollee's eligibility to receive a particular SSBCI; and

(B) Document the written policies specified in paragraph (f)(4)(iii)(A) of this section and the objective criteria on which the written policies are based.

(iv) Document each eligibility determination for an enrollee, whether eligible or ineligible, to receive a specific SSBCI and make this information available to CMS upon request.

(v) Maintain without modification, as it relates to an SSBCI, evidentiary standards for a specific enrollee to be determined eligible for a particular SSBCI, or the specific objective criteria used by a plan as part of SSBCI eligibility determinations for the full coverage year.

(5) *CMS review of SSBCI offerings in bids.* (i) CMS may decline to approve an

MA organization's bid if CMS determines that the MA organization has not demonstrated, through relevant acceptable evidence, that an SSBCI has a reasonable expectation of improving or maintaining the health or overall function of the chronically ill enrollees that the MA organization is targeting.

(ii) CMS may annually review the items or services that an MA organization includes as SSBCI in its bid for compliance with all applicable requirements, taking into account updates to the relevant acceptable evidence applicable to each item or service.

(iii) This provision does not limit CMS's authority to review and negotiate bids or to reject bids under section 1854(a) of the Act and 42 CFR part 422 subpart F nor does it limit CMS's authority to review plan benefits and bids for compliance with all applicable requirements.

[65 FR 40320, June 29, 2000, as amended at 70 FR 4720, Jan. 28, 2005; 77 FR 22167, Apr. 12, 2012; 83 FR 16724, Apr. 16, 2018; 84 FR 15828, Apr. 16, 2019; 85 FR 33903, June 2, 2020; 86 FR 6095, Jan. 19, 2021; 89 FR 30818, Apr. 23, 2024; 89 FR 63826, Aug. 6, 2024; 90 FR 15910, Apr. 15, 2025]

§ 422.103 Benefits under an MA MSA plan.

(a) *General rule.* An MA organization offering an MA MSA plan must make available to an enrollee, or provide reimbursement for, at least the services described in § 422.101 after the enrollee incurs countable expenses equal to the amount of the plan's annual deductible.

(b) *Countable expenses.* An MA organization offering an MA MSA plan must count toward the annual deductible at least all amounts that would be paid for the particular service under original Medicare, including amounts that would be paid by the enrollee as deductibles or coinsurance.

(c) *Services after the deductible.* For services received by the enrollee after the annual deductible is satisfied, an MA organization offering an MA MSA plan must pay, at a minimum, the lesser of the following amounts:

(1) 100 percent of the expense of the services.

(2) 100 percent of the amounts that would have been paid for the services under original Medicare, including amounts that would be paid by the enrollee as deductibles and coinsurance.

(d) *Annual deductible.* The annual deductible for an MA MSA plan—

(1) For contract year 1999, may not exceed $6,000; and

(2) For subsequent contract years may not exceed the deductible for the preceding contract year, increased by the national per capita growth percentage determined under § 422.306(a)(2).

(3) Is pro-rated for enrollments occurring during a beneficiary's initial coverage election period as described at § 422.62(a)(1) of this part or during any other enrollments occurring after January 1.

(e) All MA organizations offering MSA plans must provide enrollees with available information on the cost and quality of services in their service area, and submit to CMS for approval a proposed approach to providing such information.

[63 FR 35077, June 26, 1998, as amended at 70 FR 4720, Jan. 28, 2005; 70 FR 52026, Sept. 1, 2005; 74 FR 1541, Jan. 12, 2009; 75 FR 19805, Apr. 15, 2010]

§ 422.104 Special rules on supplemental benefits for MA MSA plans.

(a) An MA organization offering an MA MSA plan may not provide supplemental benefits that cover expenses that count towards the deductible specified in § 422.103(d).

(b) In applying the limitation of paragraph (a) of this section, the following kinds of policies are not considered as covering the deductible:

(1) A policy that provides coverage (whether through insurance or otherwise) for accidents, disability, dental care, vision care, or long-term care.

(2) A policy of insurance in which substantially all of the coverage relates to liabilities incurred under workers' compensation laws, tort liabilities, liabilities relating to use or ownership of property, and any other similar liabilities that CMS may specify by regulation.

(3) A policy of insurance that provides coverage for a specified disease or illness or pays a fixed amount per day (or other period) of hospitalization.

§ 422.105 Special rules for self-referral and point of service option.

(a) *Self-referral.* When an MA plan member receives an item or service of the plan that is covered upon referral or pre-authorization from a contracted provider of that plan, the member cannot be financially liable for more than the normal in-plan cost sharing, if the member correctly identified himself or herself as a member of that plan to the contracted provider before receiving the covered item or service, unless the contracted provider can show that the enrollee was notified prior to receiving the item or service that the item or service is covered only if further action is taken by the enrollee.

(b) *Point of service option.* As a general rule, a POS benefit is an option that an MA organization may offer in an HMO plan to provide enrollees with additional choice in obtaining specified health care services. The organization may offer a POS option—

(1) Before January 1, 2006, under a coordinated care plan as an additional benefit as described in section 1854(f)(1)(A) of the Act;

(2) Under an HMO plan as a mandatory supplemental benefit as described in § 422.102(a); or

(3) Under an HMO plan as an optional supplemental benefit as described in § 422.102(b).

(c) *Ensuring availability and continuity of care.* An MA HMO plan that includes a POS benefit must continue to provide all benefits and ensure access as required under this subpart.

(d) *Enrollee information and disclosure.* The disclosure requirements specified in § 422.111 apply in addition to the following requirements:

(1) *Written rules.* MA organizations must maintain written rules on how to obtain health benefits through the POS benefit.

(2) *Evidence of coverage document.* The MA organization must provide to beneficiaries enrolling in a plan with a POS benefit an ''evidence of coverage'' document, or otherwise provide written documentation, that specifies all costs and possible financial risks to the enrollee, including—

(i) Any premiums and cost-sharing for which the enrollee is responsible;

(ii) Annual limits on benefits and on out-of-pocket expenditures;

(iii) Potential financial responsibility for services for which the plan denies payment because they were not covered under the POS benefit, or exceeded the dollar limit for the benefit; and

(iv) The annual maximum out-of-pocket expense an enrollee could incur.

(e) *Prompt payment.* Health benefits payable under the POS benefit are subject to the prompt payment requirements in § 422.520.

(f) *POS-related data.* An MA organization that offers a POS benefit through an HMO plan must report enrollee utilization data at the plan level by both plan contracting providers (in-network) and by non-contracting providers (out-of-network) including enrollee use of the POS benefit, in the form and manner prescribed by CMS.

[63 FR 35077, June 26, 1998, as amended at 65 FR 40320, June 29, 2000; 70 FR 4721, Jan. 28, 2005; 75 FR 19805, Apr. 15, 2010]

§ 422.106 Coordination of benefits with employer or union group health plans and Medicaid.

(a) *General rule.* If an MA organization contracts with an employer, labor organization, or the trustees of a fund established by one or more employers or labor organizations that cover enrollees in an MA plan, or contracts with a State Medicaid agency to provide Medicaid benefits to individuals who are eligible for both Medicare and Medicaid, and who are enrolled in an MA plan, the enrollees must be provided the same benefits as all other enrollees in the MA plan, with the employer, labor organization, fund trustees, or Medicaid benefits supplementing the MA plan benefits. Jurisdiction regulating benefits under these circumstances is as follows:

(1) All requirements of this part that apply to the MA program apply to the MA plan coverage and benefits provided to enrollees eligible for benefits under an employer, labor organization, trustees of a fund established by one or more employers or labor organizations, or Medicaid contract.

(2) Employer benefits that complement an MA plan, which are not

part of the MA plan, are not subject to review or approval by CMS.

(3) Medicaid benefits are not reviewed under this part, but are subject to appropriate CMS review under the Medicaid program. MA plan benefits provided to individuals entitled to Medicaid benefits provided by the MA organization under a contract with the State Medicaid agency are subject to MA rules and requirements.

(b) *Examples.* Permissible employer, labor organization, benefit fund trustee, or Medicaid plan benefits include the following:

(1) Payment of a portion or all of the MA basic and supplemental premiums.

(2) Payment of a portion or all of other cost-sharing amounts approved for the MA plan.

(3) Other employer-sponsored benefits that may require additional premium and cost-sharing, or other benefits provided by the organization under a contract with the State Medicaid agency.

(c) *Waiver or modification of contracts with MA organizations.* (1) MA organizations may request, in writing, from CMS, a waiver or modification of those requirements in this part that hinder the design of, the offering of, or the enrollment in, MA plans under contracts between MA organizations and employers, labor organizations, or the trustees of funds established by one or more employers or labor organizations to furnish benefits to the entity's employees, former employees, or members or former members of the labor organizations.

(2) Approved waivers or modifications under this paragraph granted to any MA organization may be used by any other similarly situated MA organization in developing its bid.

(d) *Employer sponsored MA plans for plan years beginning on or after January 1, 2006.* (1) CMS may waive or modify any requirement in this part or Part D that hinders the design of, the offering of, or the enrollment in, an employer-sponsored group MA plan (including an MA–PD plan) offered by one or more employers, labor organizations, or the trustees of a fund established by one or more employers or labor organizations (or combination thereof), or that is offered, sponsored or administered by an entity on behalf of one or more employers or labor organizations, to furnish benefits to the employers' employees, former employees (or combination thereof) or members or former members (or combination thereof) of the labor organizations. Any entity seeking to offer, sponsor, or administer such an MA plan described in this paragraph may request, in writing, from CMS, a waiver or modification of requirements in this part that hinder the design of, the offering of, or the enrollment in, such MA plan.

(2) An MA plan described in this paragraph may restrict the enrollment of individuals in that plan to individuals who are beneficiaries and participants in that plan.

(3) Approved waivers or modifications under this paragraph granted to any MA plan may be used by any other similarly situated MA plan in developing its bid.

(4) An employer-sponsored group MA plan means MA coverage offered to retirees who are Medicare eligible individuals under employment-based retiree health coverage, as defined in paragraph (d)(5) of this section, approved by CMS as an MA plan.

(5) Employment-based retiree coverage means coverage of health care costs under a group health plan, as defined in paragraph (d)(6) of this section, based on an individual's status as a retired participant in the plan, or as the spouse or dependent of a retired participant. The term includes coverage provided by voluntary insurance coverage, or coverage as a result of a statutory or contractual obligation.

(6) Group health plans include plans as defined in section 607(1) of ERISA, (29 U.S.C. 1167(1)). They also include the following plans:

(i) A Federal or State governmental plan, which is a plan providing medical care that is established or maintained for its employees by the Government of the United States, by the government of any State or political subdivision of a State (including a county or local government), or by any agency or instrumentality or any of the foregoing, including a health benefits plan offered under 5 U.S.C. 89 (the Federal Employee Health Benefit Plan (FEHBP)).

(ii) A collectively bargained plan, which is a plan providing medical care that is established or maintained under or by one or more collective bargaining agreements.

(iii) A church plan, which is a plan providing medical care that is established and maintained for its employees or their beneficiaries by a church or by a convention or association of churches that is exempt from tax under section 501 of the Internal Revenue Code of 1986 (26 U.S.C. 501).

(iv) Any of the following plans:

(A) An account-based medical plan such as a Health Reimbursement Arrangement (HRA) as defined in Internal Revenue Service Notice 2002–45, 2002–28 I.R.B. 93.

(B) A health Flexible Spending Arrangement (FSA) as defined in Internal Revenue Code (Code) section 106(c)(2).

(C) A health savings account (HSA) as defined in Code section 223.

(D) An Archer MSA as defined in Code section 220, to the extent they are subject to ERISA as employee welfare benefit plans providing medical care (or would be subject to ERISA but for the exclusion in ERISA section 4(b), 29 U.S.C.1003(b), for governmental plans or church plans).

[65 FR 40320, June 29, 2000, as amended at 68 FR 50856, Aug. 22, 2003; 70 FR 4721, Jan. 28, 2005; 76 FR 21562, Apr. 15, 2011]

§ 422.107 Requirements for dual eligible special needs plans.

(a) *Definition.* For the purpose of this section, a contract with a State Medicaid agency means a formal written agreement between an MA organization and the State Medicaid agency documenting each entity's roles and responsibilities with regard to dual eligible individuals.

(b) *General rule.* MA organizations seeking to offer a dual eligible special needs plan must have a contract consistent with this section with the State Medicaid agency.

(c) *Minimum contract requirements.* At a minimum, the contract must document—

(1) The MA organization's responsibility to—

(i) Coordinate the delivery of Medicaid benefits for individuals who are eligible for such services; and

(ii) If applicable, provide coverage of Medicaid services, including long-term services and supports and behavioral health services, for individuals eligible for such services.

(2) The category(ies) and criteria for eligibility for dual eligible individuals to be enrolled under the SNP, including as described in sections 1902(a), 1902(f), 1902(p), and 1905 of the Act.

(3) The Medicaid benefits covered under a capitated contract between the State Medicaid agency and the MA organization offering the SNP, the SNP's parent organization, or another entity that is owned and controlled by the SNP's parent organization.

(4) The cost-sharing protections covered under the SNP.

(5) The identification and sharing of information on Medicaid provider participation.

(6) The verification of an enrollee's Medicaid eligibility.

(7) The service area covered by the SNP.

(8) The contract period for the SNP.

(9) For each dual eligible special needs plan that is an applicable integrated plan as defined in § 422.561, a requirement for the use of the unified appeals and grievance procedures under §§ 422.629 through 422.634, 438.210, 438.400, and 438.402.

(d) *Additional minimum contract requirement.* (1) For any dual eligible special needs plan that is not a fully integrated or highly integrated dual eligible special needs plan, except as specified in paragraph (d)(2) of this section, the contract must also stipulate that, for the purpose of coordinating Medicare and Medicaid-covered services between settings of care, the SNP notifies, or arranges for another entity or entities to notify, the State Medicaid agency, individuals or entities designated by the State Medicaid agency, or both, of hospital and skilled nursing facility admissions for at least one group of high-risk full-benefit dual eligible individuals, identified by the State Medicaid agency. The State Medicaid agency must establish the timeframe(s) and method(s) by which notice is provided. In the event that a SNP authorizes another entity or entities to perform this notification, the SNP

must retain responsibility for complying with the requirement in this paragraph (d)(1).

(2) For a dual eligible special needs plan that, under the terms of its contract with the State Medicaid agency, only enrolls beneficiaries who are not entitled to full medical assistance under a State plan under title XIX of the Act, paragraph (d)(1) of this section does not apply if the SNP operates under the same parent organization and in the same service area as a dual eligible special needs plan limited to beneficiaries with full medical assistance under a State plan under title XIX of the Act that meets the requirements at paragraph (d)(1) of this section.

(e) *Additional opportunities in certain integrated care programs.* (1) CMS facilitates operationalization as described in paragraphs (e)(2) and (3) of this section if a State Medicaid agency requires MA organizations offering dual eligible special needs plans with exclusively aligned enrollment to do both of the following:

(i) Apply for, and seek CMS approval to establish and maintain, one or more MA contracts that only include one or more dual eligible special needs plans with a service area limited to that State.

(ii) Use required materials that integrate Medicare and Medicaid content, including at a minimum the Summary of Benefits, Formulary, and combined Provider and Pharmacy Directory that meets Medicare and Medicaid managed care requirements consistent with applicable regulations in parts 422, 423, and 438 of this chapter.

(2) The requirements, processes, and procedures applicable to dual eligible special needs plans and the MA program, including for applications, bids, and contracting procedures under §§ 422.250 through 422.530, remain applicable. Because implementation of the contract provisions described in paragraph (e)(1) of this section may require administrative steps that cannot be completed between reviewing the contract and the start of the plan year, CMS begins good faith work following receipt of a letter from the State Medicaid agency indicating intent to include the provisions described in paragraph (e)(1) of this section in a future contract year and collaborate with CMS on implementation.

(3) When the conditions of paragraph (e)(1) of this section are met—

(i) Following a State request, CMS grants access for State Medicaid agency officials to the Health Plan Management System (HPMS) (or its successor) for purposes of oversight and information-sharing related to the MA contract(s) described in paragraph (e)(1)(i) of this section, as long as State Medicaid agency officials agree to protect the proprietary nature of information to which the State Medicaid agency may not otherwise have direct access. State access to the Health Plan Management System (or its successor) is subject to compliance with HHS and CMS policies and standards and with applicable laws in the use of HPMS data and the system's functionality. CMS may terminate a State official's access to the Health Plan Management System (or its successor) if any policy is violated or if information is not adequately protected; and

(ii) CMS coordinates with States on program audits, including information-sharing on major audit findings and coordination of audits schedules for the D–SNPs subject to paragraph (e)(1) of this section.

(f) *Enrollee advisory committee.* Any MA organization offering one or more D–SNPs in a State must establish and maintain one or more enrollee advisory committees that serve the D–SNPs offered by the MA organization in that State.

(1) The enrollee advisory committee must include at least a reasonably representative sample of the population enrolled in the dual eligible special needs plan or plans, or other individuals representing those enrollees, and solicit input on, among other topics, ways to improve access to covered services, coordination of services, and health equity for underserved populations.

(2) The enrollee advisory committee may also advise managed care plans that serve D–SNP enrollees under title XIX of the Act offered by the same parent organization as the MA organization offering the D–SNP.

(g) *Permissible carve-outs of long-term services and supports for FIDE SNPs and HIDE SNPs.* A plan meets the FIDE SNP or HIDE SNP definition at § 422.2, even if its contract with the State Medicaid agency for the provision of services under title XIX of the Act has carve-outs of long-term services and supports, as approved by CMS, that—

(1) Apply primarily to a minority of the beneficiaries eligible to enroll in the dual eligible special needs plan who use long-term services and supports; or

(2) Constitute a small part of the total scope of long-term services and supports provided to the majority of beneficiaries eligible to enroll in the dual eligible special needs plan.

(h) *Permissible carve-outs of behavioral health services for FIDE SNPs and HIDE SNPs.* A plan meets the FIDE SNP or HIDE SNP definition at § 422.2, even if its contract with the State Medicaid agency for the provision of services under title XIX of the Act has carve-outs of behavioral health services, as approved by CMS, that—

(1) Apply primarily to a minority of the beneficiaries eligible to enroll in the dual eligible special needs plan who use behavioral health services; or

(2) Constitute a small part of the total scope of behavioral health services provided to the majority of beneficiaries eligible to enroll in the dual eligible special needs plan.

(i) *Date of Compliance.* (1) Effective January 1, 2010—

(i) MA organizations offering a new dual-eligible SNP must have a State Medicaid agency contract.

(ii) Existing dual-eligible SNPs that do not have a State Medicaid agency contract—

(A) May continue to operate through the 2012 contract year provided they meet all other statutory and regulatory requirements.

(B) May not expand their service areas during contract years 2010 through 2012.

(2) MA organizations offering a dual eligible SNP must comply with paragraphs (c)(9) and (d) of this section beginning January 1, 2021.

[73 FR 54248, Sept. 18, 2008, as amended at 76 FR 21563, Apr. 15, 2011; 84 FR 15828, Apr. 16, 2019; 84 FR 26579, June 7, 2019; 87 FR 27894, May 9, 2022]

§ 422.108 Medicare secondary payer (MSP) procedures.

(a) *Basic rule.* CMS does not pay for services to the extent that Medicare is not the primary payer under section 1862(b) of the Act and part 411 of this chapter.

(b) *Responsibilities of the MA organization.* The MA organization must, for each MA plan—

(1) Identify payers that are primary to Medicare under section 1862(b) of the Act and part 411 of this chapter;

(2) Identify the amounts payable by those payers; and

(3) Coordinate its benefits to Medicare enrollees with the benefits of the primary payers, including reporting, on an ongoing basis, information obtained related to requirements in paragraphs (b)(1) and (b)(2) of this section in accordance with CMS instructions.

(c) *Collecting from other entities.* The MA organization may bill, or authorize a provider to bill, other individuals or entities for covered Medicare services for which Medicare is not the primary payer, as specified in paragraphs (d) and (e) of this section.

(d) *Collecting from other insurers or the enrollee.* If a Medicare enrollee receives from an MA organization covered services that are also covered under State or Federal workers' compensation, any no-fault insurance, or any liability insurance policy or plan, including a self-insured plan, the MA organization may bill, or authorize a provider to bill any of the following—

(1) The insurance carrier, the employer, or any other entity that is liable for payment for the services under section 1862(b) of the Act and part 411 of this chapter.

(2) The Medicare enrollee, to the extent that he or she has been paid by the carrier, employer, or entity for covered medical expenses.

(e) *Collecting from group health plans (GHPs) and large group health plans (LGHPs).* An MA organization may bill a GHP or LGHP for services it furnishes to a Medicare enrollee who is also covered under the GHP or LGHP and may bill the Medicare enrollee to the extent that he or she has been paid by the GHP or LGHP.

(f) *MSP rules and State laws.* Consistent with § 422.402 concerning the

Federal preemption of State law, the rules established under this section supersede any State laws, regulations, contract requirements, or other standards that would otherwise apply to MA plans. A State cannot take away an MA organization's right under Federal law and the MSP regulations to bill, or to authorize providers and suppliers to bill, for services for which Medicare is not the primary payer. The MA organization will exercise the same rights to recover from a primary plan, entity, or individual that the Secretary exercises under the MSP regulations in subparts B through D of part 411 of this chapter.

[63 FR 35077, June 26, 1998, as amended at 65 FR 40320, June 29, 2000; 70 FR 4721, Jan. 28, 2005; 75 FR 19805, Apr. 15, 2010]

§ 422.109 Effect of national coverage determinations (NCDs) and legislative changes in benefits; coverage of clinical trials and A and B device trials.

(a) *Definitions.* The term *significant cost*, as it relates to a particular NCD or legislative change in benefits, means either of the following:

(1) The average cost of furnishing a single service exceeds a cost threshold that—

(i) For calendar years 1998 and 1999, is $100,000; and

(ii) For calendar year 2000 and subsequent calendar years, is the preceding year's dollar threshold adjusted to reflect the national per capita growth percentage described in § 422.308(a).

(2) The estimated cost of Medicare services furnished as a result of a particular NCD or legislative change in benefits represents at least 0.1 percent of the national average per capita costs.

(b) *General rule.* If CMS determines and announces that an individual NCD or legislative change in benefits meets the criteria for significant cost described in paragraph (a) of this section, a MA organization is not required to assume risk for the costs of that service or benefit until the contract year for which payments are appropriately adjusted to take into account the cost of the NCD service or legislative change in benefits. If CMS determines that an NCD or legislative change in benefits does not meet the ''significant cost'' threshold described in § 422.109(a), the MA organization is required to provide coverage for the NCD or legislative change in benefits and assume risk for the costs of that service or benefit as of the effective date stated in the NCD or specified in the legislation.

(c) *Before payment adjustments become effective.* Before the contract year that payment adjustments that take into account the significant cost of the NCD service or legislative change in benefits become effective, the service or benefit is not included in the MA organization's contract with CMS, and is not a covered benefit under the contract. The following rules apply to these services or benefits:

(1) Medicare payment for the service or benefit is made directly by the fiscal intermediary and carrier to the provider furnishing the service or benefit in accordance with original Medicare payment rules, methods, and requirements.

(2) Costs for NCD services or legislative changes in benefits for which CMS intermediaries and carriers will not make payment and are the responsibility of the MA organization are—

(i) Services necessary to diagnose a condition covered by the NCD or legislative changes in benefits;

(ii) Most services furnished as follow-up care to the NCD service or legislative change in benefits;

(iii) Any service that is already a Medicare-covered service and included in the annual MA capitation rate or previously adjusted payments; and

(iv) Any services, including the costs of the NCD service or legislative change in benefits, to the extent the MA organization is already obligated to cover it as a supplemental benefit under § 422.102.

(3) Costs for significant cost NCD services or legislative changes in benefits for which CMS fiscal intermediaries and carriers will make payment are those Medicare costs not listed in paragraphs (c)(2)(i) through (c)(2)(iv) of this section.

(4) Beneficiaries are liable for any applicable coinsurance amounts.

(d) *After payment adjustments become effective.* For the contract year in which payment adjustments that take into account the significant cost of the

NCD service or legislative change in benefits are in effect, the service or benefit is included in the MA organization's contract with CMS, and is a covered benefit under the contract. Subject to all applicable rules under this part, the MA organization must furnish, arrange, or pay for the NCD service or legislative change in benefits. MA organizations may establish separate plan rules for these services and benefits, subject to CMS review and approval. CMS may, at its discretion, issue overriding instructions limiting or revising the MA plan rules, depending on the specific NCD or legislative change in benefits. For these services or benefits, the Medicare enrollee will be responsible for MA plan cost sharing, as approved by CMS or unless otherwise instructed by CMS.

(e) *Clinical trials specified in NCD 310.1.* (1) With the exception specified in paragraph (e)(3) of this section, original Medicare is responsible for coverage of MA enrollees participating in CMS-approved clinical trials to include routine costs, as specified in NCD 310.1, and any coverage for the diagnosis or treatment of complications related to the clinical trial.

(2) MA enrollees are not charged traditional Medicare Part A and B deductibles for clinical trial coverage.

(3) MA plans are responsible for paying the difference between traditional Medicare cost-sharing incurred for qualifying clinical trial items and services and the MA plan's in-network cost-sharing for the same category of items and services.

(4) An enrollee's in-network cost-sharing portion must be included in the MA plan's maximum out-of-pocket calculation.

(5) MA plans may not require prior authorization for participation in a Medicare-qualified clinical trial not sponsored by the plan, nor may it create impediments to an enrollee's participation in a non-plan-sponsored clinical trial.

(f) *A and B IDE trials.* (1) MA plans are responsible for payment of routine care items and services in CMS-approved Category A and Category B IDE studies that are covered under § 405.211(a) of this chapter.

(2) MA plans are responsible for coverage of CMS-approved Category B devices that are covered under § 405.211(b) of this chapter.

[68 FR 50856, Aug. 22, 2003, as amended at 70 FR 4721, Jan. 28, 2005; 70 FR 52026, Sept. 1, 2005; 88 FR 22329, Apr. 12, 2023]

§ 422.110 Discrimination against beneficiaries prohibited.

(a) *General prohibition.* Except as provided in paragraph (b) of this section, an MA organization may not deny, limit, or condition the coverage or furnishing of benefits to individuals eligible to enroll in an MA plan offered by the organization on the basis of any factor that is related to health status, including, but not limited to the following:

(1) Medical condition, including mental as well as physical illness.

(2) Claims experience.

(3) Receipt of health care.

(4) Medical history.

(5) Genetic information.

(6) Evidence of insurability, including conditions arising out of acts of domestic violence.

(7) Disability.

(b) *Exception.* For coverage before January 1, 2021, an MA organization may not enroll an individual who has been medically determined to have end-stage renal disease. However, an enrollee who develops end-stage renal disease while enrolled in a particular MA organization may not be disenrolled for that reason. An individual who is an enrollee of a particular MA organization, and who resides in the MA plan service area at the time he or she first becomes MA eligible, or, an individual enrolled by an MA organization that allows those who reside outside its MA service area to enroll in an MA plan as set forth at § 422.50(a)(3)(ii), then that individual is considered to be ''enrolled'' in the MA organization for purposes of the preceding sentence.

[63 FR 35077, June 26, 1998; 63 FR 52612, Oct. 1, 1998; 64 FR 7980, Feb. 17, 1999, as amended at 65 FR 40321, June 29, 2000; 70 FR 4721, Jan. 28, 2005; 85 FR 33904, June 2, 2020]

§ 422.111 Disclosure requirements.

(a) *Detailed description.* An MA organization must disclose the information

specified in paragraph (b) of this section in the manner specified by CMS—

(1) To each enrollee electing an MA plan it offers;

(2) In clear, accurate, and standardized form; and

(3) At the time of enrollment and at least annually thereafter, by the first day of the annual coordinated election period.

(b) *Content of plan description.* The description must include the following information:

(1) *Service area.* The MA plan's service area and any enrollment continuation area.

(2) *Benefits.* The benefits offered under a plan, including applicable conditions and limitations, premiums and cost-sharing (such as copayments, deductibles, and coinsurance) and any other conditions associated with receipt or use of benefits; and to the extent it offers Part D as an MA-PD plan, the information in § 423.128 of this chapter; and for purposes of comparison-

(i) The benefits offered under original Medicare, including the content specified in paragraph (f)(1) of this section;

(ii) For an MA MSA plan, the benefits under other types of MA plans; and

(iii) By a dual eligible special needs plan, prior to enrollment, for each prospective enrollee, a comprehensive written statement describing cost sharing protections and benefits that the individual is entitled to under title XVIII and the State Medicaid program under title XIX.

(iv) The availability of the Medicare hospice option and any approved hospices in the service area, including those the MA organization owns, controls, or has a financial interest in.

(3) *Access.* (i) The number, mix, and distribution (addresses) of providers from whom enrollees may reasonably be expected to obtain services; each provider's cultural and linguistic capabilities, including languages (including American Sign Language) offered by the provider or a skilled medical interpreter at the provider's office; any out-of-network coverage; any point-of-service option, including the supplemental premium for that option; and how the MA organization meets the requirements of §§ 422.112 and 422.114 for access to services offered under the plan.

(ii) The process MA regional plan enrollees should follow to secure in-network cost sharing when covered services are not readily available from contracted network providers.

(4) Out-of-area coverage provided under the plan, including coverage provided to individuals eligible to enroll in the plan under § 422.50(a)(3)(ii).

(5) *Emergency coverage.* Coverage of emergency services, including—

(i) Explanation of what constitutes an emergency, referencing the definitions of emergency services and emergency medical condition at § 422.113;

(ii) The appropriate use of emergency services, stating that prior authorization cannot be required;

(iii) The process and procedures for obtaining emergency services, including use of the 911 telephone system or its local equivalent; and

(iv) The locations where emergency care can be obtained and other locations at which contracting physicians and hospitals provide emergency services and post-stabilization care included in the MA plan.

(6) *Supplemental benefits.* Any mandatory or optional supplemental benefits and the premium for those benefits.

(7) *Prior authorization and review rules.* Prior authorization rules and other review requirements that must be met in order to ensure payment for the services. The MA organization must instruct enrollees that, in cases where noncontracting providers submit a bill directly to the enrollee, the enrollee should not pay the bill, but submit it to the MA organization for processing and determination of enrollee liability, if any.

(8) *Grievance and appeals procedures.* All grievance and appeals rights and procedures.

(9) *Quality improvement program.* A description of the quality improvement program required under § 422.152.

(10) Disenrollment rights and responsibilities.

(11) *Catastrophic caps and single deductible.* MA organizations sponsoring MA regional plans are required to provide enrollees a description of the catastrophic stop-loss coverage and single

deductible (if any) applicable under the plan.

(c) *Disclosure upon request.* Upon request of an individual eligible to elect an MA plan, an MA organization must provide to the individual the following information:

(1) The information required in paragraph (f) of this section.

(2) The procedures the organization uses to control utilization of services and expenditures.

(3) The number of disputes, and the disposition in the aggregate, in a manner and form described by the Secretary. Such disputes shall be categorized as

(i) Grievances according to § 422.564; and

(ii) Appeals according to § 422.578 et. seq.

(4) A summary description of the method of compensation for physicians.

(5) Financial condition of the MA organization, including the most recently audited information regarding, at least, a description of the financial condition of the MA organization offering the plan.

(d) *Changes in rules.* If an MA organization intends to change its rules for an MA plan, it must:

(1) Submit the changes for CMS review under procedures of subpart V of this part.

(2) For changes that take effect on January 1, notify all enrollees at least 15 days before the beginning of the Annual Coordinated Election Period defined in section 1851(e)(3)(B) of the Act.

(3) For all other changes, notify all enrollees at least 30 days before the intended effective date of the changes.

(e) *Changes to provider network.* The MA organization must provide enrollees notice of a termination of a contracted provider, irrespective of whether the termination was for cause or without cause, in accordance with § 422.2267(e)(12). The MA organization must make a good faith effort to provide enrollees notice of a for-cause termination of a contracted provider within the timeframes required by this paragraph (e). For all terminations, the MA organization must meet the following requirements:

(1) For contract terminations that involve a primary care or behavioral health provider:

(i) Provide written notice and make one attempt at telephonic notice to those enrollees identified in paragraph (e)(1)(iii) of this section who have not opted out of calls regarding plan business as described in § 422.2264(b),

(ii) At least 45 calendar days before the termination effective date, and

(iii) To all enrollees who are currently assigned to that primary care provider and to enrollees who have been patients of that primary care or behavioral health provider within the past three years.

(2) For contract terminations that involve specialty types other than primary care or behavioral health:

(i) Provide written notice,

(ii) At least 30 calendar days before the termination effective date, and

(iii) To all enrollees who are patients seen on a regular basis by the provider whose contract is terminating. The phrase ''enrollees who are patients seen on a regular basis by the provider whose contract is terminating'' means enrollees who are assigned to, currently receiving care from, or have received care within the past three months from a provider or facility being terminated.

(f) *Disclosable information*—(1) *Benefits under original Medicare.* (i) Covered services.

(ii) Beneficiary cost-sharing, such as deductibles, coinsurance, and copayment amounts.

(iii) Any beneficiary liability for balance billing.

(2) *Enrollment procedures.* Information and instructions on how to exercise election options under this subpart.

(3) *Rights.* A general description of procedural rights (including grievance and appeals procedures) under original Medicare and the MA program and the right to be protected against discrimination based on factors related to health status in accordance with § 422.110.

(4) *Potential for contract termination.* The fact that an MA organization may terminate or refuse to renew its contract, or reduce the service area included in its contract, and the effect that any of those actions may have on

individuals enrolled in that organization's MA plan.

(5) *Benefits.* (i) Covered services beyond those provided under original Medicare.

(ii) Any beneficiary cost-sharing.

(iii) Any maximum limitations on out-of-pocket expenses.

(iv) In the case of an MA MSA plan, the amount of the annual MSA deposit.

(v) The extent to which an enrollee may obtain benefits through out-of-network health care providers.

(vi) The types of providers that participate in the plan's network and the extent to which an enrollee may select among those providers.

(vii) The coverage of emergency and urgently needed services.

(6) *Premiums.* (i) The MA monthly basic beneficiary premiums.

(ii) The MA monthly supplemental beneficiary premium.

(iii) The reduction in Part B premiums, if any.

(7) The plan's service area.

(8) *Quality and performance indicators* for benefits under a plan to the extent they are available as follows (and how they compare with indicators under original Medicare):

(i) Disenrollment rates for Medicare enrollees for the 2 previous years, excluding disenrollment due to death or moving outside the plan's service area, calculated according to CMS guidelines.

(ii) Medicare enrollee satisfaction.

(iii) Health outcomes.

(iv) Plan-level appeal data.

(v) The recent record of plan compliance with the requirements of this part, as determined by the Secretary.

(vi) Other performance indicators.

(9) *Supplemental benefits.* Whether the plan offers mandatory and optional supplemental benefits, including any reductions in cost sharing offered as a mandatory supplemental benefit as permitted under section 1852(a)(3) of the Act (and implementing regulations at §422.102) and the terms, conditions, and premiums for those benefits.

(10) The names, addresses, and phone numbers of contracted providers from whom the enrollee may obtain in-network coverage in other parts of the service area.

(11) If an MA organization exercises the option in §422.101(b)(3) or (b)(4) related to an MA plan, then it must make the local coverage determination that applies to members of that plan readily available to providers, including through a web site on the Internet.

(g) CMS may require an MA organization to disclose to its enrollees or potential enrollees, the MA organization's performance and contract compliance deficiencies in a manner specified by CMS.

(h) *Provision of specific information.* Each MA organization must have mechanisms for providing specific information on a timely basis to current and prospective enrollees upon request. These mechanisms must include all of the following:

(1) A toll-free customer service call center that meets all of the following:

(i)(A)Is open during usual business hours.

(B) For coverage beginning on and after January 1, 2022, is open at least from 8:00 a.m. to 8:00 p.m. in all service areas served by the Part C plan, with the following exceptions:

(1) From October 1 through March 31 of the following year, a customer call center may be closed on Thanksgiving Day and Christmas Day so long as the interactive voice response (IVR) system or similar technology records messages from incoming callers and such messages are returned within one (1) business day.

(2) From April 1 through September 30, a customer call center may be closed any Federal holiday, Saturday, or Sunday, so long as the interactive voice response (IVR) system or similar technology records messages from incoming callers and such messages are returned within one (1) business day.

(ii) Provides customer telephone service in accordance with standard business practices.

(A) For coverage beginning on and after January 1, 2022, limits average hold time to no longer than 2 minutes. The hold time is defined as the time spent on hold by callers following the interactive voice response (IVR) system, touch-tone response system, or recorded greeting, before reaching a live person.

(B) For coverage beginning on and after January 1, 2022, answers 80 percent of incoming calls within 30 seconds after the interactive voice response (IVR), touch-tone response system, or recorded greeting interaction.

(C) For coverage beginning on and after January 1, 2022, limits the disconnect rate of all incoming calls to no higher than 5 percent. The disconnect rate is defined as the number of calls unexpectedly dropped divided by the total number of calls made to the customer call center.

(iii)(A) Provides interpreters for non-English speaking and limited English proficient (LEP) individuals.

(B) For coverage beginning on and after January 1, 2022, interpreters must be available for 80 percent of incoming calls requiring an interpreter within 8 minutes of reaching the customer service representative and be made available at no cost to the caller.

(iv) At a minimum, for coverage beginning on and after January 1, 2022:

(A) Provides effective real-time communication with individuals using auxiliary aids and services, including TTYs and all forms of Federal Communication Commission-approved telecommunications relay systems, when using automated-attendant systems. See 28 CFR 35.161 and 36.303(d).

(B) Establishes contact with a customer service representative within 7 minutes on no fewer than 80 percent of incoming calls requiring TTY services.

(2) An Internet Web site that includes, at a minimum the following:

(i) The information required in paragraph (b) of this section.

(ii) Copies of its evidence of coverage and information (names, addresses, phone numbers, and specialty) on the network of contracted providers. Posting does not relieve the MA organization of its responsibility under paragraph (a) of this section to provide hard copies to enrollees upon request.

(iii) Posting does not relieve the MA organization of its responsibility under paragraph (a) of this section to provide hard copies of the Summary of Benefits to enrollees when CMS determines hard copy delivery of the Summary of Benefits is in the best interest of the beneficiary.

(3) The provision of information in writing, upon request.

(i) *Provision of information required for access to covered services.* MA plans must issue and reissue (as appropriate) member identification cards that enrollees may use to access covered services under the plan. The cards must comply with standards established by CMS.

(j) *Safe disposal of certain prescription drugs.* Information regarding the safe disposal of prescription drugs that are controlled substances and drug takeback programs must be provided in the case of an individual enrolled under an MA plan who is furnished an in-home health risk assessment on or after January 1, 2022. For purposes of this paragraph (j), a health risk assessment furnished to an individual who is residing in an institutional setting, such as a nursing facility, that has the primary responsibility for the disposal of unused medications, is not considered an in-home health risk assessment. As part of the in-home health risk assessment, the enrollee must be furnished written supporting materials describing how to safely dispose of medications that are controlled substances as well as a verbal summary of the written information as described at paragraphs (j)(1) through (6) of this section when possible. The written information furnished to enrollees about the safe disposal of medications and takeback programs must include the following information for enrollees:

(1) Unused medications should be disposed of as soon as possible.

(2) The U.S. Drug Enforcement Administration (DEA) allows unused prescription medications to be mailed back to pharmacies and other authorized sites using packages made available at such pharmacies or other authorized sites. Include a web link to the information available on the DEA website at *www.deatakeback.com* and the web link to the DEA search engine which enables beneficiaries to identify drug take back sites in their community at the following web address: *https://apps2.deadiversion.usdoj.gov/pubdispsearch/spring/main?execution=e2s1*.

(3) Community take back sites are the preferred method of disposing of unused controlled substances.

(4) The location of two or more drug take back sites that are available in the community where the enrollee resides.

(5) Instructions on how to safely dispose of medications in household trash or of cases when a medication can be safely flushed. Include instructions on removing personal identification information when disposing of prescription containers. If applicable, the instructions may also include information on the availability of in-home drug deactivation kits in the enrollee's community.

(6) Include a web link to the information available on the United States Department of Health and Human Services website identifying methods for the safe disposal of drugs available at the following web address: *www.hhs.gov/opioids/prevention/safely-dispose-drugs/index.html*

(k) *Claims information.* MA organizations must furnish directly to enrollees, in the manner specified by CMS and in a form easily understandable to such enrollees, a written explanation of benefits, when benefits are provided under this part.

(1) *Information requirements for the reporting period.* Claims data elements presented on the explanation of benefits must include all of the following for the reporting period:

(i) The descriptor and billing code for the item or service billed by the provider, and the corresponding amount billed.

(ii) The total cost approved by the plan for reimbursement.

(iii) The share of total cost paid for by the plan.

(iv) The share of total cost for which the enrollee is liable.

(2) *Information requirements for year-to-date totals.* Claims data elements presented on the explanation of benefits must include specific year-to-date totals as follows:

(i) The cumulative amount billed by all providers.

(ii) The cumulative total costs approved by the plan.

(iii) The cumulative share of total cost paid for by the plan.

(iv) The cumulative share of total cost for which the enrollee is liable.

(v) The amount an enrollee has incurred toward the MOOP limit, as applicable.

(vi) The amount an enrollee has incurred toward the deductible, as applicable.

(3) *Additional information requirements.* (i) Each explanation of benefits must include clear contact information for enrollee customer service.

(ii) Each explanation of benefits must include instructions on how to report fraud.

(iii) Each EOB that includes a denied claim must clearly identify the denied claim and provide information about enrollee appeal rights, but the EOB does not replace the notice required by §§ 422.568 and 422.570.

(4) *Reporting cycles for explanation of benefits.* MA organizations must send an explanation of benefits on either a monthly cycle or a quarterly cycle with per-claim notifications.

(i) A monthly explanation of benefits must include all claims processed in the prior month and, for each claim, the information in paragraphs (k)(1) and (2) of this section as of the last day of the prior month.

(A) The monthly explanation of benefits must be sent before the end of each month that follows the month a claim was filed.

(B) [Reserved]

(ii) A quarterly explanation of benefits must include all claims processed in the quarter and, for each claim, the information in paragraphs (k)(1) and (2) of this section as of the last day of the quarter; a per-claim notification must include all claims processed in the prior month and, for each claim, the information specified in paragraph (k)(1) of this section as of the last day of the prior month.

(A) MA organizations that send the explanation of benefits on a quarterly cycle with per-claim notifications must send the quarterly explanation of benefits before the end of each month that follows the quarter in which a claim was filed.

(B) MA organizations that send the explanation of benefits on a quarterly cycle with per-claim notifications must send the per-claim notification

before the end of each month that follows the month in which a claim was filed.

(5) *Exceptions.* MA organizations are not required to send the explanation of benefits to dual-eligible enrollees.

(l) *Mid-year notice of unused supplemental benefits.* Beginning January 1, 2026, MA organizations must send notification annually, no sooner than June 30 and no later than July 31, to each enrollee with unused supplemental benefits consistent with the requirements of § 422.2267(e)(42).

[63 FR 35077, June 26, 1998, as amended at 64 FR 7980, Feb. 17, 1999; 65 FR 40321, June 29, 2000; 68 FR 50857, Aug. 22, 2003; 70 FR 4722, Jan. 28, 2005; 70 FR 52026, Sept. 1, 2005; 73 FR 54220, 54249, Sept. 18, 2008; 75 FR 19805, Apr. 15, 2010; 76 FR 21563, Apr. 15, 2011; 77 FR 22167, Apr. 12, 2012; 80 FR 7959, Feb. 12, 2015; 83 FR 16724, Apr. 16, 2018; 84 FR 15828, Apr. 16, 2019; 86 FR 6095, Jan. 19, 2021; 88 FR 22329, Apr. 12, 2023; 89 FR 30818, Apr. 23, 2024]

EFFECTIVE DATE NOTE: At 90 FR 45151, Sept. 19, 2025, § 422.111 was amended, effective Nov. 17, 2025.

§ 422.112 Access to services.

(a) *Rules for coordinated care plans.* An MA organization that offers an MA coordinated care plan may specify the networks of providers from whom enrollees may obtain services if the MA organization ensures that all covered services, including supplemental services contracted for by (or on behalf of) the Medicare enrollee, are available and accessible under the plan. To accomplish this, the MA organization must meet the following requirements:

(1) *Provider network.* (i) Maintain and monitor a network of appropriate providers that is supported by written agreements and is sufficient to provide adequate access to covered services to meet the needs of the population served. These providers are typically used in the network as primary care providers (PCPs), specialists, hospitals, skilled nursing facilities, home health agencies, ambulatory clinics, and other providers. The network must include providers that specialize in behavioral health services.

(ii) *Exception*: MA regional plans, upon CMS pre-approval, can use methods other than written agreements to establish that access requirements are met.

(iii) Arrange for and cover any medically necessary covered benefit outside of the plan provider network, but at in-network cost sharing, when an in-network provider or benefit is unavailable or inadequate to meet an enrollee's medical needs.

(2) *PCP panel.* Establish a panel of PCPs from which the enrollee may select a PCP. If an MA organization requires its enrollees to obtain a referral in most situations before receiving services from a specialist, the MA organization must either assign a PCP for purposes of making the needed referral or make other arrangements to ensure access to medically necessary specialty care.

(3) *Specialty care.* Provide or arrange for necessary specialty care, and in particular give women enrollees the option of direct access to a women's health specialist within the network for women's routine and preventive health care services provided as basic benefits (as defined in § 422.2).

(4) *Service area expansion.* If seeking a service area expansion for an MA plan, demonstrate that the number and type of providers available to plan enrollees are sufficient to meet projected needs of the population to be served.

(5) *Credentialed providers.* Demonstrate to CMS that its providers in an MA plan are credentialed through the process set forth at § 422.204(a).

(6) *Written standards.* Establish written standards for the following:

(i) Timeliness of access to care and member services that meet or exceed standards in this paragraph. The MA organization must continuously monitor access to care and member services and must take corrective action as necessary to ensure that appointment wait times in the provider network comply with these standards. The minimum standards for appointment wait times for primary care and behavioral health services are as follows for appointments:

(A) Urgently needed services or emergency—immediately;

(B) Services that are not emergency or urgently needed, but the enrollee requires medical attention—within 7 business days; and

(C) Routine and preventive care—within 30 business days.

(ii) Policies and procedures (coverage rules, practice guidelines, payment policies, and utilization management) that allow for individual medical necessity determinations.

(iii) Provider consideration of beneficiary input into the provider's proposed treatment plan.

(7) *Hours of operation.* Ensure that—

(i) The hours of operation of its MA plan providers are convenient to the population served under the plan and do not discriminate against Medicare enrollees; and

(ii) Plan services are available 24 hours a day, 7 days a week, when medically necessary.

(8) *Ensuring equitable access to Medicare Advantage (MA) Services.* Ensure that services are provided in a culturally competent manner and to promote equitable access to all enrollees, including the following:

(i) People with limited English proficiency or reading skills.

(ii) People of ethnic, cultural, racial, or religious minorities.

(iii) People with disabilities.

(iv) People who identify as lesbian, gay, bisexual, or other diverse sexual orientations.

(v) People who identify as transgender, nonbinary, and other diverse gender identities, or people who were born intersex.

(vi) People living in rural areas and other areas with high levels of deprivation.

(vii) People otherwise adversely affected by persistent poverty or inequality.

(9) *Ambulance services, emergency and urgently needed services, and post-stabilization care services coverage.* Provide coverage for ambulance services, emergency and urgently needed services, and post-stabilization care services in accordance with § 422.113.

(10) *Prevailing patterns of community health care delivery.* MA plans that meet Medicare access and availability requirements through direct contracting network providers must do so consistent with the prevailing community pattern of health care delivery in the areas where the network is being offered. Factors making up community patterns of health care delivery that CMS will use as a benchmark in evaluating a proposed MA plan health care delivery network include, but are not limited to the following:

(i) The number and geographical distribution of eligible health care providers available to potentially contract with an MAO to furnish plan covered services within the proposed service area of the MA plans.

(ii) The prevailing market conditions in the service area of the MA plan. Specifically, the number and distribution of health care providers contracting with other health care plans (both commercial and Medicare) operating in the service area of the plan.

(iii) Whether the service area is comprised of rural or urban areas or some combination of the two.

(iv) Whether the MA plan's proposed provider network meet Medicare time and distance standards for member access to health care providers including specialties.

(v) Other factors that CMS determines are relevant in setting a standard for an acceptable health care delivery network in a particular service area.

(b) *Continuity of care.* MA organizations offering coordinated care plans must ensure continuity of care and integration of services through arrangements with contracted providers that include—

(1) Policies that specify under what circumstances services are coordinated and the methods for coordination;

(2) Offering to provide each enrollee with an ongoing source of primary care and providing a primary care source to each enrollee who accepts the offer;

(3) Programs for coordination of plan services with community and social services generally available through contracting or noncontracting providers in the area served by the MA plan, including nursing home and community-based services, and behavioral health services; and

(4) Procedures to ensure that the MA organization and its provider network have the information required for effective and continuous patient care and quality review, including procedures to ensure that—

(i) The MA organization makes a ''best-effort'' attempt to conduct an initial assessment of each enrollee's

health care needs, including following up on unsuccessful attempts to contact an enrollee, within 90 days of the effective date of enrollment;

(ii) Each provider, supplier, and practitioner furnishing services to enrollees maintains an enrollee health record in accordance with standards established by the MA organization, taking into account professional standards; and

(iii) There is appropriate and confidential exchange of information among provider network components.

(5) Procedures to ensure that enrollees are informed of specific health care needs that require follow-up and receive, as appropriate, training in self-care and other measures they may take to promote their own health; and

(6) Systems to address barriers to enrollee compliance with prescribed treatments or regimens.

(7) With respect to drugs for which payment as so prescribed and dispensed or administered to an individual may be available under Part A or Part B, or under Part D, MA–PD plans must coordinate all benefits administered by the plan and—

(i) Establish and maintain a process to ensure timely and accurate point-of-sale transactions; and

(ii) Issue the determination and authorize or provide the benefit under Part A or Part B or as a benefit under Part D as expeditiously as the enrollee's health condition requires, in accordance with the requirements of subpart M of this part and subpart M of part 423 of this chapter, as appropriate, when a party requests a coverage determination.

(8)(i) With respect to basic benefits, policies for using prior authorization that at a minimum include that for enrollees undergoing an active course of treatment—

(A) Approval of a prior authorization request for a course of treatment must be valid for as long as medically necessary to avoid disruptions in care, in accordance with applicable coverage criteria, the individual patient's medical history, and the treating provider's recommendation; and

(B) A minimum 90-day transition period for any active course(s) of treatment when an enrollee has enrolled in an MA plan after starting a course of treatment, even if the service is furnished by an out-of-network provider. This includes enrollees new to a plan and enrollees new to Medicare. The MA organization must not disrupt or require reauthorization for an active course of treatment for new plan enrollees for a period of at least 90 days.

(ii) For purposes of this paragraph (b)(8), the following definitions apply:

(A) *Course of treatment* means as a prescribed order or ordered course of treatment for a specific individual with a specific condition is outlined and decided upon ahead of time with the patient and provider. A course of treatment may but is not required to be part of a treatment plan.

(B) *Active course of treatment* means a course of treatment in which a patient is actively seeing the provider and following the course of treatment.

(c) *Essential hospital.* An MA regional plan may seek, upon application to CMS, to designate a noncontracting hospital as an essential hospital as defined in section 1858(h) of the Act under the following conditions:

(1) The hospital that the MA regional plan seeks to designate as essential is a general acute care hospital identified as a ''subsection(d)'' hospital as defined in section 1886(d)(1)(B) of the Act.

(2) The MA regional plan provides convincing evidence to CMS that the MA regional plan needs to contract with the hospital as a condition of meeting access requirements under this section.

(3) The MA regional plan must establish that it made a ''good faith'' effort to contract with the hospital to be designated as an essential hospital and that the hospital refused to contract with it despite its ''good faith'' effort. A ''good faith'' effort to contract will be established to the extent that the MA regional plan can show it has offered the hospital a contract providing for the payment of rates in an amount no less than the amount the hospital would have received had payment been made under section 1886(d) of the Act.

(4) The MA regional plan must establish that there are no competing Medicare participating hospitals in the area to which MA regional plan enrollees

could reasonably be referred for inpatient hospital services.

(5) The hospital that is an essential hospital under this paragraph provides convincing evidence to CMS that the amounts normally payable under section 1886 of the Act (and which the MA regional plan has agreed to pay) will be less than the hospital's actual costs of providing care to the MA regional plan's enrollee.

(6) If CMS determines the requirements in paragraphs (c)(1) through (c)(5) of this section have been met, it will make payment to the essential hospital in accordance with section 1858(h)(2) of the Act based on the order in which claims are received, as limited by the amounts specified in section 1858(h)(3) of the Act.

(7) If CMS determines the requirements in paragraphs (c)(1) through (c)(4) of this section have been met, (and if they continue to be met upon annual renewal of the CMS contract with the MA organization offering the MA regional plan), then the hospital designated by the MA regional plan in paragraph (c)(1) of this section shall be ''deemed'' to be a network hospital to that MA regional plan based on the exception in paragraph (a)(1)(ii) of this section and normal in-network inpatient hospital cost sharing levels (including the catastrophic limit described in § 422.101(d)(2)) shall apply to all plan members accessing covered inpatient hospital services in that hospital.

[64 FR 7980, Feb. 17, 1999, as amended at 65 FR 40321, June 29, 2000; 70 FR 4722, Jan. 28, 2005; 70 FR 76197, Dec. 23, 2005; 75 FR 19805, Apr. 15, 2010; 76 FR 21563, Apr. 15, 2011; 80 FR 7959, Feb. 12, 2015; 88 FR 22330, Apr. 12, 2023]

§ 422.113 Special rules for ambulance services, emergency and urgently needed services, and maintenance and post-stabilization care services.

(a) *Ambulance services.* The MA organization is financially responsible for ambulance services, including ambulance services dispatched through 911 or its local equivalent, where other means of transportation would endanger the beneficiary's health.

(b) *Emergency and urgently needed services*—(1) *Definitions.* (i) *Emergency medical condition* means a medical condition, mental or physical, manifesting itself by acute symptoms of sufficient severity (including severe pain) such that a prudent layperson, with an average knowledge of health and medicine, could reasonably expect the absence of immediate medical attention to result in—

(A) Serious jeopardy to the health of the individual or, in the case of a pregnant woman, the health of the woman or her unborn child;

(B) Serious impairment to bodily functions; or

(C) Serious dysfunction of any bodily organ or part.

(ii) *Emergency services* means covered inpatient and outpatient services that are—

(A) Furnished by a provider qualified to furnish emergency services; and

(B) Needed to evaluate or stabilize an emergency medical condition.

(iii) *Urgently needed services* means covered services that are not emergency services as defined in this section, provided when an enrollee is temporarily absent from the MA plan's service (or, if applicable, continuation) area (or provided when the enrollee is in the service or continuation area but the organization's provider network is temporarily unavailable or inaccessible) when the services are medically necessary and immediately required—

(A) As a result of an unforeseen illness, injury, or condition; and

(B) It was not reasonable given the circumstances to obtain the services through the organization offering the MA plan.

(2) *MA organization financial responsibility.* The MA organization is financially responsible for emergency and urgently needed services—

(i) Regardless of whether the services are obtained within or outside the MA organization;

(ii) Regardless of whether there is prior authorization for the services.

(A) Instructions to seek prior authorization for emergency or urgently needed services may not be included in any materials furnished to enrollees (including wallet card instructions), and enrollees must be informed of their right to call 911.

(B) Instruction to seek prior authorization before the enrollee has been

stabilized may not be included in any materials furnished to providers (including contracts with providers);

(iii) In accordance with the prudent layperson definition of *emergency medical condition* regardless of final diagnosis;

(iv) For which a plan provider or other MA organization representative instructs an enrollee to seek emergency services within or outside the plan; and

(v) With a dollar limit on emergency services costs for enrollees that is the lower of—

(A) The cost sharing established by the MA plan if the emergency services were provided through the MA organization; or

(B) A maximum cost sharing limit permitted per visit that corresponds to the MA plan MOOP limit as follows:

(*1*) For 2023, $95 for a mandatory MOOP limit, $110 for an intermediate MOOP limit, and $125 for a lower MOOP limit.

(*2*) For 2024, $100 for a mandatory MOOP limit, $120 for an intermediate MOOP limit, and $135 for a lower MOOP limit.

(*3*) For 2025, $110 for a mandatory MOOP limit, $125 for an intermediate MOOP limit, and $140 for a lower MOOP limit.

(*4*) For 2026 and subsequent years, $115 for a mandatory MOOP limit, $130 for an intermediate MOOP limit, and $150 for a lower MOOP limit.

(vi) For each year beginning on or after January 1, 2023, with a cost sharing limit on urgently needed services that does not exceed the limits specified for professional services in § 422.100(f)(6)(iii).

(3) *Stabilized condition.* The physician treating the enrollee must decide when the enrollee may be considered stabilized for transfer or discharge, and that decision is binding on the MA organization.

(c) *Maintenance care and post-stabilization care services* (hereafter together referred to as ''post-stabilization care services'').

(1) *Definition. Post-stabilization care services* means covered services, related to an emergency medical condition, that are provided after an enrollee is stabilized in order to maintain the stabilized condition, or, under the circumstances described in paragraph (c)(2)(iii) of this section, to improve or resolve the enrollee's condition.

(2) *MA organization financial responsibility.* The MA organization—

(i) Is financially responsible (consistent with § 422.214) for post-stabilization care services obtained within or outside the MA organization that are pre-approved by a plan provider or other MA organization representative;

(ii) Is financially responsible for post-stabilization care services obtained within or outside the MA organization that are not pre-approved by a plan provider or other MA organization representative, but administered to maintain the enrollee's stabilized condition within 1 hour of a request to the MA organization for pre-approval of further post-stabilization care services;

(iii) Is financially responsible for post-stabilization care services obtained within or outside the MA organization that are not pre-approved by a plan provider or other MA organization representative, but administered to maintain, improve, or resolve the enrollee's stabilized condition if—

(A) The MA organization does not respond to a request for pre-approval within 1 hour;

(B) The MA organization cannot be contacted; or

(C) The MA organization representative and the treating physician cannot reach an agreement concerning the enrollee's care and a plan physician is not available for consultation. In this situation, the MA organization must give the treating physician the opportunity to consult with a plan physician and the treating physician may continue with care of the patient until a plan physician is reached or one of the criteria in § 422.113(c)(3) is met; and

(iv) Must limit charges to enrollees for post-stabilization care services to an amount no greater than what the organization would charge the enrollee if he or she had obtained the services through the MA organization. For purposes of cost sharing, post-stabilization care services begin upon inpatient admission.

(3) *End of MA organization's financial responsibility.* The MA organization's financial responsibility for post-stabilization care services it has not preapproved ends when—

(i) A plan physician with privileges at the treating hospital assumes responsibility for the enrollee's care;

(ii) A plan physician assumes responsibility for the enrollee's care through transfer;

(iii) An MA organization representative and the treating physician reach an agreement concerning the enrollee's care; or

(iv) The enrollee is discharged.

[65 FR 40322, June 29, 2000, as amended at 70 FR 4723, Jan. 28, 2005; 76 FR 21563, Apr. 15, 2011; 80 FR 7959, Feb. 12, 2015; 87 FR 22428, Apr. 14, 2022; 88 FR 22330, Apr. 12, 2023]

§ 422.114 Access to services under an MA private fee-for-service plan.

(a) *Sufficient access.* (1) An MA organization that offers an MA private fee-for-service plan must demonstrate to CMS that it has sufficient number and range of providers willing to furnish services under the plan.

(2) Subject to paragraphs (a)(3) and (a)(4) of this section, CMS finds that an MA organization meets the requirement in paragraph (a)(1) of this section if, with respect to a particular category of health care providers, the MA organization has—

(i) Payment rates that are not less than the rates that apply under original Medicare for the provider in question;

(ii) Subject to paragraph (A) of section (a)(2)(ii), contracts or agreements with a sufficient number and range of providers to furnish the services covered under the MA private fee-for-service plan; or

(A) For plan year 2010 and subsequent plan years, contracts or agreements with a sufficient number and range of providers to meet the access standards described in section 1852(d)(1) of the Act.

(B) [Reserved]

(iii) A combination of paragraphs (a)(2)(i) and (a)(2)(ii) of this section.

(3) For plan year 2011 and subsequent plan years, an MA organization that offers an MA private fee-for-service plan (other than a plan described in section 1857(i)(1) or (2) of the Act) that is operating in a network area (as defined in paragraph (a)(3)(i) of this section) meets the requirement in paragraph (a)(1) of this section only if the MA organization has contracts or agreements with providers in accordance with paragraph (a)(2)(ii)(A) of this section.

(i) Network area is defined, for a given plan year, as the area that the Secretary identifies in the announcement of the risk and other factors to be used in adjusting MA capitation rates for each MA payment area for the previous plan year as having at least 2 network-based plans (as defined in paragraph (a)(3)(ii) of this section) with enrollment as of the first day of the year in which the announcement is made.

(ii) Network-based plan as defined in § 422.2.

(4) For plan year 2011 and subsequent plan years, an MA organization that offers an MA private fee-for-service plan that is described in section 1857(i)(1) or (2) of the Act meets the requirement in paragraph (a)(1) of this section only if the MA organization has contracts or agreements with providers in accordance with paragraph (a)(2)(ii)(A) of this section.

(b) *Freedom of choice.* MA fee-for-service plans must permit enrollees to obtain services from any entity that is authorized to provide services under Medicare Part A and Part B and agrees to provide services under the terms of the plan.

(c) *Contracted network.* Private fee-for-service plans that meet network adequacy requirements for a category of health care professional or provider by meeting the requirements in paragraph (a)(2)(ii) of this section may provide for a higher beneficiary copayment in the case of health care professionals or providers of that same category who do not have contracts or agreements to provide covered services under the terms of the plan.

[63 FR 35077, June 26, 1998, as amended at 70 FR 4723, Jan. 28, 2005; 73 FR 54249, Sept. 18, 2008; 89 FR 30819, Apr. 23, 2024]

§ 422.116 Network adequacy.

(a) *General rules*—(1) *Definition of county. County,* for purposes of this section, is defined as the primary political

and administrative division of most States and includes functionally equivalent divisions called ''county equivalents'' as recognized by the United States Census Bureau (for economic census purposes).

(2) *Access.* (i) A network-based MA plan, as described in § 422.2 but not including MSA plans, must demonstrate that it has an adequate contracted provider network that is sufficient to provide access to covered services in accordance with access standards described in section 1852(d)(1) of the Act and in §§ 422.112(a) and 422.114(a)(1) and by meeting the standard in paragraph (a)(3) of this section. When required by CMS, an MA organization must attest that it has an adequate network for access and availability of a specific provider or facility type that CMS does not independently evaluate in a given year.

(ii) Beginning with contract year 2024, an applicant for a new or expanding service area must demonstrate compliance with this section as part of its application for a new or expanding service area and CMS may deny an application on the basis of an evaluation of the applicant's network for the new or expanding service area.

(3) *Standards.* An MA plan must meet maximum time and distance standards and contract with a specified minimum number of each provider and facility-specialty type.

(i) Each contract provider type must be within maximum time and distance of at least one beneficiary (in the MA Medicare Sample Census) in order to count toward the minimum number.

(ii) The minimum number criteria and the time and distance criteria vary by the county type.

(4) *Applicability of MA network adequacy criteria.* (i) The following providers and facility types do not count toward meeting network adequacy criteria:

(A) Specialized, long-term care, and pediatric/children's hospitals.

(B) Providers that are only available in a residential facility.

(C) Providers and facilities contracted with the organization only for its commercial, Medicaid, or other products.

(ii) [Reserved]

(5) *Annual updates by CMS.* CMS annually updates and makes the following available:

(i) A Health Service Delivery (HSD) Reference file that identifies the following:

(A) All minimum provider and facility number requirements.

(B) All provider and facility time and distance standards.

(C) Ratios established in paragraph (e) of this section in advance of network reviews for the applicable year.

(ii) A Provider Supply file that lists available providers and facilities and their corresponding office locations and specialty types.

(A) The Provider Supply file is updated annually based on information in the Integrated Data Repository (IDR), which has comprehensive claims data, and information from public sources.

(B) CMS may also update the Provider Supply file based on findings from validation of provider information submitted on Exception Requests to reflect changes in the supply of health care providers and facilities.

(b) *Provider and facility-specialty types.* The provider and facility-specialty types to which the network adequacy evaluation under this section applies are specified in this paragraph (b).

(1) *Provider-specialty types.* The provider-specialty types are as follows:

(i) Primary Care.
(ii) Allergy and Immunology.
(iii) Cardiology.
(iv) Chiropractor.
(v) Dermatology.
(vi) Endocrinology.
(vii) ENT/Otolaryngology.
(viii) Gastroenterology.
(ix) General Surgery.
(x) Gynecology, OB/GYN.
(xi) Infectious Diseases.
(xii) Nephrology.
(xiii) Neurology.
(xiv) Neurosurgery.
(xv) Oncology—Medical, Surgical.
(xvi) Oncology—Radiation/Radiation Oncology.
(xvii) Ophthalmology.
(xviii) Orthopedic Surgery.
(xix) Physiatry, Rehabilitative Medicine.
(xx) Plastic Surgery.
(xxi) Podiatry.
(xxii) Psychiatry.

(xxiii) Pulmonology.
(xxiv) Rheumatology.
(xxv) Urology.
(xxvi) Vascular Surgery.
(xxvii) Cardiothoracic Surgery.
(xxviii) Clinical Psychology.
(xxix) Clinical Social Work.

(2) *Facility-specialty types.* The facility specialty types are as follows:
(i) Acute Inpatient Hospitals.
(ii) Cardiac Surgery Program.
(iii) Cardiac Catheterization Services.
(iv) Critical Care Services—Intensive Care Units (ICU).
(v) Surgical Services (Outpatient or ASC).
(vi) Skilled Nursing Facilities.
(vii) Diagnostic Radiology.
(viii) Mammography.
(ix) Physical Therapy.
(x) Occupational Therapy.
(xi) Speech Therapy.
(xii) Inpatient Psychiatric Facility Services.
(xiii) Outpatient Infusion/Chemotherapy.
(xiv) Outpatient behavioral health, which can include marriage and family therapists (as defined in section 1861(lll) of the Act), mental health counselors (as defined in section 1861(lll) of the act), opioid treatment programs (as defined in section 1861(jjj) of the act), community mental health centers (as defined in section 1861(ff)(3)(b) of the act), or those of the following who regularly furnish or will regularly furnish behavioral health counseling or therapy services including psychotherapy or prescription of medication for substance use disorders; physician assistants, nurse practitioners and clinical nurse specialists (as defined in section 1861(aa)(5) of the Act); addiction medicine physicians; or outpatient mental health and substance use treatment facilities.

(A) To be considered as regularly furnishing behavioral health services for the purposes of this regulation, a physician assistant (PA), nurse practitioner (NP), and clinical nurse specialist (CNS) must have furnished specific psychotherapy or medication prescription services (including, buprenorphine and methadone, for substance use disorders) to at least 20 patients within a 12-month period. CMS will identify, by detailed descriptions or Healthcare Common Procedure Coding System (HCPCS) code(s), the specific services in the HSD Reference File described in paragraph (a)(5)(i) of this section.

(B) To determine that a PA, NP, or CNS meets the standard in paragraph (b)(2)(xiv)(A) of this section, an MA organization must do all of the following:

(*1*) On an annual basis, independently verify that the provider has furnished such services within a recent 12-month period, using reliable information about services furnished by the provider such as the MA organization's claims data, prescription drug claims data, electronic health records, or similar data.

(*2*) If there is insufficient evidence of past practice by the provider, have a reasonable and supportable basis for concluding that the provider will meet the standard in paragraph (b)(2)(xiv)(A) of this section in the next 12 months.

(*3*) Submit evidence and documentation to CMS, upon request and in the form and manner specified by CMS, of the MA organization's determination that the provider meets the standard in paragraph (b)(2)(xiv)(A) of this section.

(3) *Removal of a provider or facility-specialty type.* CMS may remove a specialty or facility type from the network adequacy evaluation for a particular year by not including the type in the annual publication of the HSD reference file.

(c) *County type designations.* Counties are designated as a specific type using the following population size and density parameters:

(1) *Large metro.* A large metro designation is assigned to any of the following combinations of population sizes and density parameters:

(i) A population size greater than or equal to 1,000,000 persons with a population density greater than or equal to 1,000 persons per square mile.

(ii) A population size greater than or equal to 500,000 and less than or equal to 999,999 persons with a population density greater than or equal to 1,500 persons per square mile.

(iii) Any population size with a population density of greater than or equal to 5,000 persons per square mile.

(2) *Metro.* A metro designation is assigned to any of the following combinations of population sizes and density parameters:

(i) A population size greater than or equal to 1,000,000 persons with a population density greater than or equal to 10 persons per square mile and less than or equal to 999.9 persons per square mile.

(ii) A population size greater than or equal to 500,000 persons and less than or equal to 999,999 persons with a population density greater than or equal to 10 persons per square mile and less than or equal to 1,499.9 persons per square mile.

(iii) A population size greater than or equal to 200,000 persons and less than or equal to 499,999 persons with a population density greater than or equal to 10 persons per square mile and less than or equal to 4,999.9 persons per square mile.

(iv) A population size greater than or equal to 50,000 persons and less than or equal to 199,999 persons with a population density greater than or equal to 100 persons per square mile and less than or equal to 4999.9 persons per square mile.

(v) A population size greater than or equal to 10,000 persons and less than or equal to 49,999 persons with a population density greater than or equal to 1,000 persons per square mile and less than or equal to 4999.9 persons per square mile.

(3) *Micro.* A micro designation is assigned to any of the following combinations of population sizes and density parameters:

(i) A population size greater than or equal to 50,000 persons and less than or equal to 199,999 persons with a population density greater than or equal to 10 persons per square mile and less than or equal to 99.9 persons per square mile.

(ii) A population size greater than or equal to 10,000 persons and less than or equal to 49,999 persons with a population density greater than or equal to 50 persons per square mile and less than 999.9 persons per square mile.

(4) *Rural.* A rural designation is assigned to any of the following combinations of population sizes and density parameters:

(i) A population size greater than or equal to 10,000 persons and less than or equal to 49,999 persons with a population density of greater than or equal to 10 persons per square mile and less than or equal to 49.9 persons per square mile.

(ii) A population size less than 10,000 persons with a population density greater than or equal 50 persons per square mile and less than or equal to 999.9 persons per square mile.

(5) *Counties with extreme access considerations (CEAC).* For any population size with a population density of less than 10 persons per square mile.

(d) *Maximum time and distance standards*—(1) *General rule.* CMS determines and annually publishes maximum time and distance standards for each combination of provider or facility specialty type and each county type in accordance with paragraphs (d)(2) and (3) of this section.

(i) Time and distance metrics measure the relationship between the approximate locations of beneficiaries and the locations of the network providers and facilities.

(ii) [Reserved]

(2) *By county designation.* The following base maximum time (in minutes) and distance (in miles) standards apply for each county type designation, unless modified through customization as described in paragraph (d)(3) of this section.

TABLE 1 TO PARAGRAPH (d)(2)

Provider/facility type	Large metro		Metro		Micro		Rural		CEAC	
	Max time	Max distance	Max time	Max distance	Max time	Max distance	Max time	Max distance	Max time	Max distance
Primary Care	10	5	15	10	30	20	40	30	70	60
Allergy and Immunology	30	15	45	30	80	60	90	75	125	110
Cardiology	20	10	30	20	50	35	75	60	95	85
Chiropractor	30	15	45	30	80	60	90	75	125	110
Clinical Psychology	20	10	45	30	60	45	75	60	145	130
Dermatology	20	10	45	30	60	45	75	60	110	100
Endocrinology	30	15	60	40	100	75	110	90	145	130
ENT/Otolaryngology	30	15	45	30	80	60	90	75	125	110
Gastroenterology	20	10	45	30	60	45	75	60	110	100
General Surgery	20	10	30	20	50	35	75	60	95	85
Gynecology, OB/GYN	30	15	45	30	80	60	90	75	125	110
Infectious Diseases	30	15	60	40	100	75	110	90	145	130
Licensed Clinical Social Work	20	10	30	20	50	35	75	60	125	110
Nephrology	30	15	45	30	80	60	90	75	125	110
Neurology	20	10	45	30	60	45	75	60	110	100
Neurosurgery	30	15	60	40	100	75	110	90	145	130
Oncology—Medical, Surgical	20	10	45	30	60	45	75	60	110	100
Oncology—Radiation/Radiation Oncology	30	15	60	40	100	75	110	90	145	130
Ophthalmology	20	10	30	20	50	35	75	60	95	85
Orthopedic Surgery	20	10	30	20	50	35	75	60	95	85
Outpatient Behavioral Health	20	10	40	25	55	40	60	50	110	100
Physiatry, Rehabilitative Medicine	30	15	45	30	80	60	90	75	125	110
Plastic Surgery	30	15	60	40	100	75	110	90	145	130
Podiatry	20	10	45	30	60	45	75	60	110	100
Psychiatry	20	10	45	30	60	45	75	60	110	100
Pulmonology	20	10	45	30	60	45	75	60	110	100
Rheumatology	30	15	60	40	100	75	110	90	145	130
Urology	20	10	45	30	60	45	75	60	110	100
Vascular Surgery	30	15	60	40	100	75	110	90	145	130
Cardiothoracic Surgery	30	15	60	40	100	75	110	90	145	130
Acute Inpatient Hospitals	20	10	45	30	80	60	75	60	110	100
Cardiac Surgery Program	30	15	60	40	160	120	145	120	155	140
Cardiac Catheterization Services	30	15	60	40	160	120	145	120	155	140
Critical Care Services—Intensive Care Units (ICU)	20	10	45	30	160	120	145	120	155	140
Surgical Services (Outpatient or ASC)	20	10	45	30	80	60	75	60	110	100

TABLE 1 TO PARAGRAPH (d)(2)—Continued

Provider/facility type	Large metro		Metro		Micro		Rural		CEAC	
	Max time	Max distance	Max time	Max distance	Max time	Max distance	Max time	Max distance	Max time	Max distance
Skilled Nursing Facilities	20	10	45	30	80	60	75	60	95	85
Diagnostic Radiology	20	10	45	30	80	60	75	60	110	100
Mammography	20	10	45	30	80	60	75	60	110	100
Physical Therapy	20	10	45	30	80	60	75	60	110	100
Occupational Therapy	20	10	45	30	80	60	75	60	110	100
Speech Therapy	20	10	45	30	80	60	75	60	110	100
Inpatient Psychiatric Facility Services	30	15	70	45	100	75	90	75	155	140
Outpatient Infusion/Chemotherapy	20	10	45	30	80	60	75	60	110	100

(3) *By customization.* When necessary due to utilization or supply patterns, CMS may set maximum time and distance standards for provider or facility types for specific counties by customization in accordance with the following rules:

(i) CMS maps provider location data from the Provider Supply file against its MA Medicare Sample Census (which provides MA enrollee population distribution data) or uses claims data to identify the distances beneficiaries travel according to the usual patterns of care for the county.

(ii) CMS identifies the distance at which 90 percent of the population would have access to at least one provider or facility in the applicable specialty type.

(iii) The resulting distance is then rounded up to the next multiple of 5, and a multiplier specific to the county designation is applied to determine the analogous maximum time.

(iv) Customization may only be used to increase the base time and distance standards specified in paragraph (d)(2) of this section and may not be used to decrease the base time and distance standards.

(4) *Percentage of beneficiaries residing within maximum time and distance standards.* MA plans must ensure both of the following:

(i) At least 85 percent of the beneficiaries residing in micro, rural, or CEAC counties have access to at least one provider/facility of each specialty type within the published time and distance standards.

(ii) At least 90 percent of the beneficiaries residing in large metro and metro counties have access to at least one provider/facility of each specialty type within the published time and distance standards.

(5) *MA telehealth providers.* An MA plan receives a 10 percentage point credit towards the percentage of beneficiaries residing within published time and distance standards for the applicable provider specialty type and county when the plan includes one or more telehealth providers that provide additional telehealth benefits, as defined in § 422.135, in its contracted networks for the following provider specialty types:

(i) Dermatology.

(ii) Psychiatry.

(iii) Cardiology.

(iv) Neurology.

(v) Otolaryngology.

(vi) Ophthalmology.

(vii) Allergy and Immunology.

(viii) Nephrology.

(ix) Primary Care.

(x) Gynecology/OB/GYN.

(xi) Endocrinology.

(xii) Infectious Diseases.

(xiii) Clinical Psychology.

(xiv) [Reserved]

(xv) Outpatient Behavioral Health, described in paragraph (b)(2)(xiv) of this section.

(xvi)–(xxiii) [Reserved]

(xxiv) Clinical Social Work.

(6) *State Certificate of Need (CON) laws.* In a State with CON laws, or other state imposed anti-competitive restrictions that limit the number of providers or facilities in the State or a county in the State, CMS will award the MA organization a 10-percentage point credit towards the percentage of beneficiaries residing within published time and distance standards for affected providers and facilities in paragraph (b) of this section or, when necessary due to utilization or supply patterns, customize the base time and distance standards.

(7) *New or expanding service area applicants.* Beginning with contract year 2024, an applicant for a new or expanding service area receives a 10-percentage point credit towards the percentage of beneficiaries residing within published time and distance standards for the contracted network in the pending service area, at the time of application and for the duration of the application review. In addition, applicants may use a Letter of Intent (LOI), signed by both the MA organization (MAO) and the provider or facility with which the MAO has started or intends to negotiate, in lieu of a signed contract at the time of application and for the duration of the application review, to meet network standards. As part of the network adequacy review process, applicants must notify CMS of their use of LOIs to meet network standards in lieu of a signed contract and submit copies upon request and in the form and manner directed by CMS. At the beginning of the applicable contract

year, the credit and the use of LOIs no longer apply and if the application is approved, the MA organization must be in full compliance with this section, including having signed contracts with the provider or facility.

(e) *Minimum number standard.* CMS annually determines the minimum number standard for each provider and facility-specialty type as follows:

(1) *General rule.* The provider or facility must—

(i) Be within the maximum time and distance of at least one beneficiary in order to count towards the minimum number standard (requirement); and

(ii) Not be a telehealth-only provider.

(2) *Minimum number requirement for provider and facility-specialty types.* The minimum number for provider and facility-specialty types are as follows:

(i) For provider-specialty types described in paragraph (b)(1) of this section, CMS calculates the minimum number as specified in paragraph (e)(3) of this section.

(ii) For facility-specialty types described in paragraph (b)(2)(i) of this section, CMS calculates the minimum number as specified in paragraph (e)(3) of this section.

(iii) For facility-specialty types described in paragraphs (b)(2)(ii) through (xiv) of this section, the minimum requirement number is 1.

(3) *Determination of the minimum number of for certain provider and facility-specialty types.* For specialty types in paragraphs (b)(1) and (b)(2)(i) of this section, CMS multiplies the minimum ratio by the number of beneficiaries required to cover, divides the resulting product by 1,000, and rounds it up to the next whole number.

(i)(A) The minimum ratio for provider specialty types represents the minimum number of providers per 1,000 beneficiaries.

(B) The minimum ratio for facility specialty type specified in paragraph (b)(2)(i) of this section (acute inpatient hospital) represents the minimum number of beds per 1,000 beneficiaries.

(C) The minimum ratios are as follows:

TABLE 2 TO PARAGRAPH (E)(3)(i)(C)

Minimum ratio	Large metro	Metro	Micro	Rural	CEAC
Primary Care	1.67	1.67	1.42	1.42	1.42
Allergy and Immunology	0.05	0.05	0.04	0.04	0.04
Cardiology	0.27	0.27	0.23	0.23	0.23
Chiropractor	0.10	0.10	0.09	0.09	0.09
Clinical Psychology	0.15	0.15	0.13	0.13	0.13
Clinical Social Work	0.25	0.25	0.22	0.22	0.22
Dermatology	0.16	0.16	0.14	0.14	0.14
Endocrinology	0.04	0.04	0.03	0.03	0.03
ENT/Otolaryngology	0.06	0.06	0.05	0.05	0.05
Gastroenterology	0.12	0.12	0.10	0.10	0.10
General Surgery	0.28	0.28	0.24	0.24	0.24
Gynecology, OB/GYN	0.04	0.04	0.03	0.03	0.03
Infectious Diseases	0.03	0.03	0.03	0.03	0.03
Nephrology	0.09	0.09	0.08	0.08	0.08
Neurology	0.12	0.12	0.10	0.10	0.10
Neurosurgery	0.01	0.01	0.01	0.01	0.01
Oncology—Medical, Surgical	0.19	0.19	0.16	0.16	0.16
Oncology—Radiation/Radiation Oncology	0.06	0.06	0.05	0.05	0.05
Ophthalmology	0.24	0.24	0.20	0.20	0.20
Orthopedic Surgery	0.20	0.20	0.17	0.17	0.17
Physiatry, Rehabilitative Medicine	0.04	0.04	0.03	0.03	0.03
Plastic Surgery	0.01	0.01	0.01	0.01	0.01
Podiatry	0.19	0.19	0.16	0.16	0.16
Psychiatry	0.14	0.14	0.12	0.12	0.12
Pulmonology	0.13	0.13	0.11	0.11	0.11
Rheumatology	0.07	0.07	0.06	0.06	0.06
Urology	0.12	0.12	0.10	0.10	0.10
Vascular Surgery	0.02	0.02	0.02	0.02	0.02
Cardiothoracic Surgery	0.01	0.01	0.01	0.01	0.01
Acute Inpatient Hospitals	12.2	12.2	12.2	12.2	12.2

(ii)(A) *Number of beneficiaries required to cover.* (*1*) The number of beneficiaries required to cover is calculated by multiplying the 95th percentile base population ratio by the total number of Medicare beneficiaries residing in a county.

(*2*) CMS uses its MA State/County Penetration data to calculate the total number of beneficiaries residing in a county.

(B) *95th percentile base population ratio.* (*1*) The 95th percentile base population ratio is:

(*i*) Calculated annually for each county type and varies over time as MA market penetration and plan enrollment change across markets; and

(*ii*) Represents the proportion of Medicare beneficiaries enrolled in the 95th percentile MA plan (that is, 95 percent of plans have enrollment lower than this level).

(*2*) CMS calculates the 95th percentile base population ratio as follows:

(*i*) Uses its most recent List of PFFS Network Counties to exclude any private-fee-for-service (PFFS) plans in non-networked counties from the calculation at the county-type level.

(*ii*) Uses its most recent MA State/County Penetration data to determine the number of eligible Medicare beneficiaries in each county.

(*iii*) Uses its Monthly MA Enrollment By State/County/Contract data to determine enrollment at the contract ID and county level, including only enrollment in regional preferred provider organization (RPPO), local preferred provider organization (LPPO), HMO, HMO/provider sponsored organization (POS), healthcare prepayment plans under section 1833 of the Act, and network PFFS plan types.

(*iv*) Calculates penetration at the contract ID and county level by dividing the number of enrollees for a given contract ID and county by the number of eligible beneficiaries in that county.

(*v*) Groups counties by county designation to determine the 95th percentile of penetration among MA plans for each county type.

(f) *Exception requests.* (1) An MA plan may request an exception to network adequacy criteria in paragraphs (b) through (e) of this section when either paragraph (f)(1)(i) or (ii) of this section is met:

(i)(A) Certain providers or facilities are not available for the MA plan to meet the network adequacy criteria as shown in the Provider Supply file for the year for a given county and specialty type; and

(B) The MA plan has contracted with other providers and facilities that may be located beyond the limits in the time and distance criteria, but are currently available and accessible to most enrollees, consistent with the local pattern of care.

(ii)(A) A facility-based Institutional-Special Needs Plan (I–SNP) is unable to contract with certain specialty types required under §422.116(b) because of the way enrollees in facility-based I–SNPs receive care; or

(B) A facility-based I–SNP provides sufficient and adequate access to basic benefits through additional telehealth benefits (in compliance with §422.135) when using telehealth providers of the specialties listed in paragraph (d)(5) of this section in place of in-person providers to fulfill network adequacy standards in paragraphs (b) through (e) of this section.

(2) In evaluating exception requests, CMS considers whether—

(i) The current access to providers and facilities is different from the HSD reference and Provider Supply files for the year;

(ii) There are other factors present, in accordance with §422.112(a)(10)(v), that demonstrate that network access is consistent with or better than the original Medicare pattern of care; and

(iii) Approval of the exception is in the best interests of beneficiaries.

(iv) As applicable, the facility-based I–SNP submits:

(A) Evidence of the inability to contract with certain specialty types required under this section due to the way enrollees in facility-based I–SNPs receive care; or

(B) Substantial and credible evidence that sufficient and adequate access to basic benefits is provided to enrollees using additional telehealth benefits (in compliance with §422.135) furnished by providers of the specialties listed in paragraph (d)(5) of this section and the

facility-based I–SNP covers out-of-network services furnished by a provider in person when requested by the enrollee as provided in § 422.135(c)(1) and (2), with in-network cost sharing for the enrollee.

(3) Any MA organization that receives the exception provided for facility-based I–SNPs must agree to offer only facility-based I–SNPs under the MA contract that receives the exception.

[85 FR 33904, June 2, 2020, as amended at 87 FR 27895, May 9, 2022; 88 FR 22330, Apr. 12, 2023; 89 FR 30819, Apr. 23, 2024; 89 FR 63827, Aug. 6, 2024; 90 FR 15910, Apr. 15, 2025]

§ 422.118 Confidentiality and accuracy of enrollee records.

For any medical records or other health and enrollment information it maintains with respect to enrollees, an MA organization must establish procedures to do the following:

(a) Abide by all Federal and State laws regarding confidentiality and disclosure of medical records, or other health and enrollment information. The MA organization must safeguard the privacy of any information that identifies a particular enrollee and have procedures that specify—

(1) For what purposes the information will be used within the organization; and

(2) To whom and for what purposes it will disclose the information outside the organization.

(b) Ensure that medical information is released only in accordance with applicable Federal or State law, or pursuant to court orders or subpoenas.

(c) Maintain the records and information in an accurate and timely manner.

(d) Ensure timely access by enrollees to the records and information that pertain to them.

[65 FR 40323, June 29, 2000]

§ 422.119 Access to and exchange of health data and plan information.

(a) *Application Programming Interface to support MA enrollees.* A Medicare Advantage (MA) organization must implement and maintain a standards-based Application Programming Interface (API) that permits third-party applications to retrieve, with the approval and at the direction of a current individual MA enrollee or the enrollee's personal representative, data specified in paragraph (b) of this section through the use of common technologies and without special effort from the enrollee.

(b) *Accessible content.* (1) An MA organization must make the following information accessible to its current enrollees or the enrollee's personal representative through the API described in paragraph (a) of this section:

(i) Data concerning adjudicated claims, including claims data for payment decisions that may be appealed, were appealed, or are in the process of appeal, and provider remittances and enrollee cost-sharing pertaining to such claims, no later than one (1) business day after a claim is processed;

(ii) Encounter data from capitated providers, no later than one (1) business day after data concerning the encounter is received by the MA organization;

(iii) All data classes and data elements included in a content standard in 45 CFR 170.213 that are maintained by the MA organization no later than 1 business day after the MA organization receives the data; and

(iv) Beginning January 1, 2027, the information in paragraph (b)(1)(iv)(A) of this section about prior authorizations for items and services (excluding drugs, as defined in paragraph (b)(1)(v) of this section), according to the timelines in paragraph (b)(1)(iv)(B) of this section.

(A) The prior authorization request and decision, including all of the following, as applicable:

(*1*) The prior authorization status.

(*2*) The date the prior authorization was approved or denied.

(*3*) The date or circumstance under which the prior authorization ends.

(*4*) The items and services approved.

(*5*) If denied, a specific reason why the request was denied.

(*6*) Related structured administrative and clinical documentation submitted by a provider.

(B) The information in paragraph (b)(1)(iv)(A) of this section must—

(*1*) Be accessible no later than 1 business day after the MA organization receives a prior authorization request;

(*2*) Be updated no later than 1 business day after any status change; and

(*3*) Continue to be accessible for the duration that the authorization is active and at least 1 year after the prior authorization's last status change.

(v) Drugs are defined for the purposes of paragraph (b)(1)(iv) of this section as any and all drugs covered by the MA organization, including any products that constitute a Part D drug, as defined by §423.100 of this chapter, and are covered under the Medicare Part D benefit.

(2) In addition to the information specified in paragraph (b)(1) of this section, an MA organization that offers an MA–PD plan must make the following information accessible to its enrollees through the API described in paragraph (a) of this section:

(i) Data concerning adjudicated claims for covered Part D drugs, including remittances and enrollee cost-sharing, no later than one (1) business day after a claim is adjudicated; and,

(ii) Formulary data that includes covered Part D drugs, and any tiered formulary structure or utilization management procedure which pertains to those drugs.

(c) *Technical requirements.* An MA organization implementing an API under paragraph (a) of this section:

(1) Must implement and maintain API technology conformant with 45 CFR 170.215(a)(1), (b)(1)(i), (c)(1), and (e)(1);

(2) Must conduct routine testing and monitoring, and update as appropriate, to ensure the API functions properly, including assessments to verify that the API is fully and successfully implementing privacy and security features such as, but not limited to, those required to comply with HIPAA privacy and security requirements in 45 CFR parts 160 and 164, 42 CFR parts 2 and 3, and other applicable law protecting the privacy and security of individually identifiable data;

(3) Must comply with the content and vocabulary standard requirements in paragraphs (c)(3)(i) and (ii) of this section, as applicable to the data type or data element, unless alternate standards are required by other applicable law:

(i) Content and vocabulary standards at 45 CFR 170.213 where such standards are applicable to the data type or element, as appropriate; and

(ii) Content and vocabulary standards at 45 CFR part 162 and §423.160 of this chapter where required by law or where such standards are applicable to the data type or element, as appropriate.

(4) May use an updated version of any standard or all standards required under paragraph (c)(1) or (3) of this section, where:

(i) Use of the updated version of the standard is required by other applicable law; or

(ii) Use of the updated version of the standard is not prohibited under other applicable law, provided that:

(A) For content and vocabulary standards other than those at 45 CFR 170.213, the Secretary has not prohibited use of the updated version of a standard for purposes of this section or 45 CFR part 170;

(B) For standards at 45 CFR 170.213 and 45 CFR 170.215, the National Coordinator has approved the updated version for use in the ONC Health IT Certification Program; and

(C) Using the updated version of the standard, implementation guide, or specification does not disrupt an end user's ability to access the data specified in paragraph (b) of this section or §§422.120, 422.121, and 422.122 through the required APIs.

(d) *Documentation requirements for APIs.* For each API implemented in accordance with paragraph (a) of this section, an MA organization must make publicly accessible, by posting directly on its website or via publicly accessible hyperlink(s), complete accompanying documentation that contains, at a minimum the information listed in this paragraph. For the purposes of this section, ''publicly accessible'' means that any person using commonly available technology to browse the internet could access the information without any preconditions or additional steps, such as a fee for access to the documentation; a requirement to receive a copy of the material via email; a requirement to register or create an account to receive the documentation; or

a requirement to read promotional material or agree to receive future communications from the organization making the documentation available;

(1) API syntax, function names, required and optional parameters supported and their data types, return variables and their types/structures, exceptions and exception handling methods and their returns;

(2) The software components and configurations an application must use in order to successfully interact with the API and process its response(s); and

(3) All applicable technical requirements and attributes necessary for an application to be registered with any authorization server(s) deployed in conjunction with the API.

(e) *Denial or discontinuation of access to the API.* An MA organization may deny or discontinue any third party application's connection to the API required under paragraph (a) of this section if the MA organization:

(1) Reasonably determines, consistent with its security risk analysis under 45 CFR part 164 subpart C, that allowing an application to connect or remain connected to the API would present an unacceptable level of risk to the security of protected health information on the MA organization's systems; and

(2) Makes this determination using objective, verifiable criteria that are applied fairly and consistently across all apps and developers through which parties seek to access electronic health information, as defined in 45 CFR 171.102, including but not limited to, criteria that rely on automated monitoring and risk mitigation tools.

(f) *Reporting on Patient Access API usage.* Beginning in 2026, by March 31 following any calendar year that it offers an MA plan, an MA organization must report to CMS the following metrics, in the form of aggregated, deidentified data, for the previous calendar year at the contract level in the form and manner specified by the Secretary:

(1) The total number of unique enrollees whose data are transferred via the Patient Access API to a health app designated by the enrollee.

(2) The total number of unique enrollees whose data are transferred more than once via the Patient Access API to a health app designated by the enrollee.

(g) *Enrollee resources regarding privacy and security.* An MA organization must provide in an easily accessible location on its public website and through other appropriate mechanisms through which it ordinarily communicates with current and former enrollees seeking to access their health information held by the MA organization, educational resources in non-technical, simple and easy-to-understand language explaining at a minimum:

(1) General information on steps the individual may consider taking to help protect the privacy and security of their health information including factors to consider in selecting an application including secondary uses of data, and the importance of understanding the security and privacy practices of any application to which they will entrust their health information; and

(2) An overview of which types of organizations or individuals are and are not likely to be HIPAA covered entities, the oversight responsibilities of the Office for Civil Rights (OCR) and the Federal Trade Commission (FTC), and how to submit a complaint to:

(i) The HHS Office for Civil Rights (OCR); and

(ii) The Federal Trade Commission (FTC).

(h) *Applicability.* An MA organization must comply with the requirements of this section beginning in paragraphs (a) through (e) and (g) of this section beginning January 1, 2021, unless otherwise specified, and with the requirements in paragraph (f) of this section beginning in 2026, with regard to data:

(1) With a date of service on or after January 1, 2016; and

(2) That are maintained by the MA organization.

[85 FR 25632, May 1, 2020, as amended at 89 FR 8974, Feb. 8, 2024]

§ 422.120 Access to published provider directory information.

(a) An MA organization must implement and maintain a publicly accessible, standards-based Application Programming Interface (API) that is

conformant with the technical requirements at § 422.119(c), excluding the security protocols related to user authentication and authorization and any other protocols that restrict the availability of this information to particular persons or organizations, the documentation requirements at § 422.119(d), and is accessible via a public-facing digital endpoint on the MA organization's website.

(b) The API must provide a complete and accurate directory of—

(1) The MA plan's network of contracted providers, including names, addresses, phone numbers, and specialties, updated no later than 30 calendar days after the MA organizations receives provider directory information or updates to provider directory information; and

(2) For an MA organization that offers an MA–PD plan, the MA–PD's pharmacy directory, including the pharmacy name, address, phone number, number of pharmacies in the network, and mix (specifically the type of pharmacy, such as ''retail pharmacy'') updated no later than 30 calendar days after the MA organization receives pharmacy directory information or updates to pharmacy directory information.

(c) This section is applicable beginning January 1, 2021.

[85 FR 25633, May 1, 2020]

§ 422.121 Access to and exchange of health data for providers and payers.

(a) *Application programming interface to support data exchange from payers to providers—Provider Access API.* Beginning January 1, 2027, an MA organization must do the following:

(1) *API requirements.* Implement and maintain an application programming interface (API) conformant with all of the following:

(i) Section 422.119(c)(2) through (4), (d), and (e).

(ii) The standards in 45 CFR 170.215(a)(1), (b)(1)(i), (c)(1), and (d)(1).

(2) *Provider access.* Make the data specified at § 422.119(b) with a date of service on or after January 1, 2016, excluding provider remittances and enrollee cost-sharing information, that are maintained by the MA organization available to in-network providers via the API required in paragraph (a)(1) of this section no later than 1 business day after receiving a request from such a provider, if all the following conditions are met:

(i) The MA organization authenticates the identity of the provider that requests access and attributes the enrollee to the provider under the attribution process described in paragraph (a)(3) of this section.

(ii) The enrollee does not opt out as described in paragraph (a)(4) of this section.

(iii) Disclosure of the data is not prohibited by other applicable law.

(3) *Attribution.* Establish and maintain a process to associate enrollees with their in-network providers to enable data exchange via the Provider Access API.

(4) *Opt out and patient educational resources.* (i) Establish and maintain a process to allow an enrollee or the enrollee's personal representative to opt out of the data exchange described in paragraph (a)(2) of this section and to change their permission at any time. That process must be available before the first date on which the MA organization makes enrollee information available via the Provider Access API and at any time while the enrollee is enrolled with the MA organization.

(ii) Provide information to enrollees in plain language about the benefits of API data exchange with their providers, their opt out rights, and instructions both for opting out of data exchange and for subsequently opting in, as follows:

(A) Before the first date on which the MA organization makes enrollee information available through the Provider Access API.

(B) No later than 1 week after the coverage start date or no later than 1 week after receiving acceptance of enrollment from CMS, whichever is later.

(C) At least annually.

(D) In an easily accessible location on its public website.

(5) *Provider resources.* Provide on its website and through other appropriate provider communications, information in plain language explaining the process for requesting enrollee data using the Provider Access API required in

paragraph (a)(1) of this section. The resources must include information about how to use the MA organization's attribution process to associate enrollees with their providers.

(b) *Application programming interface to support data exchange between payers—Payer-to-Payer API.* Beginning January 1, 2027, an MA organization must do the following:

(1) *API requirements.* Implement and maintain an API conformant with all of the following:

(i) Section 422.119(c)(2) through (4), (d), and (e).

(ii) The standards in 45 CFR 170.215(a)(1), (b)(1)(i), and (d)(1).

(2) *Opt in.* Establish and maintain a process to allow enrollees or their personal representatives to opt into the MA organization's payer to payer data exchange with the enrollee's previous payer(s), described in paragraphs (b)(4) and (5) of this section, and with concurrent payer(s), described in paragraph (b)(6) of this section, and to change their permission at any time.

(i) The opt in process must be offered as follows:

(A) To current enrollees, no later than the compliance date.

(B) To new enrollees, no later than 1 week after the coverage start date or no later than 1 week after receiving acceptance of enrollment from CMS, whichever is later.

(ii) If an enrollee does not respond or additional information is necessary, the MA organization must make reasonable efforts to engage with the enrollee to collect this information.

(3) *Identify previous and concurrent payers.* Establish and maintain a process to identify a new enrollee's previous and concurrent payer(s) to facilitate the Payer-to-Payer API data exchange. The information request process must start as follows:

(i) For current enrollees, no later than the compliance date.

(ii) For new enrollees, no later than 1 week after the coverage start date or no later than 1 week after receiving acceptance of enrollment from CMS, whichever is later.

(iii) If an enrollee does not respond or additional information is necessary, the MA organization must make reasonable efforts to engage with the enrollee to collect this information.

(4) *Exchange request requirements.* Exchange enrollee data with other payers, consistent with the following requirements:

(i) The MA organization must request the data listed in paragraph (b)(4)(ii) of this section through the enrollee's previous payers' API, if all the following conditions are met:

(A) The enrollee has opted in, as described in paragraph (b)(2) of this section.

(B) The exchange is not prohibited by other applicable law.

(ii) The data to be requested are all of the following with a date of service within 5 years before the request:

(A) Data specified in § 422.119(b) excluding the following:

(*1*) Provider remittances and enrollee cost-sharing information.

(*2*) Denied prior authorizations.

(B) Unstructured administrative and clinical documentation submitted by a provider related to prior authorizations.

(iii) The MA organization must include an attestation with this request affirming that the enrollee is enrolled with the MA organization and has opted into the data exchange.

(iv) The MA organization must complete this request as follows:

(A) No later than 1 week after the payer has sufficient identifying information about previous payers and the enrollee has opted in.

(B) At an enrollee's request, within 1 week of the request.

(v) The MA organization must receive, through the API required in paragraph (b)(1) of this section, and incorporate into its records about the enrollee, any data made available by other payers in response to the request.

(5) *Exchange response requirements.* Make available the data specified in paragraph (b)(4)(ii) of this section that are maintained by the MA organization to other payers via the API required in paragraph (b)(1) of this section within 1 business day of receiving a request, if all the following conditions are met:

(i) The payer that requests access has its identity authenticated and includes an attestation with the request that

the patient is enrolled with the payer and has opted into the data exchange.

(ii) Disclosure of the data is not prohibited by other applicable law.

(6) *Concurrent coverage data exchange requirements.* When an enrollee has provided sufficient identifying information about concurrent payers and has opted in as described in paragraph (b)(2) of this section, an MA organization must do the following, through the API required in paragraph (b)(1) of this section:

(i) Request the enrollee's data from all known concurrent payers as described in paragraph (b)(4) of this section, and at least quarterly thereafter while the enrollee is enrolled with both payers.

(ii) Respond as described in paragraph (b)(5) of this section within 1 business day of a request from any concurrent payers. If agreed upon with the requesting payer, the MA organization may exclude any data that were previously sent to or originally received from the concurrent payer.

(7) *Patient educational resources.* Provide information to enrollees in plain language, explaining at a minimum: the benefits of Payer-to-Payer API data exchange, their ability to opt in or withdraw that permission, and instructions for doing so. The MA organization must provide the following resources:

(i) When requesting an enrollee's permission for Payer-to-Payer API data exchange, as described in paragraph (b)(2) of this section.

(ii) At least annually, in appropriate mechanisms through which it ordinarily communicates with current enrollees.

(iii) In an easily accessible location on its public website.

[89 FR 8974, Feb. 8, 2024]

§ 422.122 Prior authorization requirements.

(a) *Communicating a reason for denial.* Beginning January 1, 2026, if the MA organization denies a prior authorization request (excluding request for coverage of drugs as defined in § 422.119(b)(1)(v)), in accordance with the timeframes established in §§ 422.568(b)(1) and 422.572(a)(1), the response to the provider must include a specific reason for the denial, regardless of the method used to communicate that information.

(b) *Prior Authorization Application Programming Interface (API).* Beginning January 1, 2027, an MA organization must implement and maintain an API conformant with § 422.119(c)(2) through (4), (d), and (e), and the standards in 45 CFR 170.215(a)(1), (b)(1)(i), and (c)(1) that—

(1) Is populated with the MA organization's list of covered items and services (excluding drugs, as defined in § 422.119(b)(1)(v)) that require prior authorization;

(2) Can identify all documentation required by the MA organization for approval of any items or services that require prior authorization;

(3) Supports a Health Insurance Portability and Accountability Act (HIPAA)-compliant prior authorization request and response, as described in 45 CFR part 162; and

(4) Communicates the following information about prior authorization requests:

(i) Whether the MA organization—

(A) Approves the prior authorization request (and the date or circumstance under which the authorization ends);

(B) Denies the prior authorization request; or

(C) Requests more information.

(ii) If the MA organization denies the prior authorization request, it must include a specific reason for the denial.

(5) In addition to the requirements of this section, an MA organization using prior authorization polices or making prior authorization decisions must meet all other applicable requirements under this part, including § 422.138 and the requirements in subpart M of this part.

(c) *Publicly reporting prior authorization metrics.* Beginning in 2026, following each calendar year that it offers an MA plan, an MA organization must report prior authorization data, excluding data on drugs as defined in § 422.119(b)(1)(v), at the MA contract level by March 31. The MA organization must make the following data from the previous calendar year publicly accessible by posting them on its website:

(1) A list of all items and services that require prior authorization.

(2) The percentage of standard prior authorization requests that were approved, aggregated for all items and services.

(3) The percentage of standard prior authorization requests that were denied, aggregated for all items and services.

(4) The percentage of standard prior authorization requests that were approved after appeal, aggregated for all items and services.

(5) The percentage of prior authorization requests for which the timeframe for review was extended, and the request was approved, aggregated for all items and services.

(6) The percentage of expedited prior authorization requests that were approved, aggregated for all items and services.

(7) The percentage of expedited prior authorization requests that were denied, aggregated for all items and services.

(8) The average and median time that elapsed between the submission of a request and a determination by the MA plan, for standard prior authorizations, aggregated for all items and services.

(9) The average and median time that elapsed between the submission of a request and a decision by the MA plan for expedited prior authorizations, aggregated for all items and services.

[89 FR 8976, Feb. 8, 2024]

§ 422.125 Resolution of complaints in a Complaints Tracking Module.

(a) *Definitions.* For the purposes of this section, the terms have the following meanings:

Assignment date is the date CMS assigns a complaint to a particular MA organization in the Complaints Tracking Module.

Complaints Tracking Module means an electronic system maintained by CMS to record and track complaints submitted to CMS about Medicare health and drug plans from beneficiaries and others.

Immediate need complaint means a complaint involving a situation that prevents a beneficiary from accessing care or a service for which they have an immediate need. This includes when the beneficiary currently has enough of the drug or supply to which they are seeking access to last for 2 or fewer days.

Urgent complaint means a complaint involving a situation that prevents a beneficiary from accessing care or a service for which they do not have an immediate need. This includes when the beneficiary currently has enough of the drug or supply to which they are seeking access to last for 3 to 14 days.

(b) *Timelines for complaint resolution—* (1) *Immediate need complaints.* The MA organization must resolve immediate need complaints within 2 calendar days of the assignment date.

(2) *Urgent complaints.* The MA organization must resolve urgent complaints within 7 calendar days of the assignment date.

(3) *All other complaints.* The MA organization must resolve all other complaints within 30 calendar days of the assignment date.

(4) *Extensions.* Except for immediate need complaints, urgent complaints, and any complaint that requires expedited treatment under §§ 422.564(f) or 422.630(d), if a complaint is also a grievance within the scope of §§ 422.564 or 422.630 and the requirements for an extension of the time to provide a response in §§ 422.564(e)(2) or 422.630(e)(2) are met, the MA organization may extend the timeline to provide a response.

(5) *Coordination with timeframes for grievances, PACE service determination requests, and PACE appeals.* When a complaint under this section is also a grievance within the scope of §§ 422.564, 422.630, or 460.120, a PACE service determination request within the scope of § 460.121, or a PACE appeal within the definition of § 460.122, the MA organization must comply with the shortest applicable timeframe for resolution of the complaint.

(c) *Timeline for contacting individual filing a complaint.:* Regardless of the type of complaint received, the MA organization must attempt to contact the individual who filed a complaint within 7 calendar days of the assignment date.

[89 FR 30820, Apr. 23, 2024]

§ 422.128 Information on advance directives.

(a) Each MA organization must maintain written policies and procedures that meet the requirements for advance directives, as set forth in subpart I of part 489 of this chapter. For purposes of this part, *advance directive* has the meaning given the term in § 489.100 of this chapter.

(b) An MA organization must maintain written policies and procedures concerning advance directives with respect to all adult individuals receiving medical care by or through the MA organization.

(1) An MA organization must provide written information to those individuals with respect to the following:

(i) Their rights under the law of the State in which the organization furnishes services (whether statutory or recognized by the courts of the State) to make decisions concerning their medical care, including the right to accept or refuse medical or surgical treatment and the right to formulate advance directives. Providers may contract with other entities to furnish this information but remain legally responsible for ensuring that the requirements of this section are met. The information must reflect changes in State law as soon as possible, but no later than 90 days after the effective date of the State law.

(ii) The MA organization's written policies respecting the implementation of those rights, including a clear and precise statement of limitation if the MA organization cannot implement an advance directive as a matter of conscience. At a minimum, this statement must do the following:

(A) Clarify any differences between institution-wide conscientious objections and those that may be raised by individual physicians.

(B) Identify the state legal authority permitting such objection.

(C) Describe the range of medical conditions or procedures affected by the conscience objection.

(D) Provide the information specified in paragraph (a)(1) of this section to each enrollee at the time of initial enrollment. If an enrollee is incapacitated at the time of initial enrollment and is unable to receive information (due to the incapacitating condition or a mental disorder) or articulate whether or not he or she has executed an advance directive, the MA organization may give advance directive information to the enrollee's family or surrogate in the same manner that it issues other materials about policies and procedures to the family of the incapacitated enrollee or to a surrogate or other concerned persons in accordance with State law. The MA organization is not relieved of its obligation to provide this information to the enrollee once he or she is no longer incapacitated or unable to receive such information. Follow-up procedures must be in place to ensure that the information is given to the individual directly at the appropriate time.

(E) Document in a prominent part of the individual's current medical record whether or not the individual has executed an advance directive.

(F) Not condition the provision of care or otherwise discriminate against an individual based on whether or not the individual has executed an advance directive.

(G) Ensure compliance with requirements of State law (whether statutory or recognized by the courts of the State) regarding advance directives.

(H) Provide for education of staff concerning its policies and procedures on advance directives.

(I) Provide for community education regarding advance directives that may include material required in paragraph (a)(1)(i) of this section, either directly or in concert with other providers or entities. Separate community education materials may be developed and used, at the discretion of the MA organization. The same written materials are not required for all settings, but the material should define what constitutes an advance directive, emphasizing that an advance directive is designed to enhance an incapacitated individual's control over medical treatment, and describe applicable State law concerning advance directives. An MA organization must be able to document its community education efforts.

(2) The MA organization—

(i) Is not required to provide care that conflicts with an advance directive; and

(ii) Is not required to implement an advance directive if, as a matter of conscience, the MA organization cannot implement an advance directive and State law allows any health care provider or any agent of the provider to conscientiously object.

(3) The MA organization must inform individuals that complaints concerning noncompliance with the advance directive requirements may be filed with the State survey and certification agency.

§ 422.132 Protection against liability and loss of benefits.

Enrollees of MA organizations are entitled to the protections specified in § 422.504(g).

[63 FR 35077, June 26, 1998, as amended at 70 FR 52026, Sept. 1, 2005]

§ 422.133 Return to home skilled nursing facility.

(a) *General rule.* MA plans must provide coverage of posthospital extended care services to Medicare enrollees through a home skilled nursing facility if the enrollee elects to receive the coverage through the home skilled nursing facility, and if the home skilled nursing facility either has a contract with the MA organization or agrees to accept substantially similar payment under the same terms and conditions that apply to similar skilled nursing facilities that contract with the MA organization.

(b) *Definitions.* In this subpart, *home skilled nursing facility* means—

(1) The skilled nursing facility in which the enrollee resided at the time of admission to the hospital preceding the receipt of posthospital extended care services;

(2) A skilled nursing facility that is providing posthospital extended care services through a continuing care retirement community in which the MA plan enrollee was a resident at the time of admission to the hospital. A continuing care retirement community is an arrangement under which housing and health-related services are provided (or arranged) through an organization for the enrollee under an agreement that is effective for the life of the enrollee or for a specified period; or

(3) The skilled nursing facility in which the spouse of the enrollee is residing at the time of discharge from the hospital.

(4) If an MA organization elects to furnish SNF care in the absence of a prior qualifying hospital stay under § 422.101(c), then that SNF care is also subject to the home skilled nursing facility rules in this section. In applying the provisions of this section to coverage under this paragraph, references to a hospitalization, or discharge from a hospital, are deemed to refer to wherever the enrollee resides immediately before admission for extended care services.

(c) *Coverage no less favorable.* The posthospital extended care scope of services, cost-sharing, and access to coverage provided by the home skilled nursing facility must be no less favorable to the enrollee than posthospital extended care services coverage that would be provided to the enrollee by a skilled nursing facility that would be otherwise covered under the MA plan.

(d) *Exceptions.* The requirement to allow an MA plan enrollee to elect to return to the home skilled nursing facility for posthospital extended care services after discharge from the hospital does not do the following:

(1) Require coverage through a skilled nursing facility that is not otherwise qualified to provide benefits under Part A for Medicare beneficiaries not enrolled in the MA plan.

(2) Prevent a skilled nursing facility from refusing to accept, or imposing conditions on the acceptance of, an enrollee for the receipt of posthospital extended care services.

[68 FR 50857, Aug. 22, 2003, as amended at 70 FR 4723, Jan. 28, 2005]

§ 422.134 Reward and incentive programs.

(a) *Definitions.* As used in this section, the following definitions are applicable:

Incentive item means the same things as reward item.

Incentive(s) program, *reward(s) program*, and *R&I program* mean the same thing as rewards and incentives program.

Incentive(s), R&I, and *rewards and incentives* mean the same things as reward(s).

Qualifying individual in the context of a plan-covered health benefit means any plan enrollee who would qualify for coverage of the benefit. In the context of a non-plan-covered health benefit, qualifying individual means any plan enrollee.

Reward and incentive program is a program offered by an MA plan to qualifying individuals to voluntarily perform specified target activities in exchange for reward items.

Reward item (or incentive item) means the item furnished to a qualifying individual who performs a target activity as specified by the plan in the reward program.

Target activity means the activity for which the reward is provided to the qualifying individual by the MA plan.

(b) *Offering an R&I program.* An MA plan may offer R&I program(s) consistent with the requirements of this section.

(c) *Target activities.* (1) A target activity in an R&I program must meet all of the following:

(i) Directly involve the qualifying individual and performance by the qualifying individual.

(ii) Be specified, in detail, as to the level of completion needed in order to qualify for the reward item.

(iii) Be health-related by doing at least one of the following:

(A) Promoting improved health.

(B) Preventing injuries and illness,

(C) Promoting the efficient use of health care resources.

(iv) Uniformly offer any qualifying individual the opportunity to participate in the target activity.

(v) Be provided with accommodations consistent with the goal of the target activity to otherwise qualifying individuals who are unable to perform the target activity in a manner that satisfies the intended goal of the target activity.

(2) The target activity in an R&I program must not do any of the following:

(i) Be related to Part D benefits.

(ii) Discriminate against enrollees. To ensure that anti-discrimination requirements are met, an MA organization, in providing a rewards and incentives program, must comply with paragraph (g)(1) of this section and must not design a program based on the achievement of a health status measurement.

(d) *Reward items.* (1) The reward item for a target activity must meet all of the following:

(i) Be offered identically to any qualifying individual who performs the target activity.

(ii) Be a direct tangible benefit to the qualifying individual who performs the target activity.

(iii) Be provided, to the enrollee, such as through transfer of ownership or delivery, for a target activity completed in the contract year during which this R&I program was offered, regardless if the enrollee is likely to use the reward item after the contract year.

(2) The reward item for a target activity must not:

(i) Be offered in the form of cash, cash equivalents, or other monetary rebates (including reduced cost sharing or premiums). An item is classified as a cash equivalent if it either:

(A) Is convertible to cash (such as a check); or

(B) Can be used like cash (such as a general purpose debit card).

(ii) Have a value that exceeds the value of the target activity itself.

(iii) Involve elements of chance.

(3) Permissible reward items for a target activity may be reward items that:

(i) Consist of ''points'' or ''tokens'' that can be used to acquire tangible items.

(ii) Are offered in the form of a gift card that can be redeemed only at specific retailers or retail chains or for a specific category of items or services.

(e) *Marketing and communication requirements.* An MA organization that offers an R&I program must comply with all marketing and communications requirements in subpart V of this part.

(f) *R&I disclosure.* MA organization must make information available to CMS upon request about the form and manner of any rewards and incentives programs it offers and any evaluations of the effectiveness of such programs.

(g) *Miscellaneous.* (1) The MA organization's reward and incentive program must comply with all relevant fraud and abuse laws, including, when applicable, the anti-kickback statute and civil monetary penalty prohibiting inducements to beneficiaries. Additionally, all MA program anti-discrimination prohibitions continue to apply. The R&I program may not discriminate against enrollees based on race, color, national origin, including limited English proficiency, sex, age, disability, chronic disease, whether a person resides or receives services in an institutional setting, frailty, health status, or other prohibited basis.

(2) Failure to comply with R&I program requirements may result in a violation of one or more of the basis for sanction at § 422.752(a).

(3) The reward and incentive program is classified as a non-benefit expense in the plan bid.

(i) If offering a reward and incentive program, the MA organization must include all costs associated with the reward and incentive program as an administrative cost and non-benefit expense in the bid for the year in which the reward and incentive program operates.

(ii) Disputes on rewards and incentives must be treated as a grievance under § 422.564.

[86 FR 6096, Jan. 19, 2021]

§ 422.135 Additional telehealth benefits.

(a) *Definitions.* For purposes of this section, the following definitions apply:

Additional telehealth benefits means services:

(1) For which benefits are available under Medicare Part B but which are not payable under section 1834(m) of the Act; and

(2) That have been identified by the MA plan for the applicable year as clinically appropriate to furnish through electronic exchange when the physician (as defined in section 1861(r) of the Act) or practitioner (described in section 1842(b)(18)(C) of the Act) providing the service is not in the same location as the enrollee.

Electronic exchange means electronic information and telecommunications technology.

(b) *General rule.* An MA plan may treat additional telehealth benefits as basic benefits covered under the original Medicare fee-for-service program for purposes of this part 422 provided that the requirements of this section are met. If the MA plan fails to comply with the requirements of this section, then the MA plan may not treat the benefits provided through electronic exchange as additional telehealth benefits, but may treat them as supplemental benefits as described in § 422.102, subject to CMS approval.

(c) *Requirements.* An MA plan furnishing additional telehealth benefits must:

(1) Furnish in-person access to the specified Part B service(s) at the election of the enrollee.

(2) Advise each enrollee that the enrollee may receive the specified Part B service(s) through an in-person visit or through electronic exchange.

(3) Comply with the provider selection and credentialing requirements provided in § 422.204, and, when providing additional telehealth benefits, ensure through its contract with the provider that the provider meet and comply with applicable State licensing requirements and other applicable laws for the State in which the enrollee is located and receiving the service.

(4) Make information about coverage of additional telehealth benefits available to CMS upon request. Information may include, but is not limited to, statistics on use or cost, manner(s) or method of electronic exchange, evaluations of effectiveness, and demonstration of compliance with the requirements of this section.

(d) *Requirement to use contracted providers.* An MA plan furnishing additional telehealth benefits may only do so using contracted providers. Coverage of benefits furnished by a non-contracted provider through electronic exchange may only be covered as a supplemental benefit.

(e) *Bidding.* An MA plan that fully complies with this section may include additional telehealth benefits in its bid for basic benefits in accordance with § 422.254.

(f) *Cost sharing.* MA plans offering additional telehealth benefits may maintain different cost sharing for the specified Part B service(s) furnished through an in-person visit and the specified Part B service(s) furnished through electronic exchange.

[84 FR 15829, Apr. 16, 2019]

§ 422.136 Medicare Advantage (MA) and step therapy for Part B drugs.

(a) *General.* If an MA plan implements a step therapy program to control the utilization of Part B-covered drugs, the MA organization must—

(1) Apply step therapy only to new administrations of Part B drugs, using at least a 365 day lookback period;

(2) Establish policies and procedures to educate and inform health care providers and enrollees concerning its step therapy policies.

(3) Prior to implementation of a step therapy program, ensure that the step therapy program has been reviewed and approved by the MA organization's pharmacy and therapeutic (P&T) committee.

(b) *Step therapy and pharmacy and therapeutic committee requirements.* An MA plan must establish a P&T committee prior to implementing any step therapy program. An MA plan must use a P&T committee to review and approve step therapy programs used in connection with Part B drugs. To meet this requirement, a MA–PD plan may utilize an existing Part D P&T committee established for purposes of administration of the Part D benefit under part 423 of this chapter and an MA plan may utilize an existing Part D P&T committee established by an MA–PD plan operated under the same contract as the MA plan. The P&T committee must—

(1) Include a majority of members who are practicing physicians or practicing pharmacists.

(2) Include at least one practicing physician and at least one practicing pharmacist who are independent and free of conflict relative to—

(i) The MA organization and MA plan; and

(ii) Pharmaceutical manufacturers.

(3) Include at least one practicing physician and one practicing pharmacist who are experts regarding care of elderly or disabled individuals.

(4) Clearly articulate and document processes to determine that the requirements under paragraphs (b)(1) through (3) of this section have been met, including the determination by an objective party of whether disclosed financial interests are conflicts of interest and the management of any recusals due to such conflicts.

(5) Base clinical decisions on the strength of scientific evidence and standards of practice, including assessing peer-reviewed medical literature, pharmacoeconomic studies, outcomes research data, and other such information as it determines appropriate.

(6) Consider whether the inclusion of a particular Part B drug in a step therapy program has any therapeutic advantages in terms of safety and efficacy.

(7) Review policies that guide exceptions and other step therapy processes.

(8) Evaluate and analyze treatment protocols and procedures related to the plan's step therapy policies at least annually consistent with written policy guidelines and other CMS instructions.

(9) Document in writing its decisions regarding the development and revision of step therapy activities and make this documentation available to CMS upon request.

(10) Review and approve all step therapy criteria applied to each covered Part B drug.

(11) Meet other requirements consistent with written policy guidelines and other CMS instructions.

(c) *Off-label drug requirement.* An MA plan may include a drug supported only by an off-label indication in step therapy protocols only if the off-label indication is supported by widely used treatment guidelines or clinical literature that CMS considers to represent best practices.

(d) *Non-covered drugs.* A step therapy program must not include as a component of a step therapy protocol or other condition or requirement any drugs not covered by the applicable MA plan as a Part B drug or, in the case of an MA–PD plan, a Part D drug.

[84 FR 23880, May 23, 2019]

§ 422.137 Medicare Advantage Utilization Management Committee.

(a) *General.* An MA organization that uses utilization management (UM) policies and procedures, including prior authorization (PA), must establish a UM committee that is led by a plan's medical director (described in § 422.562(a)(4)).

(b) *Limit on use of UM policies and procedures.* An MA plan may not use any UM policies and procedures for basic or supplemental benefits on or after January 1, 2024 unless those policies and procedures have been reviewed and approved by the UM committee.

(c) *Utilization Management Committee Composition.* The UM committee must—

(1) Include a majority of members who are practicing physicians.

(2) Include at least one practicing physician who is independent and free of conflict relative to the MA organization and MA plan.

(3) Include at least one practicing physician who is an expert regarding care of elderly or disabled individuals.

(4) Include members representing various clinical specialties (for example, primary care, behavioral health) to ensure that a wide range conditions are adequately considered in the development of the MA plan's utilization management policies.

(5) Beginning January 1, 2025, include at least one member with expertise in health equity. Expertise in health equity includes educational degrees or credentials with an emphasis on health equity; experience conducting studies identifying disparities amongst different population groups; experience leading organization-wide policies, programs, or services to achieve health equity; or experience leading advocacy efforts to achieve health equity.

(d) *Utilization Management Committee Responsibilities.* The UM committee must—

(1) At least annually, review the policies and procedures for all utilization management, including prior authorization, used by the MA plan. Such review must consider:

(i) The services to which the utilization management applies;

(ii) Coverage decisions and guidelines for Traditional Medicare, including NCDs, LCDs, and laws; and

(iii) Relevant current clinical guidelines.

(2) Approve only utilization management policies and procedures that:

(i) Use or impose coverage criteria that comply with the requirements and standards at § 422.101(b);

(ii) For prior authorization policies, comply with requirements and standards at § 422.138;

(iii) Comply with the standards in § 422.202(b)(1); and

(iv) Apply and rely on medical necessity criteria that comply with § 422.101(c)(1).

(3) Revise the utilization management policies and procedures as necessary to comply with the standards in this regulation, including removing requirements for UM for services and items that no longer warrant UM.

(4) Clearly articulate and document processes to determine that the requirements under paragraphs (c)(1) through (4) of this section have been met, including the determination by an objective party of whether disclosed financial interests are conflicts of interest and the management of any recusals due to such conflicts.

(5) Document in writing the reason for its decisions regarding the development of UM policies and make this documentation available to CMS upon request.

(6) Beginning in 2025, annually conduct a health equity analysis of the use of prior authorization.

(i) The final report of the analysis must be approved by the member of the committee with expertise in health equity before it is publicly posted.

(ii) The analysis must examine the impact of prior authorization on enrollees with one or more of the following social risk factors:

(A) Receipt of the low-income subsidy or being dually eligible for Medicare and Medicaid.

(B) Disability status is determined using the variable original reason for entitlement code (OREC) for Medicare using the information from the Social Security Administration and Railroad Retirement Board record systems.

(iii) The analysis must use the following metrics, calculated for enrollees with the specified social risk factors

and enrollees without the specified social risk factors, to conduct the analysis at the plan level using data from the prior contract year regarding coverage of items and services excluding data on drugs as defined in § 422.119(b)(1)(v):

(A) The percentage of standard prior authorization requests that were approved, aggregated for all items and services.

(B) The percentage of standard prior authorization requests that were denied, aggregated for all items and services.

(C) The percentage of standard prior authorization requests that were approved after appeal, aggregated for all items and services.

(D) The percentage of prior authorization requests for which the timeframe for review was extended, and the request was approved, aggregated for all items and services.

(E) The percentage of expedited prior authorization requests that were approved, aggregated for all items and services.

(F) The percentage of expedited prior authorization requests that were denied, aggregated for all items and services.

(G) The average and median time that elapsed between the submission of a request and a determination by the MA plan, for standard prior authorizations, aggregated for all items and services.

(H) The average and median time that elapsed between the submission of a request and a decision by the MA plan for expedited prior authorizations, aggregated for all items and services.

(7) By July 1, 2025, and annually thereafter, publicly post the results of the health equity analysis of the utilization management policies and procedures on the plan's website meeting the following requirements:

(i) In a prominent manner and clearly identified in the footer of the website.

(ii) Easily accessible to the general public, without barriers, including but not limited to ensuring the information is accessible:

(A) Free of charge.

(B) Without having to establish a user account or password.

(C) Without having to submit personal identifying information.

(iii) In a machine-readable format with the data contained within that file being digitally searchable and downloadable.

(iv) Include a txt file in the root directory of the website domain that includes a direct link to the machine-readable file to establish and maintain automated access.

[88 FR 22331, Apr. 12, 2023, as amended at 89 FR 30820, Apr. 23, 2024]

§ 422.138 Prior authorization.

(a) *Requirement.* When a coordinated care plan, as specified in § 422.4(a)(iii) (including MSA network plans), uses prior authorization processes in connection with basic benefits or supplemental benefits, the MA organization must comply with the requirements in this section. (MA PFFS are not permitted to use prior authorization policies or ''prior notification'' policies that reduce cost sharing for enrollees based on whether the enrollee or provider notifies the PFFS plan in advance that services will be furnished). Prior authorization processes include all policies and procedures used in prior authorization unless otherwise noted.

(b) *Application.* Prior authorization processes for coordinated care plans may only be used for one or more the following purposes:

(1) To confirm the presence of diagnoses or other medical criteria that are the basis for coverage determinations for the specific item or service; or

(2) For basic benefits, to ensure an item or service is medically necessary based on standards specified in § 422.101(c)(1), or

(3) For supplemental benefits, to ensure that the furnishing of a service or benefit is clinically appropriate.

(c) *Effect of prior authorization, preservice, or concurrent approval.* If the MA organization approved the furnishing of a covered item or service through a prior authorization or preservice determination of coverage or payment, or a concurrent determination made during the enrollee's receipt of inpatient or outpatient services, it may not deny coverage later on the basis of lack of medical necessity and

may not reopen such a decision for any reason except for good cause (as provided at § 405.986 of this chapter and § 422.616) or if there is reliable evidence of fraud or similar fault per the reopening provisions at § 422.616. The definitions of the terms ''reliable evidence'' and ''similar fault'' in § 405.902 of this chapter apply to this paragraph (c).

[88 FR 22331, Apr. 12, 2023, as amended at 90 FR 15910, Apr. 15, 2025]

Subpart D—Quality Improvement

SOURCE: 63 FR 35082, June 26, 1998, unless otherwise noted.

§ 422.152 Quality improvement program.

(a) *General rule.* Each MA organization that offers one or more MA plan must have, for each plan, an ongoing quality improvement program that meets applicable requirements of this section for the service it furnishes to its MA enrollees. As part of its ongoing quality improvement program, a plan must do all of the following:

(1) Create a quality improvement program plan that sufficiently outlines the elements of the plan's quality improvement program.

(2) Have a chronic care improvement program that meets the requirements of paragraph (c) of this section concerning elements of a chronic care program and addresses populations identified by CMS based on a review of current quality performance.

(3) [Reserved]

(4) Encourage its providers to participate in CMS and HHS quality improvement initiatives.

(5) Incorporate one or more activities that reduce disparities in health and health care. These activities must be broadly accessible irrespective of race, ethnicity, national origin, religion, sex, or gender. These activities may be based upon health status and health needs, geography, or factors not listed in the previous sentence only as appropriate to address the relevant disparities in health and health care.

(b) *Requirements for MA coordinated care plans (except for regional MA plans) and including local PPO plans that are offered by organizations that are licensed or organized under State law as HMOs.* An MA coordinated care plan's (except for regional PPO plans and local PPO plans as defined in paragraph (e) of this section) quality improvement program must—

(1) In processing requests for initial or continued authorization of services, follow written policies and procedures that reflect current standards of medical practice.

(2) Have in effect mechanisms to detect both underutilization and overutilization of services.

(3) Measure and report performance. The organization offering the plan must do the following:

(i) Measure performance under the plan, using the measurement tools required by CMS, and report its performance to CMS. The standard measures may be specified in uniform data collection and reporting instruments required by CMS.

(ii) Collect, analyze, and report quality performance data identified by CMS that are of the same type as those under paragraph (b)(3)(i) of this section.

(iii) Make available to CMS information on quality and outcomes measures that will enable beneficiaries to compare health coverage options and select among them, as provided in § 422.64.

(4) Special rule for MA local PPO-type plans that are offered by an organization that is licensed or organized under State law as a health maintenance organization must meet the requirements specified in paragraphs (b)(1) through (b)(3) of this section.

(5) All coordinated care contracts (including local and regional PPOs, contracts with exclusively SNP benefit packages, private fee-for-service contracts, and MSA contracts), and all cost contracts under section 1876 of the Act, with 600 or more enrollees in July of the prior year, must contract with approved Medicare Consumer Assessment of Healthcare Providers and Systems (CAHPS) survey vendors to conduct the Medicare CAHPS satisfaction survey of Medicare plan enrollees in accordance with CMS specifications and submit the survey data to CMS.

(6) For 2021 Star Ratings only, MA organizations are not required to submit HEDIS and CAHPS data that would

otherwise be required for the calculation of the 2021 Star Ratings.

(c) *Chronic care improvement program requirements.* (1) Develop criteria for a chronic care improvement program. These criteria must include the following:

(i) Methods for identifying MA enrollees with multiple or sufficiently severe chronic conditions that would benefit from participating in a chronic care improvement program.

(ii) Mechanisms for monitoring MA enrollees that are participating in the chronic improvement program and evaluating participant outcomes such as changes in health status.

(iii) Performance assessments that use quality indicators that are objective, clearly and unambiguously defined, and based on current clinical knowledge or research.

(iv) Systematic and ongoing follow-up on the effect of the program.

(2) The organization must report the status and results of each program to CMS as requested.

(d) [Reserved]

(e) *Requirements for MA regional plans and MA local plans that are PPO plans as defined in this section*—(1) *Definition of local preferred provider organization plan.* For purposes of this section, the term local preferred provider organization (PPO) plan means an MA plan that—

(i) Has a network of providers that have agreed to a contractually specified reimbursement for covered benefits with the organization offering the plan;

(ii) Provides for reimbursement for all covered benefits regardless of whether the benefits are provided within the network of providers; and

(iii) Is offered by an organization that is not licensed or organized under State law as a health maintenance organization.

(2) MA organizations offering an MA regional plan or local PPO plan as defined in this section must:

(i) Measure performance under the plan using standard measures required by CMS and report its performance to CMS. The standard measures may be specified in uniform data collection and reporting instruments required by CMS.

(ii) Collect, analyze, and report quality performance data identified by CMS that are of the same type as those described under paragraph (e)(2)(i) of this section.

(iii) Evaluate the continuity and coordination of care furnished to enrollees.

(iv) If the organization uses written protocols for utilization review, the organization must—

(A) Base those protocols on current standards of medical practice; and

(B) Have mechanisms to evaluate utilization of services and to inform enrollees and providers of services of the results of the evaluation.

(f) *Requirements for all types of plans*—(1) *Health information.* For all types of plans that it offers, an organization must—

(i) Maintain a health information system that collects, analyzes, and integrates the data necessary to implement its quality improvement program;

(ii) Ensure that the information it receives from providers of services is reliable and complete; and

(iii) Make all collected information available to CMS.

(2) *Program review.* For each plan, there must be in effect a process for formal evaluation, at least annually, of the impact and effectiveness of its quality improvement program.

(3) *Remedial action.* For each plan, the organization must correct all problems that come to its attention through internal surveillance, complaints, or other mechanisms.

(g) *Special requirements for specialized MA plans for special needs individuals.* All special needs plans (SNPs) must be approved by the National Committee for Quality Assurance (NCQA) effective January 1, 2012 and subsequent years. SNPs must submit their model of care (MOC), as defined under § 422.101(f), to CMS for NCQA evaluation and approval, in accordance with CMS guidance. In addition to the requirements under paragraphs (a) and (f) of this section, a SNP must conduct a quality improvement program that does the following:

(1) Provides for the collection, analysis, and reporting of data that measures health outcomes and indices of

quality pertaining to its targeted special needs population (that is, dual-eligible, institutionalized, or chronic condition) at the plan level.

(2) Measures the effectiveness of its model of care through the collection, aggregation, analysis, and reporting of data that demonstrate the following:

(i) Access to care as evidenced by measures from the care coordination domain (for example, service and benefit utilization rates, or timeliness of referrals or treatment).

(ii) Improvement in beneficiary health status as evidenced by measures from functional, psychosocial, or clinical domains (for example, quality of life indicators, depression scales, or chronic disease outcomes).

(iii) Staff implementation of the SNP model of care as evidenced by measures of care structure and process from the continuity of care domain (for example, National Committee for Quality Assurance accreditation measures or medication reconciliation associated with care setting transitions indicators).

(iv) Comprehensive health risk assessment as evidenced by measures from the care coordination domain (for example, accuracy of acuity stratification, safety indicators, or timeliness of initial assessments or annual reassessments).

(v) Implementation of an individualized plan of care as evidenced by measures from functional, psychosocial, or clinical domains (for example, rate of participation by IDT members and beneficiaries in care planning).

(vi) A provider network having targeted clinical expertise as evidenced by measures from medication management, disease management, or behavioral health domains.

(vii) Delivery of services across the continuum of care.

(viii) Delivery of extra services and benefits that meet the specialized needs of the most vulnerable beneficiaries as evidenced by measures from the psychosocial, functional, and end-of-life domains.

(ix) Use of evidence-based practices and nationally recognized clinical protocols.

(x) Use of integrated systems of communication as evidenced by measures from the care coordination domain (for example, call center utilization rates, rates of beneficiary involvement in care plan development, etc.).

(3) Makes available to CMS information on quality and outcomes measures that will—

(i) Enable beneficiaries to compare health coverage options; and

(ii) Enable CMS to monitor the plan's model of care performance.

(h) *Requirements for MA private-fee-for-service plans and Medicare medical savings account plans.* MA PFFS and MSA plans are subject to the requirement that may not exceed the requirement specified in § 422.152(e).

[70 FR 4723, Jan. 28, 2005, as amended at 70 FR 52026, Sept. 1, 2005; 73 FR 54249, Sept. 18, 2008; 75 FR 19805, Apr. 15, 2010; 76 FR 21564, Apr. 15, 2011; 80 FR 7959, Feb. 12, 2015; 83 FR 16725, Apr. 16, 2018; 85 FR 19290, Apr. 6, 2020; 88 FR 22332, Apr. 12, 2023]

§ 422.153 Use of quality improvement organization review information.

CMS will acquire from quality improvement organizations (QIOs) as defined in part 475 of this chapter data collected under section 1886(b)(3)(B)(viii) of the Act and subject to the requirements in § 480.140(g). CMS will acquire this information, as needed, and may use it for the following functions:

(a) Enable beneficiaries to compare health coverage options and select among them.

(b) Evaluate plan performance.

(c) Ensure compliance with plan requirements under this part.

(d) Develop payment models.

(e) Other purposes related to MA plans as specified by CMS.

[76 FR 26546, May 6, 2011]

§ 422.156 Compliance deemed on the basis of accreditation.

(a) *General rule.* An MA organization is deemed to meet all of the requirements of any of the areas described in paragraph (b) of this section if—

(1) The MA organization is fully accredited (and periodically reaccredited) for the standards related to the applicable area under paragraph (b) of this section by a private, national accreditation organization approved by CMS; and

(2) The accreditation organization used the standards approved by CMS for the purposes of assessing the MA organization's compliance with Medicare requirements.

(b) *Deemable requirements.* The requirements relating to the following areas are deemable:

(1) *Quality improvement.* The deeming process should focus on evaluating and assessing the overall quality improvement (QI) program. However, the chronic care improvement programs (CCIPs) will be excluded from the deeming process.

(2) Antidiscrimination.

(3) Access to services.

(4) Confidentiality and accuracy of enrollee records.

(5) Information on advance directives.

(6) Provider participation rules.

(7) The requirements listed in § 423.165 (b)(1) through (3) of this chapter for MA organizations that offer prescription drug benefit programs.

(c) *Effective date of deemed status.* The date on which the organization is deemed to meet the applicable requirements is the later of the following:

(1) The date on which the accreditation organization is approved by CMS.

(2) The date the MA organization is accredited by the accreditation organization.

(d) *Obligations of deemed MA organizations.* An MA organization deemed to meet Medicare requirements must—

(1) Submit to surveys by CMS to validate its accreditation organization's accreditation process; and

(2) Authorize its accreditation organization to release to CMS a copy of its most recent accreditation survey, together with any survey-related information that CMS may require (including corrective action plans and summaries of unmet CMS requirements).

(e) *Removal of deemed status.* CMS removes part or all of an MA organization's deemed status for any of the following reasons:

(1) CMS determines, on the basis of its own investigation, that the MA organization does not meet the Medicare requirements for which deemed status was granted.

(2) CMS withdraws its approval of the accreditation organization that accredited the MA organization.

(3) The MA organization fails to meet the requirements of paragraph (d) of this section.

(f) *Authority.* Nothing in this subpart limits CMS' authority under subparts K and O of this part, including but not limited to, the ability to impose intermediate sanctions, civil money penalties, and terminate a contract with an MA organization.

[63 FR 35082, June 26, 1998, as amended at 65 FR 40323, June 29, 2000; 65 FR 59749, Oct. 6, 2000; 70 FR 4724, Jan. 28, 2005; 75 FR 19806, Apr. 15, 2010; 76 FR 21564, Apr. 15, 2011; 84 FR 15829, Apr. 16, 2019]

§ 422.157 Accreditation organizations.

(a) *Conditions for approval.* CMS may approve an accreditation organization with respect to a given standard under this part if it meets the following conditions:

(1) In accrediting MA organizations, it applies and enforces standards that are at least as stringent as Medicare requirements with respect to the standard or standards in question.

(2) It complies with the application and reapplication procedures set forth in § 422.158.

(3) It ensures that:

(i) Any individual associated with it, who is also associated with an entity it accredits, does not influence the accreditation decision concerning that entity.

(ii) The majority of the membership of its governing body is not comprised of managed care organizations or their representatives.

(iii) Its governing body has a broad and balanced representation of interests and acts without bias.

(b) *Notice and comment*—(1) *Proposed notice.* CMS publishes a notice in the FEDERAL REGISTER whenever it is considering granting an accreditation organization's application for approval. The notice—

(i) Announces CMS's receipt of the accreditation organization's application for approval;

(ii) Describes the criteria CMS will use in evaluating the application; and

(iii) Provides at least a 30-day comment period.

(2) *Final notice.* (i) After reviewing public comments, CMS publishes a final FEDERAL REGISTER notice indicating whether it has granted the accreditation organization's request for approval.

(ii) If CMS grants the request, the final notice specifies the effective date and the term of the approval, which may not exceed 6 years.

(c) *Ongoing responsibilities of an approved accreditation organization.* An accreditation organization approved by CMS must undertake the following activities on an ongoing basis:

(1) Provide to CMS in written form and on a monthly basis all of the following:

(i) Copies of all accreditation surveys, together with any survey-related information that CMS may require (including corrective action plans and summaries of unmet CMS requirements).

(ii) Notice of all accreditation decisions.

(iii) Notice of all complaints related to deemed MA organizations.

(iv) Information about any MA organization against which the accrediting organization has taken remedial or adverse action, including revocation, withdrawal or revision of the MA organization's accreditation. (The accreditation organization must provide this information within 30 days of taking the remedial or adverse action.)

(v) Notice of any proposed changes in its accreditation standards or requirements or survey process. If the organization implements the changes before or without CMS approval, CMS may withdraw its approval of the accreditation organization.

(2) Within 30 days of a change in CMS requirements, submit to CMS—

(i) An acknowledgment of CMS's notification of the change;

(ii) A revised cross-walk reflecting the new requirements; and

(iii) An explanation of how the accreditation organization plans to alter its standards to conform to CMS's new requirements, within the time-frames specified in the notification of change it receives from CMS.

(3) Permit its surveyors to serve as witnesses if CMS takes an adverse action based on accreditation findings.

(4) Within 3 days of identifying, in an accredited MA organization, a deficiency that poses immediate jeopardy to the organization's enrollees or to the general public, give CMS written notice of the deficiency.

(5) Within 10 days of CMS's notice of withdrawal of approval, give written notice of the withdrawal to all accredited MA organizations.

(6) Provide, on an annual basis, summary data specified by CMS that relate to the past year's accreditation activities and trends.

(d) *Continuing Federal oversight of approved accreditation organizations.* This paragraph establishes specific criteria and procedures for continuing oversight and for withdrawing approval of an accreditation organization.

(1) *Equivalency review.* CMS compares the accreditation organization's standards and its application and enforcement of those standards to the comparable CMS requirements and processes when—

(i) CMS imposes new requirements or changes its survey process;

(ii) An accreditation organization proposes to adopt new standards or changes in its survey process; or

(iii) The term of an accreditation organization's approval expires.

(2) *Validation review.* CMS or its agent may conduct a survey of an accredited organization, examine the results of the accreditation organization's own survey, or attend the accreditation organization's survey, in order to validate the organization's accreditation process. At the conclusion of the review, CMS identifies any accreditation programs for which validation survey results—

(i) Indicate a 20 percent rate of disparity between certification by the accreditation organization and certification by CMS or its agent on standards that do not constitute immediate jeopardy to patient health and safety if unmet;

(ii) Indicate any disparity between certification by the accreditation organization and certification by CMS or its agent on standards that constitute immediate jeopardy to patient health and safety if unmet; or

(iii) Indicate that, irrespective of the rate of disparity, there are widespread

or systematic problems in an organization's accreditation process such that accreditation no longer provides assurance that the Medicare requirements are met or exceeded.

(3) *Onsite observation.* CMS may conduct an onsite inspection of the accreditation organization's operations and offices to verify the organization's representations and assess the organization's compliance with its own policies and procedures. The onsite inspection may include, but is not limited to, reviewing documents, auditing meetings concerning the accreditation process, evaluating survey results or the accreditation status decision making process, and interviewing the organization's staff.

(4) *Notice of intent to withdraw approval.* If an equivalency review, validation review, onsite observation, or CMS's daily experience with the accreditation organization suggests that the accreditation organization is not meeting the requirements of this subpart, CMS gives the organization written notice of its intent to withdraw approval.

(5) *Withdrawal of approval.* CMS may withdraw its approval of an accreditation organization at any time if CMS determines that—

(i) Deeming based on accreditation no longer guarantees that the MA organization meets the MA requirements, and failure to meet those requirements could jeopardize the health or safety of Medicare enrollees and constitute a significant hazard to the public health; or

(ii) The accreditation organization has failed to meet its obligations under this section or under § 422.156 or § 422.158.

(6) *Reconsideration of withdrawal of approval.* An accreditation organization dissatisfied with a determination to withdraw CMS approval may request a reconsideration of that determination in accordance with subpart D of part 488 of this chapter.

[63 FR 35082, June 26, 1998, as amended at 65 FR 40323, June 29, 2000; 65 FR 59749, Oct. 6, 2000]

§ 422.158 Procedures for approval of accreditation as a basis for deeming compliance.

(a) *Required information and materials.* A private, national accreditation organization applying for approval must furnish to CMS all of the following information and materials. (When reapplying for approval, the organization need furnish only the particular information and materials requested by CMS.)

(1) The types of MA plans that it would review as part of its accreditation process.

(2) A detailed comparison of the organization's accreditation requirements and standards with the Medicare requirements (for example, a crosswalk).

(3) Detailed information about the organization's survey process, including—

(i) Frequency of surveys and whether surveys are announced or unannounced.

(ii) Copies of survey forms, and guidelines and instructions to surveyors.

(iii) Descriptions of—

(A) The survey review process and the accreditation status decision making process;

(B) The procedures used to notify accredited MA organizations of deficiencies and to monitor the correction of those deficiencies; and

(C) The procedures used to enforce compliance with accreditation requirements.

(4) Detailed information about the individuals who perform surveys for the accreditation organization, including—

(i) The size and composition of accreditation survey teams for each type of plan reviewed as part of the accreditation process;

(ii) The education and experience requirements surveyors must meet;

(iii) The content and frequency of the in-service training provided to survey personnel;

(iv) The evaluation systems used to monitor the performance of individual surveyors and survey teams; and

(v) The organization's policies and practice with respect to the participation, in surveys or in the accreditation decision process by an individual who is professionally or financially affiliated with the entity being surveyed.

(5) A description of the organization's data management and analysis system with respect to its surveys and accreditation decisions, including the kinds of reports, tables, and other displays generated by that system.

(6) A description of the organization's procedures for responding to and investigating complaints against accredited organizations, including policies and procedures regarding coordination of these activities with appropriate licensing bodies and ombudsmen programs.

(7) A description of the organization's policies and procedures with respect to the withholding or removal of accreditation for failure to meet the accreditation organization's standards or requirements, and other actions the organization takes in response to noncompliance with its standards and requirements.

(8) A description of all types (for example, full, partial) and categories (for example, provisional, conditional, temporary) of accreditation offered by the organization, the duration of each type and category of accreditation and a statement identifying the types and categories that would serve as a basis for accreditation if CMS approves the accreditation organization.

(9) A list of all currently accredited MA organizations and the type, category, and expiration date of the accreditation held by each of them.

(10) A list of all full and partial accreditation surveys scheduled to be performed by the accreditation organization as requested by CMS.

(11) The name and address of each person with an ownership or control interest in the accreditation organization.

(b) *Required supporting documentation.* A private, national accreditation organization applying or reapplying for approval must also submit the following supporting documentation:

(1) A written presentation that demonstrates its ability to furnish CMS with electronic data in CMS compatible format.

(2) A resource analysis that demonstrates that its staffing, funding, and other resources are adequate to perform the required surveys and related activities.

(3) A statement acknowledging that, as a condition for approval, it agrees to comply with the ongoing responsibility requirements of § 422.157(c).

(c) *Additional information.* If CMS determines that it needs additional information for a determination to grant or deny the accreditation organization's request for approval, it notifies the organization and allows time for the organization to provide the additional information.

(d) *Onsite visit.* CMS may visit the accreditation organization's offices to verify representations made by the organization in its application, including, but not limited to, review of documents, and interviews with the organization's staff.

(e) *Notice of determination.* CMS gives the accreditation organization, within 210 days of receipt of its completed application, a formal notice that—

(1) States whether the request for approval has been granted or denied;

(2) Gives the rationale for any denial; and

(3) Describes the reconsideration and reapplication procedures.

(f) *Withdrawal.* An accreditation organization may withdraw its application for approval at any time before it receives the formal notice specified in paragraph (e) of this section.

(g) *Reconsideration of adverse determination.* An accreditation organization that has received notice of denial of its request for approval may request reconsideration in accordance with subpart D of part 488 of this chapter.

(h) *Request for approval following denial.* (1) Except as provided in paragraph (h)(2) of this section, an accreditation organization that has received notice of denial of its request for approval may submit a new request if it—

(i) Has revised its accreditation program to correct the deficiencies on which the denial was based;

(ii) Can demonstrate that the MA organizations that it has accredited meet or exceed applicable Medicare requirements; and

(iii) Resubmits the application in its entirety.

(2) An accreditation organization that has requested reconsideration of CMS's denial of its request for approval may not submit a new request until

the reconsideration is administratively final.

[63 FR 35082, June 26, 1998, as amended at 65 FR 40324, June 29, 2000]

§ 422.160 Basis and scope of the Medicare Advantage Quality Rating System.

(a) *Basis.* This subpart is based on sections 1851(d), 1852(e), 1853(o) and 1854(b)(3)(iii), (v), and (vi) of the Act and the general authority under section 1856(b) of the Act requiring the establishment of standards consistent with and to carry out Part C.

(b) *Purpose.* Ratings calculated and assigned under this subpart will be used by CMS for the following purposes:

(1) To provide comparative information on plan quality and performance to beneficiaries for their use in making knowledgeable enrollment and coverage decisions in the Medicare program.

(2) To provide quality ratings on a 5-star rating system to be used in determining quality bonus payment (QBP) status and in determining rebate retention allowances.

(3) To provide a means to evaluate and oversee overall and specific compliance with certain regulatory and contract requirements by MA plans, where appropriate and possible to use data of the type described in § 422.162(c).

(c) *Applicability.* Except for § 422.162(b)(3), the regulations in this subpart will be applicable beginning with the 2019 measurement period and the associated 2021 Star Ratings that are released prior to the annual coordinated election period for the 2021 contract year and used to assign QBP ratings for the 2022 payment year.

[83 FR 16725, Apr. 16, 2018]

§ 422.162 Medicare Advantage Quality Rating System.

(a) *Definitions.* In this subpart the following terms have the meanings:

Absolute percentage cap is a cap applied to non-CAHPS measures that are on a 0 to 100 scale that restricts movement of the current year's measure-threshold-specific cut point to no more than the stated percentage as compared to the prior year's cut point.

CAHPS refers to a comprehensive and evolving family of surveys that ask consumers and patients to evaluate the interpersonal aspects of health care. CAHPS surveys probe those aspects of care for which consumers and patients are the best or only source of information, as well as those that consumers and patients have identified as being important. CAHPS initially stood for the Consumer Assessment of Health Plans Study, but as the products have evolved beyond health plans the acronym now stands for Consumer Assessment of Healthcare Providers and Systems.

Case-mix adjustment means an adjustment to the measure score made prior to the score being converted into a Star Rating to take into account certain enrollee characteristics that are not under the control of the plan. For example age, education, chronic medical conditions, and functional health status that may be related to the enrollee's survey responses.

Categorical Adjustment Index (CAI) means the factor that is added to or subtracted from an overall or summary Star Rating (or both) to adjust for the average within-contract (or within-plan as applicable) disparity in performance associated with the percentages of beneficiaries who are dually eligible for Medicare and enrolled in Medicaid, beneficiaries who receive a Low Income Subsidy, or have disability status in that contract (or plan as applicable).

Clustering refers to a variety of techniques used to partition data into distinct groups such that the observations within a group are as similar as possible to each other, and as dissimilar as possible to observations in any other group. Clustering of the measure-specific scores means that gaps that exist within the distribution of the scores are identified to create groups (clusters) that are then used to identify the four cut points resulting in the creation of five levels (one for each Star Rating), such that the scores in the same Star Rating level are as similar as possible and the scores in different Star Rating levels are as different as possible. Technically, the variance in measure scores is separated into within-cluster and between-cluster sum of

squares components. The clusters reflect the groupings of numeric value scores that minimize the variance of scores within the clusters. The Star Ratings levels are assigned to the clusters that minimize the within-cluster sum of squares. The cut points for star assignments are derived from the range of measure scores per cluster, and the star levels associated with each cluster are determined by ordering the means of the clusters.

Consolidation means when an MA organization that has at least two contracts for health and/or drug services of the same plan type under the same parent organization in a year combines multiple contracts into a single contract for the start of the subsequent contract year.

Consumed contract means a contract that will no longer exist after a contract year's end as a result of a consolidation.

Cut point cap is a restriction on the change in the amount of movement a measure-threshold-specific cut point can make as compared to the prior year's measure-threshold-specific cut point. A cut point cap can restrict upward movement, downward movement, or both.

Display page means the CMS website on which certain measures and scores are publicly available for informational purposes; the measures that are presented on the display page are not used in assigning Part C and D Star Ratings.

Domain rating means the rating that groups measures together by dimensions of care.

Dual-eligible (DE) means a beneficiary who is enrolled in both Medicare and Medicaid.

Guardrail is a bidirectional cap that restricts both upward and downward movement of a measure-threshold-specific cut point for the current year's measure-level Star Ratings as compared to the prior year's measure-threshold-specific cut point.

Health equity index means an index that summarizes contract performance among those with specified social risk factors (SRFs) across multiple measures into a single score.

HEDIS is the Healthcare Effectiveness Data and Information Set which is a widely used set of performance measures in the managed care industry, developed and maintained by the National Committee for Quality Assurance (NCQA). HEDIS data include clinical measures assessing the effectiveness of care, access/availability measures, and service use measures.

Highest rating means the overall rating for MA–PDs, the Part C summary rating for MA-only contracts, and the Part D summary rating for PDPs.

Highly-rated contract means a contract that has 4 or more stars for its highest rating when calculated without the improvement measures and with all applicable adjustments in § 422.166(f).

HOS means the Medicare Health Outcomes Survey which is the first patient reported outcomes measure that was used in Medicare managed care. The goal of the Medicare HOS program is to gather valid, reliable, and clinically meaningful health status data in the Medicare Advantage (MA) program for use in quality improvement activities, pay for performance, program oversight, public reporting, and improving health. All managed care organizations with MA contracts must participate.

Low income subsidy (LIS) means the subsidy that a beneficiary receives to help pay for prescription drug coverage (see § 423.34 of this chapter for definition of a low-income subsidy eligible individual).

Mean resampling refers to a technique where measure-specific scores for the current year's Star Ratings are randomly separated into 10 equal-sized groups. The hierarchal clustering algorithm is done 10 times, each time leaving one of the 10 groups out. By leaving out one of the 10 groups for each run, 9 of the 10 groups, which is 90 percent of the applicable measure scores, are used for each run of the clustering algorithm. The method results in 10 sets of measure-specific cut points. The mean cut point for each threshold per measure is calculated using the 10 values.

Measurement period means the period for which data are collected for a measure or the performance period that a measures covers.

Measure score means the numeric value of the measure or an assigned 'missing data' message.

Measure star means the measure's numeric value is converted to a Star Rating. It is displayed to the nearest whole star, using a 1–5 star scale.

Overall rating means a global rating that summarizes the quality and performance for the types of services offered across all unique Part C and Part D measures.

Part C summary rating means a global rating that summarizes the health plan quality and performance on Part C measures.

Part D summary rating means a global rating that summarizes prescription drug plan quality and performance on Part D measures.

Plan benefit package (PBP) means a set of benefits for a defined MA or PDP service area. The PBP is submitted by Part D plan sponsors and MA organizations to CMS for benefit analysis, bidding, marketing, and beneficiary communication purposes.

Reliability means a measure of the fraction of the variation among the observed measure values that is due to real differences in quality (''signal'') rather than random variation (''noise''); it is reflected on a scale from 0 (all differences in plan performance measure scores are due to measurement error) to 1 (the difference in plan performance scores is attributable to real differences in performance).

Restricted range is the difference between the maximum and minimum measure score values using the prior year measure scores excluding outer fence outliers (first quartile −3*Interquartile Range (IQR) and third quartile + 3*IQR).

Restricted range cap is a cap applied to non-CAHPS measures that restricts movement of the current year's measure-threshold-specific cut point to no more than the stated percentage of the restricted range of a measure calculated using the prior year's measure score distribution.

Reward factor means a rating-specific factor added to the contract's summary or overall ratings (or both) if a contract has both high and stable relative performance.

Statistical significance assesses how likely differences observed in performance are due to random chance alone under the assumption that plans are actually performing the same.

Surviving contract means the contact that will still exist under a consolidation, and all of the beneficiaries enrolled in the consumed contract(s) are moved to the surviving contracts.

Traditional rounding rules mean that the last digit in a value will be rounded. If rounding to a whole number, look at the digit in the first decimal place. If the digit in the first decimal place is 0, 1, 2, 3, or 4, then the value should be rounded down by deleting the digit in the first decimal place. If the digit in the first decimal place is 5 or greater, then the value should be rounded up by 1 and the digit in the first decimal place deleted.

Tukey outer fence outliers are measure scores that are below a certain point (first quartile − 3.0 × (third quartile − first quartile)) or above a certain point (third quartile + 3.0 × (third quartile − first quartile)).

(b) *Contract ratings*—(1) *General.* CMS calculates an overall Star Rating, Part C summary rating, and Part D summary rating for each MA–PD contract, and a Part C summary rating for each MA-only contract using the 5-star rating system described in this subpart. Measures are assigned stars at the contract level and weighted in accordance with § 422.166(a). Domain ratings are the unweighted mean of the individual measure ratings under the topic area in accordance with § 422.166(b). Summary ratings are the weighted mean of the individual measure ratings for Part C or Part D in accordance with § 422.166(c), with the applicable adjustments provided in paragraph (f) of this section. Overall Star Ratings are calculated by using the weighted mean of the individual measure ratings in accordance with § 422.166(d), with the applicable adjustments provided in paragraph (f) of this section. CMS includes the Star Ratings measures in the overall and summary ratings that are associated with the contract type for the Star Ratings year.

(2) *Plan benefit packages.* All plan benefit packages (PBPs) offered under an MA contract have the same overall and/or summary Star Ratings as the contract under which the PBP is offered by the MA organization. Data

from all the PBPs offered under a contract are used to calculate the measure and domain ratings for the contract except for Special Needs Plan (SNP)-specific measures collected at the PBP level; a contract level score for such measures is calculated using an enrollment-weighted mean of the PBP scores and enrollment reported as part of the measure specification in each PBP.

(3) *Contract consolidations.* (i) In the case of contract consolidations involving two or more contracts for health or drug services of the same plan type under the same parent organization, CMS assigns Star Ratings for the first and second years following the consolidation based on the enrollment-weighted mean of the measure scores of the surviving and consumed contract(s) as provided in paragraph (b)(3)(iv) of this section. Paragraph (b)(3)(iii) of this section is applied to subsequent years that are not addressed in paragraph (b)(3)(ii) of this section for assigning the QBP rating.

(ii) For the first year after a consolidation, CMS will determine the QBP status of a contract using the enrollment-weighted means (using traditional rounding rules) of what would have been the QBP Ratings of the surviving and consumed contracts based on the contract enrollment in November of the year the preliminary QBP ratings were released in the Health Plan Management System (HPMS).

(iii) In subsequent years following the first year after the consolidation, CMS will determine QBP status based on the consolidated entity's Star Ratings displayed on Medicare Plan Finder.

(iv) The Star Ratings posted on Medicare Plan Finder for contracts that consolidate are as follows:

(A)(*1*) For the first year after consolidation, CMS uses enrollment-weighted measure scores using the July enrollment of the measurement period of the consumed and surviving contracts for all measures, except survey-based measures, call center measures, and improvement measures. The survey-based measures will use enrollment of the surviving and consumed contracts at the time the sample is pulled for the rating year. The call center measures will use average enrollment during the study period. The Part C and D improvement measures are not calculated for first year consolidations.

(*2*) For contract consolidations approved on or after January 1, 2022, if a measure score for a consumed or surviving contract is missing due to a data integrity issue as described in § 422.164(g)(1)(i) and (ii), CMS assigns a score of zero for the missing measure score in the calculation of the enrollment-weighted measure score.

(B)(*1*) For the second year after consolidation, CMS uses the enrollment-weighted measure scores using the July enrollment of the measurement year of the consumed and surviving contracts for all measures except for HEDIS, CAHPS, and HOS. HEDIS and HOS measure data are scored as reported. CMS ensures that the CAHPS survey sample includes enrollees in the sample frame from both the surviving and consumed contracts.

(*2*) For contract consolidations approved on or after January 1, 2022, for all measures except HEDIS, CAHPS, and HOS if a measure score for a consumed or surviving contract is missing due to a data integrity issue as described in § 422.164(g)(1)(i) and (ii), CMS assigns a score of zero for the missing measure score in the calculation of the enrollment-weighted measure score.

(v) This provision governing the Star Ratings of surviving contracts is applicable to contract consolidations that are approved on or after January 1, 2019.

(4) *Quality bonus payment ratings.* (i) For contracts that receive a numeric Star Rating, the final quality bonus payment (QBP) rating for the contract is released in April of each year for the following contract year. The QBP rating is the contract's highest rating from the Star Ratings published by CMS in October of the calendar year that is 2 years before the contract year to which the QBP rating applies.

(ii) The contract QBP rating is applied to each plan benefit package offered under the contract.

(c) *Data sources.* (1) CMS bases Part C Star Ratings on the type of data specified in section 1852(e) of the Act and on CMS administrative data. Part C Star Ratings measures reflect structure,

process, and outcome indices of quality. This includes information of the following types: Clinical data, beneficiary experiences, changes in physical and mental health, benefit administration information and CMS administrative data. Data underlying Star Ratings measures may include survey data, data separately collected and used in oversight of MA plans' compliance with MA requirements, data submitted by plans, and CMS administrative data.

(2) MA organizations are required to collect, analyze, and report data that permit measurement of health outcomes and other indices of quality. MA organizations must provide unbiased, accurate, and complete quality data described in paragraph (c)(1) of this section to CMS on a timely basis as requested by CMS.

[83 FR 16725, Apr. 16, 2018, as amended at 84 FR 15829, Apr. 16, 2019; 85 FR 33907, June 2, 2020; 86 FR 6097, Jan. 19, 2021; 88 FR 22332, Apr. 12, 2023]

§ 422.164 Adding, updating, and removing measures.

(a) *General.* CMS adds, updates, and removes measures used to calculate the Star Ratings as provided in this section. CMS lists the measures used for a particular Star Rating each year in the Technical Notes or similar guidance document with publication of the Star Ratings.

(b) *Review of data quality.* CMS reviews the quality of the data on which performance, scoring and rating of a measure is based before using the data to score and rate performance or in calculating a Star Rating. This includes review of variation in scores among MA organizations and Part D plan sponsors, and the accuracy, reliability, and validity of measures and performance data before making a final determination about inclusion of measures in each year's Star Ratings.

(c) *Adding measures.* (1) CMS will continue to review measures that are nationally endorsed and in alignment with the private sector, such as measures developed by National Committee for Quality Assurance (NCQA) and the Pharmacy Quality Alliance (PQA), or endorsed by the National Quality Forum for adoption and use in the Part C and Part D Quality Ratings System. CMS may develop its own measures as well when appropriate to measure and reflect performance specific to the Medicare program.

(2) In advance of the measurement period, CMS will announce potential new measures and solicit feedback through the process described for changes in and adoption of payment and risk adjustment policies in section 1853(b) of the Act and then subsequently will propose and finalize new measures through rulemaking.

(3) New measures added to the Part C Star Ratings program will be on the display page on *www.cms.gov* for a minimum of 2 years prior to becoming a Star Ratings measure.

(4) A measure will remain on the display page for longer than 2 years if CMS finds reliability or validity issues with the measure specification.

(d) *Updating measures*—(1) *Non-substantive updates.* For measures that are already used for Star Ratings, CMS will update measures so long as the changes in a measure are not substantive. CMS will announce non-substantive updates to measures that occur (or are announced by the measure steward) during or in advance of the measurement period through the process described for changes in and adoption of payment and risk adjustment policies in section 1853(b) of the Act. Non-substantive measure specification updates include those that—

(i) Narrow the denominator or population covered by the measure;

(ii) Do not meaningfully impact the numerator or denominator of the measure;

(iii) Update the clinical codes with no change in the target population or the intent of the measure;

(iv) Provide additional clarifications:

(A) Adding additional tests that would meet the numerator requirements;

(B) Clarifying documentation requirements;

(C) Adding additional instructions to identify services or procedures; or

(v) Add alternative data sources or expand modes of data collection.

(2) *Substantive updates.* For measures that are already used for Star Ratings,

in the case of measure specification updates that are substantive updates not subject to paragraph (d)(1) of this section, CMS will propose and finalize these measures through rulemaking similar to the process for adding new measures. CMS will initially solicit feedback on whether to make substantive measure updates through the process described for changes in and adoption of payment and risk adjustment policies in section 1853(b) of the Act. Once the update has been made to the measure specification by the measure steward, CMS may continue collection of performance data for the legacy measure and include it in Star Ratings until the updated measure has been on display for 2 years. CMS will place the updated measure on the display page for at least 2 years prior to using the updated measure to calculate and assign Star Ratings as specified in paragraph (c) of this section.

(e) *Removing measures.* (1) CMS will remove a measure from the Star Ratings program as follows:

(i) When the clinical guidelines associated with the specifications of the measure change such that the specifications are no longer believed to align with positive health outcomes; or

(ii) A measure shows low statistical reliability.

(iii) The measure steward other than CMS retires a measure.

(2) CMS will announce in advance of the measurement period the removal of a measure based upon its application of this paragraph (e) through the process described for changes in and adoption of payment and risk adjustment policies in section 1853(b) of the Act in advance of the measurement period.

(f) *Improvement measure.* CMS will calculate improvement measure scores based on a comparison of the measure scores for the current year to the immediately preceding year as provided in this paragraph (f); the improvement measure score would be calculated for Parts C and D separately by taking a weighted sum of net improvement divided by the weighted sum of the number of eligible measures.

(1) *Identifying eligible measures.* Annually, the subset of measures to be included in the Part C and Part D improvement measures will be announced through the process described for changes in and adoption of payment and risk adjustment policies in section 1853(b) of the Act. CMS identifies measures to be used in the improvement measures if the measures meet all of the following:

(i) CMS will include only measures available for the current and previous year in the improvement measures and that have numeric value scores in both the current and prior year.

(ii) CMS will exclude any measure for which there was a substantive specification change from the previous year.

(iii) CMS will exclude any measures that are already focused on improvement in MA organization performance from year to year.

(iv) The Part C improvement measure will include only Part C measure scores; the Part D improvement measure will include only Part D measure scores.

(v) CMS excludes any measure that receives a measure-level Star Rating reduction for data integrity concerns for either the current or prior year from the improvement measure(s).

(2) *Determining eligible contracts.* CMS will calculate an improvement score only for contracts that have numeric measure scores for both years in at least half of the measures identified for use applying the standards in paragraphs (f)(1)(i) through (iv) of this section.

(3) *Special rules for calculation of the improvement score.* For any measure used for the improvement measure for which a contract received 5 stars in each of the years examined, but for which the measure score demonstrates a statistically significant decline based on the results of the significance testing (at a level of significance of 0.05) on the change score, the measure will be categorized as having no significant change and included in the count of measures used to determine eligibility for the measure (that is, for the denominator of the improvement measure score).

(4) *Calculation of the improvement score.* The improvement measure will be calculated as follows:

(i) The improvement change score (the difference in the measure scores in the 2-year period) will be determined

for each measure that has been designated an improvement measure and for which a contract has a numeric score for each of the 2 years examined.

(ii) Each contract's improvement change score per measure will be categorized as a significant change or not a significant change by employing a two-tailed t-test with a level of significance of 0.05.

(iii) The net improvement per measure category (outcome, access, patient experience, process) would be calculated by finding the difference between the weighted number of significantly improved measures and significantly declined measures, using the measure weights associated with each measure category.

(iv) The improvement measure score will then be determined by calculating the weighted sum of the net improvement per measure category divided by the weighted sum of the number of eligible measures.

(v) The improvement measure scores will be converted to measure-level Star Ratings by determining the cut points using hierarchical clustering algorithms in accordance with § 422.166(a)(2)(i) through (iii).

(vi) The Part D improvement measure cut points for MA–PDs and PDPs will be determined using separate clustering algorithms in accordance with §§ 422.166(a)(2)(iii) and 423.186(a)(2)(iii) of this chapter.

(g) *Data integrity.* (1) CMS will reduce a contract's measure rating when CMS determines that a contract's measure data are inaccurate, incomplete, or biased; such determinations may be based on a number of reasons, including mishandling of data, inappropriate processing, or implementation of incorrect practices that have an impact on the accuracy, impartiality, or completeness of the data used for one or more specific measure(s).

(i) CMS will reduce HEDIS measures to 1 star when audited data are submitted to NCQA with a designation of ''biased rate'' or BR based on an auditor's review of the data or a designation of ''nonreport'' or NR.

(ii) CMS will reduce measures based on data that an MA organization must submit to CMS under § 422.516 to 1 star when a contract did not score at least 95 percent on data validation for the applicable reporting section or was not compliant with CMS data validation standards/substandards for data directly used to calculate the associated measure.

(iii) For the appeals measures, CMS uses statistical criteria to estimate the percentage of missing data for each contract using data from MA organizations, the independent review entity (IRE), or CMS administrative sources to determine whether the data at the IRE are complete. CMS uses scaled reductions for the Star Ratings for the applicable appeals measures to account for the degree to which the IRE data are missing.

(A)(*1*) The data reported by the MA organization on appeals, including the number of reconsiderations requested, denied, upheld, dismissed, or otherwise disposed of by the MA organization, and data from the IRE or CMS administrative sources, that align with the Star Ratings year measurement period are used to determine the scaled reduction.

(*2*) If there is a contract consolidation as described at § 422.162(b)(3), the data described in paragraph (g)(1)(iii)(A)(*1*) of this section are combined for the consumed and surviving contracts before the methodology provided in paragraphs (g)(1)(iii)(B) through (O) of this section is applied.

(B) [Reserved]

(C) The reductions range from a one-star reduction to a four-star reduction; the most severe reduction for the degree of missing IRE data is a four-star reduction.

(D) The thresholds used for determining the reduction and the associated appeals measure reduction are as follows:

(*1*) 20 percent, 1 star reduction.

(*2*) 40 percent, 2 star reduction.

(*3*) 60 percent, 3 star reduction.

(*4*) 80 percent, 4 star reduction.

(E) If a contract receives a reduction due to missing Part C IRE data, the reduction is applied to both of the contract's Part C appeals measures.

(F) [Reserved]

(G) The scaled reduction is applied after the calculation for the appeals

measure-level Star Ratings. If the application of the scaled reduction results in a measure-level star rating less than 1 star, the contract will be assigned 1 star for the appeals measure.

(H) The Part C calculated error is determined using 1 minus the quotient of the total number of cases received by the IRE that were supposed to be sent and the total number of cases that should have been forwarded to the IRE. The total number of cases that should have been forwarded to the IRE is determined by the sum of the partially favorable (adverse) reconsiderations and unfavorable (adverse) reconsiderations for the applicable measurement year.

(I)–(J) [Reserved]

(K) Contracts are subject to a possible reduction due to lack of IRE data completeness if both of the following conditions are met:

(*1*) The calculated error rate is 20 percent or more.

(*2*) The number of cases not forwarded to the IRE is at least 10 for the measurement year.

(L) A confidence interval estimate for the true error rate for the contract is calculated using a Score Interval (Wilson Score Interval) at a confidence level of 95 percent and an associated z of 1.959964 for a contract that is subject to a possible reduction.

(M) A contract's lower bound is compared to the thresholds of the scaled reductions to determine the IRE data completeness reduction.

(N) The reduction is identified by the highest threshold that a contract's lower bound exceeds.

(O) CMS reduces the measure rating to 1 star for the applicable appeals measure(s) if CMS does not have accurate, complete, and unbiased data to validate the completeness of the Part C appeals measures.

(2) CMS will reduce a measure rating to 1 star for additional concerns that data inaccuracy, incompleteness, or bias have an impact on measure scores and are not specified in paragraphs (g)(1)(i) through (iii) of this section, including a contract's failure to adhere to HEDIS, HOS, or CAHPS reporting requirements.

(h) *Review of sponsors' data.* (1) An MA organization may request that CMS or the IRE review its' contract's appeals data provided that the request is received by the annual deadline set by CMS.

(2) An MA organization may request that CMS review its' contract's Complaints Tracking Module (CTM) data provided that the request is received by the annual deadline set by CMS for the applicable Star Ratings year.

(i) [Reserved]

(3) Beginning with the 2025 measurement year (2027 Star Ratings), an MA organization may request that CMS review its contract's administrative data for Patient Safety measures provided that the request is received by the annual deadline set by CMS for the applicable Star Ratings year.

[83 FR 16725, Apr. 16, 2018, as amended at 84 FR 15829, Apr. 16, 2019; 85 FR 19290, Apr. 6, 2020; 86 FR 6097, Jan. 19, 2021; 87 FR 27895, May 9, 2022; 88 FR 22332, Apr. 12, 2023; 89 FR 30820, Apr. 23, 2024]

§ 422.166 Calculation of Star Ratings.

(a) *Measure Star Ratings*—(1) *Cut points.* CMS will determine cut points for the assignment of a Star Rating for each numeric measure score by applying either a clustering or a relative distribution and significance testing methodology. For the Part D measures, CMS will determine MA–PD and PDP cut points separately.

(2) *Clustering algorithm for all measures except CAHPS measures.*

(i) The method maximizes differences across the star categories and minimizes the differences within star categories using mean resampling with the hierarchal clustering of the current year's data. Effective for the Star Ratings issued in October 2023 and subsequent years, prior to applying mean resampling with hierarchal clustering, Tukey outer fence outliers are removed. Effective for the Star Ratings issued in October 2022 and subsequent years, CMS will add a guardrail so that the measure-threshold-specific cut points for non-CAHPS measures do not increase or decrease more than the value of the cap from 1 year to the next. The cap is equal to 5 percentage points for measures having a 0 to 100 scale (absolute percentage cap) or 5 percent of the restricted range for measures not having a 0 to 100 scale

(restricted range cap). New measures that have been in the Part C and D Star Rating program for 3 years or less use the hierarchal clustering methodology with mean resampling with no guardrail for the first 3 years in the program.

(ii) In cases where multiple clusters have the same measure score value range, those clusters would be combined, leading to fewer than 5 clusters.

(iii) The clustering algorithm for the improvement measure scores is done in two steps to determine the cut points for the measure-level Star Ratings. Clustering is conducted separately for improvement measure scores greater than or equal to zero and those with improvement measure scores less than zero.

(A) Improvement scores of zero or greater would be assigned at least 3 stars for the improvement Star Rating.

(B) Improvement scores less than zero would be assigned either 1 or 2 stars for the improvement Star Rating.

(3) *Relative distribution and significance testing for CAHPS measures.* The method combines evaluating the relative percentile distribution with significance testing and accounts for the reliability of scores produced from survey data; no measure Star Rating is produced if the reliability of a CAHPS measure is less than 0.60. Low reliability scores are defined as those with at least 11 respondents, reliability greater than or equal to 0.60 but less than 0.75, and also in the lowest 12 percent of contracts ordered by reliability. The following rules apply:

(i) A contract is assigned 1 star if both of the criteria in paragraphs (a)(3)(i)(A) and (B) of this section are met plus at least one of the criteria in paragraphs (a)(3)(i)(C) or (D) of this section is met:

(A) Its average CAHPS measure score is lower than the 15th percentile; and

(B) Its average CAHPS measure score is statistically significantly lower than the national average CAHPS measure score;

(C) The reliability is not low; or

(D) Its average CAHPS measure score is more than one standard error below the 15th percentile.

(ii) A contract is assigned 2 stars if it does not meet the 1-star criteria and meets at least one of these three criteria:

(A) Its average CAHPS measure score is lower than the 30th percentile and the measure does not have low reliability; or

(B) Its average CAHPS measure score is lower than the 15th percentile and the measure has low reliability; or

(C) Its average CAHPS measure score is statistically significantly lower than the national average CAHPS measure score and below the 60th percentile.

(iii) A contract is assigned 3 stars if it meets at least one of these three criteria:

(A) Its average CAHPS measure score is at or above the 30th percentile and lower than the 60th percentile, and it is not statistically significantly different from the national average CAHPS measure score; or

(B) Its average CAHPS measure score is at or above the 15th percentile and lower than the 30th percentile, the reliability is low, and the score is not statistically significantly lower than the national average CAHPS measure score; or

(C) Its average CAHPS measure score is at or above the 60th percentile and lower than the 80th percentile, the reliability is low, and the score is not statistically significantly higher than the national average CAHPS measure score.

(iv) A contract is assigned 4 stars if it does not meet the 5-star criteria and meets at least one of these three criteria:

(A) Its average CAHPS measure score is at or above the 60th percentile and the measure does not have low reliability; or

(B) Its average CAHPS measure score is at or above the 80th percentile and the measure has low reliability; or

(C) Its average CAHPS measure score is statistically significantly higher than the national average CAHPS measure score and above the 30th percentile.

(v) A contract is assigned 5 stars if both of the following criteria in paragraphs (a)(3)(v)(A) and (B) of this section are met plus at least one of the criteria in paragraphs (a)(3)(v)(C) or (D) of this section is met:

(A) Its average CAHPS measure score is at or above the 80th percentile; and

(B) Its average CAHPS measure score is statistically significantly higher than the national average CAHPS measure score;

(C) The reliability is not low; or

(D) Its average CAHPS measure score is more than one standard error above the 80th percentile.

(4) *5-Star Scale.* Measure scores are converted to a 5-star scale ranging from 1 (worst rating) to 5 (best rating), with whole star increments for the cut points.

(b) *Domain Star Ratings.* (1)(i) CMS groups measures by domains solely for purposes of public reporting the data on Medicare Plan Finder. They are not used in the calculation of the summary or overall ratings. Domains are used to group measures by dimensions of care that together represent a unique and important aspect of quality and performance.

(ii) The 5 domains for the MA Star Ratings are: Staying Healthy: Screenings, Tests and Vaccines; Managing Chronic (Long Term) Conditions; Member Experience with Health Plan; Member Complaints and Changes in the Health Plan's Performance; and Health Plan Customer Service. The 4 domains for the Part D Star Ratings are: Drug Plan Customer Service; Member Complaints and Changes in the Drug Plan's Performance; Member Experience with the Drug Plan; and Drug Safety and Accuracy of Drug Pricing.

(2) CMS calculates the domain ratings as the unweighted mean of the Star Ratings of the included measures.

(i) A contract must have scores for at least 50 percent of the measures required to be reported for that contract type for that domain to have a domain rating calculated.

(ii) The domain ratings are on a 1- to 5-star scale ranging from 1 (worst rating) to 5 (best rating) in whole star increments using traditional rounding rules.

(c) *Part C summary ratings.* (1) CMS will calculate the Part C summary ratings using the weighted mean of the measure-level Star Ratings for Part C, weighted in accordance with paragraph (e) of this section and with the applicable adjustments provided in paragraph (f) of this section.

(2)(i) A contract must have scores for at least 50 percent of the measures required to be reported for the contract type to have the summary rating calculated.

(ii) The Part C improvement measure is not included in the count of the minimum number of rated measures.

(3) The summary ratings are on a 1- to 5-star scale ranging from 1 (worst rating) to 5 (best rating) in half-star increments using traditional rounding rules.

(d) *Overall MA–PD rating.* (1) The overall rating for a MA–PD contract will be calculated using a weighted mean of the Part C and Part D measure-level Star Ratings, weighted in accordance with paragraph (e) of this section and with the applicable adjustments provided in paragraph (f) of this section.

(2)(i) An MA–PD must have both Part C and Part D summary ratings and scores for at least 50 percent of the measures required to be reported for the contract type to have the overall rating calculated.

(ii) The Part C and D improvement measures are not included in the count of measures needed for the overall rating.

(iii) Any measures that share the same data and are included in both the Part C and Part D summary ratings will be included only once in the calculation for the overall rating.

(iv) The overall rating is on a 1- to 5-star scale ranging from 1 (worst rating) to 5 (best rating) in half-increments using traditional rounding rules.

(v) Low enrollment contracts (as defined in § 422.252) and new MA plans (as defined in § 422.252) do not receive an overall and/or summary rating. They are treated as qualifying plans for the purposes of QBPs as described in § 422.258(d)(7) and as announced through the process described for changes in and adoption of payment and risk adjustment policies in section 1853(b) of the Act.

(vi) The QBP ratings for contracts that do not have sufficient data to calculate and assign ratings and do not meet the definition of low enrollment

or new MA plans at §422.252 are assigned as follows:

(A) For a new contract under an existing parent organization that has other MA contract(s) with numeric Star Ratings in November when the preliminary QBP ratings are calculated for the contract year that begins 14 months later, the QBP rating assigned is the enrollment-weighted average highest rating of the parent organization's other MA contract(s) that are active as of the April when the final QBP ratings are released under §422.162(b)(4). The Star Ratings used in this calculation are the rounded stars (to the whole or half star) that are publicly displayed on *www.medicare.gov*. The enrollment figures used in the enrollment-weighted calculations are the November enrollment in the year the Star Ratings are released.

(B) For a new contract under a parent organization that does not have other MA contract(s) with numeric Star Ratings in November when the preliminary QBP ratings are calculated for the contract year that begins 14 months later, the MA Star Ratings for the previous 3 years are used and the QBP rating is the enrollment-weighted average of the MA contract(s)'s highest ratings from the most recent year rated for that parent organization.

(*1*) The Star Ratings had to be publicly reported on *www.medicare.gov*.

(*2*) The Star Ratings used in this calculation are rounded to the whole or half star.

(C) The enrollment figures used in the enrollment-weighted calculations are the November enrollment in the year the Star Ratings are released.

(D) The QBP ratings are updated for any changes in a contract's parent organization that are reflected in CMS records prior to the release of the final QBP ratings in April of each year.

(E) Once the QBP ratings are finalized in April of each year for the following contract year, no additional parent organization changes are used for purposes of assigning QBP ratings.

(e) *Measure weights*—(1) *General rules.* Subject to paragraphs (e)(2) and (3) of this section, CMS will assign weights to measures based on their categorization as follows.

(i) Improvement measures receive the highest weight of 5.

(ii) Outcome and Intermediate outcome measures receive a weight of 3.

(iii) Through the 2025 Star Ratings, patient experience and complaint measures receive a weight of 4. Starting with the 2026 Star Ratings and subsequent Star Ratings years, patient experience and complaint measures receive a weight of 2.

(iv) Through the 2025 Star Ratings, access measures receive a weight of 4. Starting with the 2026 Star Ratings and subsequent Star Ratings years, access measures receive a weight of 2.

(v) Process measures receive a weight of 1.

(2) *Rules for new and substantively updated measures.* New measures to the Star Ratings program will receive a weight of 1 for their first year in the Star Ratings program. Substantively updated measures will receive a weight of 1 in their first year returning to the Star Ratings after being on the display page. In subsequent years, a new or substantively updated measure will be assigned the weight associated with its category.

(3) *Special rule for Puerto Rico.* Contracts that have service areas that are wholly located in Puerto Rico will receive a weight of zero for the Part D adherence measures for the summary and overall rating calculations and will have a weight of 3 for the adherence measures for the improvement measure calculations.

(f) *Completing the Part C summary and overall rating calculations.* CMS will adjust the summary and overall rating calculations to take into account the reward factor (if applicable) and the categorical adjustment index (CAI) as provided in this paragraph (f).

(1) *Reward factor.* Through the 2026 Star Ratings, this rating-specific reward factor is added to both the summary and overall ratings of contracts that qualify for this reward factor based on both high and stable relative performance for the rating level.

(i) The contract's performance will be assessed using its weighted mean and its ranking relative to all rated contracts in the rating level (overall for MA–PDs; Part C summary for MA–PDs and MA-only; and Part D summary

for MA–PDs and PDPs) for the same Star Ratings year. The contract's stability of performance will be assessed using the weighted variance and its ranking relative to all rated contracts in the rating type (overall for MA–PDs; Part C summary for MA–PDs and MA-only; and Part D summary for MA–PDs and PDPs). The weighted mean and weighted variance are compared separately for MA–PD and standalone Part D contracts (PDPs). The measure weights are specified in paragraph (e) of this section. Since highly-rated contracts may have the improvement measure(s) excluded in the determination of their final highest rating, each contract's weighted variance and weighted mean are calculated both with and without the improvement measures. For an MA–PD's Part C and D summary ratings, its ranking is relative to all other contracts' weighted variance and weighted mean for the rating type (Part C summary, Part D summary) with the improvement measure. For the 2022 Star Ratings only, since all contracts may have the improvement measure(s) excluded in the determination of their highest rating and summary rating(s), each contract's weighted variance and weighted mean are calculated both with and without the improvement measures.

(ii) Relative performance of the weighted variance (or weighted variance ranking) will be categorized as being high (at or above 70th percentile), medium (between the 30th and 69th percentile) or low (below the 30th percentile). Relative performance of the weighted mean (or weighted mean ranking) will be categorized as being high (at or above the 85th percentile), relatively high (between the 65th and 84th percentiles), or other (below the 65th percentile).

(iii) The combination of the relative variance and relative mean is used to determine the value of the reward factor to be added to the contract's summary and overall ratings as follows:

(A) A contract with low variance and a high mean will have a reward factor equal to 0.4.

(B) A contract with medium variance and a high mean will have a reward factor equal to 0.3.

(C) A contract with low variance and a relatively high mean will have a reward factor equal to 0.2.

(D) A contract with medium variance and a relatively high mean will have a reward factor equal to 0.1.

(E) A contract with all other combinations of variance and relative mean will have a reward factor equal to 0.0.

(iv) The reward factor is determined and applied before application of the CAI adjustment under paragraph (f)(2) of this section; the reward factor is based on unadjusted scores.

(2) *Categorical Adjustment Index.* CMS applies the categorical adjustment index (CAI) as provided in this paragraph (f)(2) to adjust for the average within-contract disparity in performance associated with the percentages of beneficiaries who receive a low income subsidy or are dual eligible (LIS/DE) or have disability status. The factor is calculated as the mean difference in the adjusted and unadjusted ratings (overall, Part C, Part D for MA–PDs, Part D for PDPs) of the contracts that lie within each final adjustment category for each rating type.

(i) The CAI is added to or subtracted from the contract's overall and summary ratings and is applied after the reward factor adjustment described in paragraph (f)(1) of this section (if applicable).

(A) The adjustment factor is monotonic (that is, as the proportion of LIS/DE and disabled increases in a contract, the adjustment factor increases in at least one of the dimensions) and varies by a contract's categorization into a final adjustment category that is determined by a contract's proportion of LIS/DE and disabled beneficiaries.

(B) To determine a contract's final adjustment category, contract enrollment is determined using enrollment data for the month of December for the measurement period of the Star Ratings year.

(*1*) For the first 2 years following a consolidation, for the surviving contract of a contract consolidation involving two or more contracts for health or drug services of the same plan type under the same parent organization, the enrollment data for the

month of December for the measurement period of the Star Ratings year are combined across the surviving and consumed contracts in the consolidation.

(*2*) The count of beneficiaries for a contract is restricted to beneficiaries that are alive for part or all of the month of December of the applicable measurement year.

(*3*) A beneficiary is categorized as LIS/DE if the beneficiary was designated as full or partially dually eligible or receiving a LIS at any time during the applicable measurement period.

(*4*) Disability status is determined using the variable original reason for entitlement (OREC) for Medicare using the information from the Social Security Administration and Railroad Retirement Board record systems.

(C) MA–PD contracts may be adjusted up to three times with the CAI; one for the overall Star Rating and one for each of the summary ratings (Part C and Part D).

(D) An MA-only contract may be adjusted only once for the CAI for the Part C summary rating.

(E) The CAI values are rounded and displayed with 6 decimal places.

(ii) In determining the CAI values, a measure will be excluded from adjustment if the measure meets any of the following:

(A) The measure is already case-mix adjusted for socioeconomic status.

(B) The focus of the measurement is not a beneficiary-level issue but rather a plan or provider-level issue.

(C) The measure is scheduled to be retired or revised.

(D) The measure is applicable only to SNPs.

(iii) The Star Ratings measures that remain after the exclusion criteria, paragraph (f)(2)(ii) of this section, have been applied will be adjusted for the determination of the CAI. CMS will announce the measures identified for adjustment in the calculations of the CAI under this paragraph (f)(2) through the process described for changes in and adoption of payment and risk adjustment policies in section 1853(b) of the Act.

(iv) The adjusted measures scores for the selected measures are determined using the results from regression models of beneficiary-level measure scores that adjust for the average within-contract difference in measure scores for MA or PDP contracts.

(A) A logistic regression model with contract fixed effects and beneficiary level indicators of LIS/DE and disability status is used for the adjustment.

(B) The adjusted measure scores are converted to a measure-level Star Rating using the measure thresholds for the Star Ratings year that corresponds to the measurement period of the data employed for the CAI determination.

(v) The rating-specific CAI values will be determined using the mean differences between the adjusted and unadjusted Star Ratings (overall, Part C summary, Part D summary for MA–PDs and Part D summary for PDPs) in each final adjustment category.

(A) For the annual development of the CAI, the distribution of the percentages for LIS/DE and disabled using the enrollment data that parallels the previous Star Ratings year's data would be examined to determine the number of equal-sized initial groups for each attribute (LIS/DE and disabled).

(B) The initial categories are created using all groups formed by the initial LIS/DE and disabled groups.

(C) The mean difference between the adjusted and unadjusted summary or overall ratings per initial category would be calculated and examined. The initial categories would then be collapsed to form the final adjustment categories. The collapsing of the initial categories to form the final adjustment categories would be done to enforce monotonicity in at least one dimension (LIS/DE or disabled).

(D) The mean difference within each final adjustment category by rating-type (overall, Part C, Part D for MA–PD, and Part D for PDPs) would be the CAI values for the next Star Ratings year.

(vi) CMS develops the model for the modified contract-level LIS/DE percentage for Puerto Rico using the following sources of information:

(A) The most recent data available at the time of the development of the model of both 1-year American Community Survey (ACS) estimates for the percentage of people living below the

Federal Poverty Level (FPL) and the ACS 5-year estimates for the percentage of people living below 150 percent of the FPL. The data to develop the model will be limited to the 10 states, drawn from the 50 states plus the District of Columbia with the highest proportion of people living below the FPL, as identified by the 1-year ACS estimates.

(B) The Medicare enrollment data from the same measurement period as the Star Ratings' year. The Medicare enrollment data would be aggregated from MA contracts that had at least 90 percent of their enrolled beneficiaries with mailing addresses in the 10 highest poverty states.

(vii) A linear regression model is developed to estimate the percentage of LIS/DE for a contacts that solely serve the population of beneficiaries in Puerto Rico.

(A) The maximum value for the modified LIS/DE indicator value per contract would be capped at 100 percent.

(B) All estimated modified LIS/DE values for Puerto Rico would be rounded to 6 decimal places when expressed as a percentage.

(C) The model's coefficient and intercept are updated annually and published in the Technical Notes.

(3) *Health equity index.* Starting with the 2027 Star Ratings year and subsequent Star Ratings years, CMS applies a health equity index rating-specific factor to both the summary and overall ratings of contracts that qualify based on an assessment of contract performance on quality measures among enrollees with certain social risk factors (SRFs).

(i) The health equity index (HEI) is calculated separately for the overall rating for MA–PDs and cost contracts including the applicable Part C and D measures; Part C summary rating for MA-only, MA–PD, and cost contracts including the applicable Part C measures; Part D summary rating for MA–PDs and cost contracts including the applicable Part D measures; and Part D summary rating for PDPs including the applicable Part D measures.

(A) The SRFs included in the HEI are receipt of the low income subsidy or being dually eligible for Medicare and Medicaid (LIS/DE), or having a disability. Enrollees will be identified as LIS/DE or as having a disability as specified in paragraph (f)(2)(i)(B) of this section. If a person meets the LIS/DE criteria for only one of the two measurement years included in the HEI, the data for that person for just that year are used. Measures that are case-mix adjusted in the Star Ratings are adjusted using all standard case-mix adjustors for the measure except for those adjusters that are the SRFs of interest in the index, are strongly correlated with the SRFs of interest, or are conceptually similar to the SRFs of interest.

(B) The HEI is calculated by combining measure-level scores for the subset of enrollees with SRFs of interest included in the HEI across the two most recent measurement years using a modeling approach that includes year as an adjustor to account for potential differences in performance across years and to adjust the data to reflect performance in the second of the 2 years of data used. Measure-level scores are used for contracts that have data for only the most recent year of the 2 years, but measure-level scores are not used for contracts that have data for only the first of the 2 years.

(ii) In determining the HEI scores, a measure will be excluded from the calculation of the index if the measure meets any of the following:

(A) The focus of the measurement is not the enrollee but rather the plan or provider.

(B) The measure is retired, moved to display, or has a substantive specification change in either year of data used to construct the HEI.

(C) The measure is applicable only to SNPs.

(D) At least 25 percent of contracts are unable to meet the criteria specified in paragraph (f)(3)(iv) of this section. For Part D measures, this criterion is assessed separately for MA–PDs and cost contracts, and for PDPs.

(iii) The Star Ratings measures that remain after the exclusion criteria in paragraph (f)(3)(ii) of this section have been applied will be included in the calculation of the HEI. CMS will announce the measures being evaluated for inclusion in the calculation of the

HEI under this paragraph (f)(3) through the process described for changes in and adoption of payment and risk adjustment policies in section 1853(b) of the Act.

(iv) For a measure to be included in the calculation of a contract's HEI score, the measure must meet both of the following criteria:

(A) The measure must have a reliability of at least 0.7 for the contract when calculated for the combined subset of enrollees with the SRF(s) specified in paragraph (f)(3)(i)(A) of this section across 2 years of data.

(B) The measure-specific denominator criteria must be met for the contract using only the combined subset of enrollees in the contract with the SRF(s) specified in paragraph (f)(3)(i)(A) of this section across 2 years of data.

(v) To calculate the rating-specific HEI score, the distribution of contract performance on each eligible measure for the subset of enrollees that have one or more of the specified SRFs will be assessed and separated into thirds, with the top third of contracts receiving 1 point, the middle third of contracts receiving 0 points, and the bottom third of contracts receiving −1 point. The rating-specific HEI will then be calculated as the weighted sum of points across all measures included in the index using the Star Ratings measure weight for each measure divided by the weighted sum of the number of eligible measures for the given contract. The measure weight for each measure is the weight used for the measure in the current Star Ratings year as specified in paragraph (e) of this section.

(vi) To have the HEI calculated, contracts must have at least 500 enrollees in the most recent measurement year used in the HEI and have at least half of the measures included in the HEI meet the criteria specified under paragraph (f)(3)(iv) of this section.

(vii) In order to qualify for the full HEI reward, contracts must have percentages of enrollees with the specified SRFs combined greater than or equal to the contract-level median in the most recent year of data used to calculate the HEI and a rating-specific minimum index score of greater than zero. In order to qualify for one-half of the HEI reward, contracts must have percentages of enrollees with SRFs greater than or equal to one-half of the contract-level median up to, but not including, the contract-level median percentage of enrollees with SRFs in the most recent year of data used to calculate the HEI and a rating-specific minimum index score of greater than zero. One-half of the contract-level median and the contract-level median enrollment percentages are assessed separately for contracts that offer Part C and stand-alone Part D contracts.

(A) For contracts with service areas wholly located in Puerto Rico, the percentage of enrollees that are LIS/DE or disabled is calculated by adding the number of DE/disabled enrollees to the estimated LIS percentage calculated by taking the percentage LIS/DE as calculated at §§422.166(f)(2)(vi) and (vii) and 423.186(f)(2)(vi) and (vii) and subtracting the percentage of DE enrollees.

(B) Contracts with service areas wholly located in Puerto Rico are excluded from the calculation of one-half of the contract-level median and the contract-level median.

(viii) For contracts that have percentages of enrollees with SRFs greater than or equal to the contract-level median enrollment percentage, the HEI reward added to the contract's summary and overall ratings will vary from 0 to 0.4 on a linear scale, with a contract receiving 0 if the contract receives a score of 0 or less on the HEI and 0.4 if the contract receives a score of 1 on the HEI. For contracts that have percentages of enrollees with SRFs greater than or equal to one-half the median percentage of enrollees with SRFs up to, but not including, the contract-level median percentage of enrollees with SRFs, the HEI reward added to the contract's summary and overall ratings will vary from 0 to 0.2 on a linear scale, with a contract receiving 0 if the contract receives a score of 0 or less on the HEI and 0.2 if the contract receives a score of 1 on the HEI. The HEI reward is rounded and displayed with 6 decimal places. Contracts that cannot have an HEI score calculated (that is, contracts that are not scored on at least half of

the measures included in the index) will not receive an HEI reward.

(A) In the case of contract consolidations involving two or more contracts for health or drug services of the same plan type under the same parent organization, CMS calculates the HEI reward for the surviving contract accounting for both the surviving and consumed contract(s). For the first year following a consolidation, the HEI reward for the surviving contract is calculated as the enrollment-weighted mean of the HEI reward of the consumed and surviving contracts using total contract enrollment from July of the most recent measurement year used in calculating the HEI reward. A reward value of zero is used in calculating the enrollment-weighted mean for contracts that do not meet the minimum percentage of enrollees with the SRF thresholds or the minimum performance threshold specified at paragraph (f)(3)(vii) of this section.

(B) For the second year following a consolidation when calculating the HEI score for the surviving contract, the patient-level data used in calculating the HEI score will be combined from the consumed and surviving contracts and used in calculating the HEI score.

(ix) The HEI reward is calculated separately for, and then added to, the overall rating, Part C rating for MA–PDs and MA-only contracts (and cost contracts), Part D rating for MA–PDs (and cost contracts), and Part D rating for PDPs after the addition of the CAI as specified in paragraph (f)(2) of this section and application of the improvement measures as specified in paragraph (g) of this section and before the final overall and Part C and D summary ratings are calculated by rounding to the nearest half star.

(g) *Applying the improvement measure scores.* (1) CMS runs the calculations twice for the highest level rating for each contract-type (overall rating for MA–PD contracts and Part C summary rating for MA-only contracts), with the reward factor adjustment if applicable and the CAI adjustment, once including the improvement measure(s) and once without including the improvement measure(s). In deciding whether to include the improvement measures in a contract's final highest rating, CMS applies the following rules:

(i) If the highest rating for each contract-type is 4 stars or more without the use of the improvement measure(s) and with all applicable adjustments (CAI and the reward factor), a comparison of the highest rating with and without the improvement measure(s) is done. The higher rating is used for the rating.

(ii) If the highest rating is less than 4 stars without the use of the improvement measure(s) and with all applicable adjustments (CAI and the reward factor), the rating will be calculated with the improvement measure(s).

(2) The Part C summary rating for MA–PDs will include the Part C improvement measure and the Part D summary rating for MA–PDs will include the Part D improvement measure.

(3) For 2022 Star Ratings only, CMS runs the calculations twice for the highest rating for each contract-type (overall rating for MA–PD contracts and Part C summary rating for MA-only contracts) and Part C summary rating for MA–PDs with all applicable adjustments (CAI and the reward factor), once including the improvement measure(s) and once without including the improvement measure(s). In deciding whether to include the improvement measures in a contract's highest and summary rating(s), CMS applies the following rules:

(i) For MA–PDs and MA-only contracts, a comparison of the highest rating with and without the improvement measure is done. The higher rating is used for the highest rating.

(ii) For MA–PDs, a comparison of the Part C summary rating with and without the improvement measure is done. The higher rating is used for the summary rating.

(h) *Posting and display of ratings.* For all ratings at the measure, domain, summary and overall level, posting and display of the ratings is based on there being sufficient data to calculate and assign ratings. If a contract does not have sufficient data to calculate a rating, the posting and display would be the flag ''Not enough data available.'' If the measurement period is prior to one year past the contract's effective

date, the posting and display would be the flag ''Plan too new to be measured''.

(1) *Medicare Plan Finder Performance icons.* Icons are displayed on Medicare Plan Finder to note performance as provided in this paragraph (h)(1):

(i) *High-performing icon.* The high performing icon is assigned to an MA-only contract for achieving a 5-star Part C summary rating and an MA–PD contract for a 5-star overall rating.

(ii) *Low-performing icon.* (A) A contract receives a low performing icon as a result of its performance on the Part C or Part D summary ratings. The low performing icon is calculated by evaluating the Part C and Part D summary ratings for the current year and the past 2 years. If the contract had any combination of Part C or Part D summary ratings of 2.5 or lower in all 3 years of data, it is marked with a low performing icon. A contract must have a rating in either Part C or Part D for all 3 years to be considered for this icon.

(B) CMS may disable the Medicare Plan Finder online enrollment function (in Medicare Plan Finder) for Medicare health and prescription drug plans with the low performing icon; beneficiaries will be directed to contact the plan directly to enroll in the low-performing plan.

(2) *Plan preview of the Star Ratings.* CMS will have plan preview periods before each Star Ratings release during which MA organizations can preview their Star Ratings data in HPMS prior to display on the Medicare Plan Finder.

(i) *Extreme and uncontrollable circumstances.* In the event of extreme and uncontrollable circumstances that may negatively impact operational and clinical systems and contracts' abilities to conduct surveys needed for accurate performance measurement, CMS calculates the Star Ratings as specified in paragraphs (i)(2) through (10) of this section for each contract that is an affected contract during the performance period for the applicable measures. We use the start date of the incident period to determine which year of Star Ratings could be affected, regardless of whether the incident period lasts until another calendar year.

(1) *Identification of affected contracts.* A contract that meets all of the following criteria is an affected contract:

(i) The contract's service area is within an ''emergency area'' during an ''emergency period'' as defined in section 1135(g) of the Act.

(ii) The contract's service area is within a county, parish, U.S. territory or tribal area designated in a major disaster declaration under the Stafford Act and the Secretary exercised authority under section 1135 of the Act based on the same triggering event(s).

(iii) As specified in paragraphs (i)(2) through (10) of this section, a certain minimum percentage (25 percent or 60 percent) of the enrollees under the contract must reside in a Federal Emergency Management Agency (FEMA)-designated Individual Assistance area at the time of the extreme and uncontrollable circumstance.

(2) *CAHPS adjustments.* (i) A contract, even if an affected contract, must administer the CAHPS survey unless exempt under paragraph (i)(2)(ii) of this section.

(ii) An affected contract with at least 25 percent of enrollees in FEMA-designated Individual Assistance areas at the time of the extreme and uncontrollable circumstance is exempt from administering the CAHPS survey if the contract completes both of the following:

(A) Demonstrates to CMS that the required sample for the survey cannot be contacted because a substantial number of the contract's enrollees are displaced due to the FEMA-designated disaster identified in paragraph (i)(1)(iii) of this section in the prior calendar year.

(B) Requests and receives a CMS approved exemption.

(iii) An affected contract with an exemption described in paragraph (i)(2)(ii) of this section receives the contract's CAHPS measure stars and corresponding measure scores from the prior year.

(iv) For an affected contract with at least 25 percent of enrollees in FEMA-designated Individual Assistance areas at the time of the extreme and uncontrollable circumstance, the contract receives the higher of the previous year's Star Rating or the current

year's Star Rating (and corresponding measure score) for each CAHPS measure.

(v) When a contract is an affected contract with at least 25 percent of enrollees in FEMA-designated Individual Assistance areas at the time of the extreme and uncontrollable circumstance with regard to separate extreme and uncontrollable circumstances that begin in successive years, it is a multiple year-affected contract. A multiple year-affected contract receives the higher of the current year's Star Rating or what the previous year's Star Rating would have been in the absence of any adjustments that took into account the effects of the previous year's disaster for each measure (using the corresponding measure score for the Star Ratings year selected).

(3) *HOS adjustments.* (i) An affected contract must administer the HOS survey unless exempt under paragraph (i)(3)(ii) of this section.

(ii) An affected contract with at least 25 percent of enrollees in FEMA-designated Individual Assistance areas at the time of the extreme and uncontrollable circumstance is exempt from administering the HOS survey if the contract completes the following:

(A) Demonstrates to CMS that the required sample for the survey cannot be contacted because a substantial number of the contract's enrollees are displaced due to the FEMA-designated disaster identified in paragraph (i)(1)(iii) of this section during the measurement period.

(B) Requests and receives a CMS approved exemption.

(iii) Affected contracts with an exemption described in paragraph (i)(3)(ii) of this section receive the prior year's HOS and Healthcare Effectiveness Data and Information Set (HEDIS)-HOS measure stars and corresponding measure scores.

(iv) For an affected contract with at least 25 percent of enrollees in FEMA-designated Individual Assistance areas at the time of the extreme and uncontrollable circumstance, the affected contract receives the higher of the previous year's Star Rating or the current year's Star Rating (and corresponding measure score) for each HOS and HEDIS–HOS measure. The adjustment is for 3 years after the extreme and uncontrollable circumstance.

(v) When a contract is an affected contract with at least 25 percent of enrollees in FEMA-designated Individual Assistance areas at the time of the extreme and uncontrollable circumstance with regard to separate extreme and uncontrollable circumstances that begin in successive years, it is a multiple year-affected contract. A multiple year-affected contract receives the higher of the current year's Star Rating or what the previous year's Star Rating would have been in the absence of any adjustments that took into account the effects of the previous year's disaster for each measure (using the corresponding measure score for the Star Ratings year selected).

(4) *HEDIS adjustments.* (i) An affected contract must report HEDIS data unless exempted under paragraph (i)(4)(ii) of this section.

(ii) An affected contract with at least 25 percent of enrollees in FEMA-designated Individual Assistance areas at the time of the extreme and uncontrollable circumstance is exempt from reporting HEDIS data if the contract completes the following:

(A) Demonstrates an inability to obtain both administrative and medical record data that are required for reporting HEDIS measures due to a FEMA-designated disaster in the prior calendar year.

(B) Requests and receives a CMS approved exemption.

(iii) Affected contracts with an exemption described in paragraph (i)(4)(ii) of this section receive the prior year's HEDIS measure stars and corresponding measure scores.

(iv) Contracts that do not have an exemption defined in paragraph (i)(4)(ii) of this section may contact National Committee for Quality Assurance (NCQA) to request modifications to the samples for measures that require medical record review.

(v) For an affected contract with at least 25 percent of enrollees in FEMA-designated Individual Assistance areas at the time of the extreme and uncontrollable circumstance, the affected contract receives the higher of the previous year's Star Rating or the current year's Star Rating (and corresponding

measure score) for each HEDIS measure.

(vi) When a contract is an affected contract with at least 25 percent of enrollees in FEMA-designated Individual Assistance areas at the time of the extreme and uncontrollable circumstance with regard to separate extreme and uncontrollable circumstances that begin in successive years, it is a multiple year-affected contract. A multiple year-affected contract receives the higher of the current year's Star Rating or what the previous year's Star Rating would have been in the absence of any adjustments that took into account the effects of the previous year's disaster for each measure (using the corresponding measure score for the Star Ratings year selected).

(5) *New measure adjustments.* For affected contracts with at least 25 percent of enrollees in a FEMA-designated Individual Assistance area at the time of the extreme and uncontrollable circumstance, CMS holds the affected contract harmless by using the higher of the contract's summary or overall rating or both with and without including all of the applicable new measures.

(6) *Other Star Ratings measure adjustments.* (i) For all other measures except those measures identified in this paragraph (i)(6)(ii) of this section, affected contracts with at least 25 percent of enrollees in a FEMA-designated Individual Assistance area at the time of the extreme and uncontrollable circumstance receive the higher of the previous or current year's measure Star Rating (and corresponding measure score).

(ii) CMS does not adjust the scores or Star Ratings for the following measures, unless the exemption in paragraph (i)(6)(iii) of this section applies.

(A) Part C Call Center—Foreign Language Interpreter and TTY Availability.

(B) Part D Call Center—Foreign Language Interpreter and TTY Availability.

(iii) CMS adjusts the measures listed in paragraph (i)(6)(ii) of this section using the adjustments listed in paragraph (i)(6)(i) of this section for contracts affected by extreme and uncontrollable circumstances where there are continuing communications issues related to loss of electricity and damage to infrastructure during the call center study.

(iv) When a contract is an affected contract with at least 25 percent of enrollees in FEMA-designated Individual Assistance areas at the time of the extreme and uncontrollable circumstance with regard to separate extreme and uncontrollable circumstances that begin in successive years, it is a multiple year-affected contract. A multiple year-affected contract receives the higher of the current year's Star Rating or what the previous year's Star Rating would have been in the absence of any adjustments that took into account the effects of the previous year's disaster for each measure (using the corresponding measure score for the Star Ratings year selected).

(7) *Exclusion from improvement measures.* Any measure that reverts back to the data underlying the previous year's Star Rating due to the adjustments made in paragraph (i) of this section is excluded from both the count of measures and the applicable improvement measures for the current and next year's Star Ratings for the affected contract. Contracts affected by extreme and uncontrollable circumstances do not have the option of reverting to the prior year's improvement rating.

(8) *Missing data.* For an affected contract that has missing data in the current or previous year, the final measure rating comes from the current year unless any of the exemptions described in paragraphs (i)(2)(ii), (i)(3)(ii), and (i)(4)(ii) of this section apply.Missing data includes data where there is a data integrity issue as defined at § 422.164(g)(1).

(9) *Cut points for non-CAHPS measures.* (i) Through the 2025 Star Ratings, CMS excludes the numeric values for affected contracts with 60 percent or more of their enrollees in the FEMA-designated Individual Assistance area at the time of the extreme and uncontrollable circumstance from the clustering algorithms described in paragraph (a)(2) of this section.

(ii) The cut points calculated as described in paragraph (i)(9)(i) of this section are used to assess all affected contracts' measure Star Ratings.

(10) *Reward Factor.* (i) Through the 2025 Star Ratings, CMS excludes the numeric values for affected contracts with 60 percent or more of their enrollees in the FEMA-designated Individual Assistance area at the time of the extreme and uncontrollable circumstance from the determination of the performance summary and variance thresholds for the reward factor described in paragraph (f)(1) of this section.

(ii) All affected contracts are eligible for the Reward Factor based on the calculations described in paragraph (i)(10)(i) of this section.

(11) *Special rules for the 2022 Star Ratings only.* For the 2022 Star Ratings only, CMS will not apply the provisions in paragraph (i)(9) or (10) of this section and CMS will not exclude the numeric values for affected contracts with 60 percent or more of their enrollees in the FEMA-designated Individual Assistance area at the time of the extreme and uncontrollable circumstance from the clustering algorithms or from the determination of the performance summary and variance thresholds for the Reward Factor.

(12) *Special rules for the 2023 Star Ratings only.* For the 2023 Star Ratings only, for measures derived from the Health Outcomes Survey only, CMS does not apply the provisions in paragraph (i)(9) or (10) of this section and CMS does not exclude the numeric values for affected contracts with 60 percent or more of their enrollees in the FEMA-designated Individual Assistance area at the time of the extreme and uncontrollable circumstance from the clustering algorithms or from the determination of the performance summary and variance thresholds for the Reward Factor.

(j) *Special rules for 2021 and 2022 Star Ratings only.* (1) For the 2021 Star Ratings:

(i) The measures calculated based on HEDIS data are calculated based on data from the 2018 performance period.

(ii) The measures calculated based on CAHPS data are calculated based on survey data collected from March through May 2019.

(iii) The measure-level change score calculation described at § 422.164(f)(4)(i) is not applied for HEDIS and CAHPS measures and the measure-level change score used for the 2020 Star Ratings is applied in its place for all HEDIS and CAHPS-based measures.

(iv) The provisions of § 422.164(g)(1) and (2) are not applied for the failure to submit HEDIS and CAHPS-based measures.

(v) [Reserved]

(2) [Reserved]

[83 FR 16725, Apr. 16, 2018, as amended at 84 FR 15830, Apr. 16, 2019; 85 FR 19290, Apr. 6, 2020; 85 FR 33907, June 2, 2020; 85 FR 54872, Sept. 2, 2020; 86 FR 6098, Jan. 19, 2021; 87 FR 27895, May 9, 2022; 88 FR 22332, Apr. 12, 2023; 89 FR 30821, Apr. 23, 2024]

Subpart E—Relationships With Providers

SOURCE: 63 FR 35085, June 26, 1998, unless otherwise noted.

§ 422.200 Basis and scope.

This subpart is based on sections 1852(a)(1), (a)(2), (b)(2), (c)(2)(D), (j), and (k) of the Act; section 1859(b)(2)(A) of the Act; and the general authority under 1856(b) of the Act requiring the establishment of standards. It sets forth the requirements and standards for the MA organization's relationships with providers including physicians, other health care professionals, institutional providers and suppliers, under contracts or arrangements or deemed contracts under MA private fee-for-service plans. This subpart also contains some requirements that apply to noncontracting providers.

§ 422.202 Participation procedures.

(a) *Notice and appeal rights.* An MA organization that operates a coordinated care plan or network MSA plan must provide for the participation of individual physicians, and the management and members of groups of physicians, through reasonable procedures that include the following:

(1) Written notice of rules of participation including terms of payment, credentialing, and other rules directly related to participation decisions.

(2) Written notice of material changes in participation rules before the changes are put into effect.

(3) Written notice of participation decisions that are adverse to physicians.

(4) A process for appealing adverse participation procedures, including the right of physicians to present information and their views on the decision. In the case of termination or suspension of a provider contract by the MA organization, this process must conform to the rules in § 422.202(d).

(b) *Consultation.* The MA organization must establish a formal mechanism to consult with the physicians who have agreed to provide services under the MA plan offered by the organization, regarding the organization's medical policy, quality improvement programs and medical management procedures and ensure that the following standards are met:

(1) Practice guidelines and utilization management guidelines—

(i) Are based on current evidence in widely used treatment guidelines or clinical literature;

(ii) Consider the needs of the enrolled population;

(iii) Are developed in consultation with contracting physicians; and

(iv) Are reviewed and updated periodically.

(2) The guidelines are communicated to providers and, as appropriate, to enrollees.

(3) Decisions with respect to utilization management, enrollee education, coverage of services, and other areas in which the guidelines apply are consistent with the guidelines.

(c) *Subcontracted groups.* An MA organization that operates an MA plan through subcontracted physician groups must provide that the participation procedures in this section apply equally to physicians within those subcontracted groups.

(d) *Suspension or termination of contract.* An MA organization that operates a coordinated care plan or network MSA plan providing benefits through contracting providers must meet the following requirements:

(1) *Notice to physician.* An MA organization that suspends or terminates an agreement under which the physician provides services to MA plan enrollees must give the affected individual written notice of the following:

(i) The reasons for the action, including, if relevant, the standards and profiling data used to evaluate the physician and the numbers and mix of physicians needed by the MA organization.

(ii) The affected physician's right to appeal the action and the process and timing for requesting a hearing.

(2) *Composition of hearing panel.* The MA organization must ensure that the majority of the hearing panel members are peers of the affected physician.

(3) *Notice to licensing or disciplinary bodies.* An MA organization that suspends or terminates a contract with a physician because of deficiencies in the quality of care must give written notice of that action to licensing or disciplinary bodies or to other appropriate authorities.

(4) *Timeframes.* An MA organization and a contracting provider must provide at least 60 days written notice to each other before terminating the contract without cause.

[64 FR 7981, Feb. 17, 1999, as amended at 65 FR 40324, June 29, 2000; 68 FR 50857, Aug. 22, 2003; 70 FR 4724, Jan. 28, 2005; 88 FR 22334, Apr. 12, 2023]

§ 422.204 Provider selection and credentialing.

(a) *General rule.* An MA organization must have written policies and procedures for the selection and evaluation of providers. These policies must conform with the credential and recredentialing requirements set forth in paragraph (b) of this section and with the antidiscrimination provisions set forth in § 422.205.

(b) *Basic requirements.* An MA organization must follow a documented process with respect to providers and suppliers who have signed contracts or participation agreements that—

(1) For providers (other than physicians and other health care professionals) requires determination, and redetermination at specified intervals, that each provider is—

(i) Licensed to operate in the State, and in compliance with any other applicable State or Federal requirements; and

(ii) Reviewed and approved by an accrediting body, or meets the standards established by the organization itself;

(2) For physicians and other health care professionals, including members of physician groups, covers—

(i) Initial credentialing that includes written application, verification of licensure or certification from primary sources, disciplinary status, eligibility for payment under Medicare, and site visits as appropriate. The application must be signed and dated and include an attestation by the applicant of the correctness and completeness of the application and other information submitted in support of the application;

(ii) Recredentialing at least every 3 years that updates information obtained during initial credentialing, considers performance indicators such as those collected through quality improvement programs, utilization management systems, handling of grievances and appeals, enrollee satisfaction surveys, and other plan activities, and that includes an attestation of the correctness and completeness of the new information; and

(iii) A process for consulting with contracting health care professionals with respect to criteria for credentialing and recredentialing.

(3) Specifies that basic benefits must be provided through, or payments must be made to, providers and suppliers that meet applicable requirements of title XVIII and part A of title XI of the Act. In the case of providers meeting the definition of ''provider of services'' in section 1861(u) of the Act, basic benefits may only be provided through these providers if they have a provider agreement with CMS permitting them to provide services under original Medicare.

(4) Ensures compliance with the requirements at §422.752(a)(8) that prohibit employment or contracts with individuals (or with an entity that employs or contracts with such an individual) excluded from participation under Medicare and with the requirements at §422.220 regarding physicians and practitioners who opt out of Medicare.

(c) An MA organization must follow a documented process that ensures compliance with the preclusion list provisions in §422.222.

[65 FR 40324, June 29, 2000, as amended at 66 FR 47413, Sept. 12, 2001; 70 FR 4724, Jan. 28, 2005; 81 FR 80556, Nov. 15, 2016; 83 FR 16731, Apr. 16, 2018]

§422.205 Provider antidiscrimination rules.

(a) *General rule.* Consistent with the requirements of this section, the policies and procedures concerning provider selection and credentialing established under §422.204, and with the requirement under §422.100(c) that all Medicare-covered services be available to MA plan enrollees, an MA organization may select the practitioners that participate in its plan provider networks. In selecting these practitioners, an MA organization may not discriminate, in terms of participation, reimbursement, or indemnification, against any health care professional who is acting within the scope of his or her license or certification under State law, solely on the basis of the license or certification. If an MA organization declines to include a given provider or group of providers in its network, it must furnish written notice to the effected provider(s) of the reason for the decision.

(b) *Construction.* The prohibition in paragraph (a)(1) of this section does not preclude any of the following by the MA organization:

(1) Refusal to grant participation to health care professionals in excess of the number necessary to meet the needs of the plan's enrollees (except for MA private-fee-for-service plans, which may not refuse to contract on this basis).

(2) Use of different reimbursement amounts for different specialties or for different practitioners in the same specialty.

(3) Implementation of measures designed to maintain quality and control costs consistent with its responsibilities.

[65 FR 40324, June 29, 2000]

§422.206 Interference with health care professionals' advice to enrollees prohibited.

(a) *General rule.* (1) An MA organization may not prohibit or otherwise restrict a health care professional, acting within the lawful scope of practice, from advising, or advocating on behalf of, an individual who is a patient and enrolled under an MA plan about—

(i) The patient's health status, medical care, or treatment options (including any alternative treatments that may be self-administered), including the provision of sufficient information to the individual to provide an opportunity to decide among all relevant treatment options;

(ii) The risks, benefits, and consequences of treatment or non-treatment; or

(iii) The opportunity for the individual to refuse treatment and to express preferences about future treatment decisions.

(2) Health care professionals must provide information regarding treatment options in a culturally-competent manner, including the option of no treatment. Health care professionals must ensure that individuals with disabilities have effective communications with participants throughout the health system in making decisions regarding treatment options.

(b) *Conscience protection.* The general rule in paragraph (a) of this section does not require the MA plan to cover, furnish, or pay for a particular counseling or referral service if the MA organization that offers the plan—

(1) Objects to the provision of that service on moral or religious grounds; and

(2) Through appropriate written means, makes available information on these policies as follows:

(i) To CMS, with its application for a Medicare contract, within 10 days of submitting its bid proposal or, for policy changes, in accordance with all applicable requirements under subpart V of this part.

(ii) To prospective enrollees, before or during enrollment.

(iii) With respect to current enrollees, the organization is eligible for the exception provided in paragraph (b)(1) of this section if it provides notice of such change within 90 days after adopting the policy at issue; however, under § 422.111(d), notice of such a change must be given in advance.

(c) *Construction.* Nothing in paragraph (b) of this section may be construed to affect disclosure requirements under State law or under the Employee Retirement Income Security Act of 1974.

(d) *Sanctions.* An MA organization that violates the prohibition of paragraph (a) of this section or the conditions in paragraph (b) of this section is subject to intermediate sanctions under subpart O of this part.

[63 FR 35085, June 26, 1998, as amended at 65 FR 40325, June 29, 2000; 70 FR 52026, Sept. 1, 2005; 83 FR 16731, Apr. 16, 2018]

§ 422.208 Physician incentive plans: requirements and limitations.

(a) *Definitions.* In this subpart, the following definitions apply:

Bonus means a payment made to a physician or physician group beyond any salary, fee-for-service payments, capitation, or returned withhold.

Capitation means a set dollar payment per patient per unit of time (usually per month) paid to a physician or physician group to cover a specified set of services and administrative costs without regard to the actual number of services provided. The services covered may include the physician's own services, referral services, or all medical services.

Combined Stop-Loss Insurance Deductible Table (Table PIP–1) means the table described and developed using the methodology in paragraph (f)(2)(iv) of this section.

Global capitation means a specific type of ''capitation'' that includes both professional and institutional services. Services covered by global capitation may also include prescription drug benefits and supplemental benefits as well as basic benefits (as those terms are defined in § 422.100(c)). For purposes of Tables PIP–1 and PIP–2 global capitation includes all Parts A and B services except hospice.

Net benefit premium means the total amount of stop-loss claims (90 percent of claims above the deductible) for that panel size divided by the panel size. It is determined for each panel size and shown in Table PIP–1, described in paragraph (f)(2)(iv) of this section. It is then used in Table PIP–2, described in paragraph (f)(2)(vi) of this section, to identify all separate institutional and separate professional deductible combinations that meet the stop-loss requirements for multi-specialty physician groups participating in PIPs.

Non-Risk Patient Equivalents (NPE) means the estimate of annual claims for physician rendered services for non-risk patients served by the physician or physician group divided by what the PMPY capitation for physician rendered services would be if the beneficiary were part of the risk arrangement. Both Medicare and non-Medicare patients are included in this calculation.

Physician group means a partnership, association, corporation, individual practice association, or other group of physicians that distributes income from the practice among members. An individual practice association is defined as a physician group for this section only if it is composed of individual physicians and has no subcontracts with physician groups.

Physician incentive plan means any compensation arrangement to pay a physician or physician group that may directly or indirectly have the effect of reducing or limiting the services provided to any plan enrollee.

Potential payments means the maximum payments possible to physicians or physician groups including payments for services they furnish directly, and additional payments based on use and costs of referral services, such as withholds, bonuses, capitation, or any other compensation to the physician or physician group. Bonuses and other compensation that are not based on use of referrals, such as quality of care furnished, patient satisfaction or committee participation, are not considered payments in the determination of substantial financial risk.

Referral services means any specialty, inpatient, outpatient, or laboratory services that a physician or physician group orders or arranges, but does not furnish directly.

Risk threshold means the maximum risk, if the risk is based on referral services, to which a physician or physician group may be exposed under a physician incentive plan without being at substantial financial risk. This is set at 25 percent risk.

Separate Stop-Loss Insurance Deductible Table (Table PIP–2) means the table described and developed using the methodology in paragraph (f)(2)(vi) of this section.

Substantial financial risk, for purposes of this section, means risk for referral services that exceeds the risk threshold.

Withhold means a percentage of payments or set dollar amounts deducted from a physician's service fee, capitation, or salary payment, and that may or may not be returned to the physician, depending on specific predetermined factors.

(b) *Applicability*. The requirements in this section apply to an MA organization and any of its subcontracting arrangements that utilize a physician incentive plan in their payment arrangements with individual physicians or physician groups. Subcontracting arrangements may include an intermediate entity, which includes but is not limited to, an individual practice association that contracts with one or more physician groups or any other organized group such as those specified in § 422.4.

(c) *Basic requirements*. Any physician incentive plan operated by an MA organization must meet the following requirements:

(1) The MA organization makes no specific payment, directly or indirectly, to a physician or physician group as an inducement to reduce or limit medically necessary services furnished to any particular enrollee. Indirect payments may include offerings of monetary value (such as stock options or waivers of debt) measured in the present or future.

(2) If the physician incentive plan places a physician or physician group at substantial financial risk (as determined under paragraph (d) of this section) for services that the physician or physician group does not furnish itself, the MA organization must assure that all physicians and physician groups at substantial financial risk have either aggregate or per-patient stop-loss protection in accordance with paragraph (f) of this section.

(3) For all physician incentive plans, the MA organization provides to CMS the information specified in § 422.210.

(d) *Determination of substantial financial risk*—(1) *Basis*. Substantial financial risk occurs when risk is based on the use or costs of referral services,

and that risk exceeds the risk threshold. Payments based on other factors, such as quality of care furnished, are not considered in this determination.

(2) *Risk threshold.* The risk threshold is 25 percent of potential payments.

(3) *Arrangements that cause substantial financial risk.* The following incentive arrangements cause substantial financial risk within the meaning of this section, if the physician's or physician group's patient panel size is not greater than 25,000 patients, as shown in the table at paragraph (f)(2)(iii) of this section:

(i) Withholds greater than 25 percent of potential payments.

(ii) Withholds less than 25 percent of potential payments if the physician or physician group is potentially liable for amounts exceeding 25 percent of potential payments.

(iii) Bonuses that are greater than 33 percent of potential payments minus the bonus.

(iv) Withholds plus bonuses if the withholds plus bonuses equal more than 25 percent of potential payments. The threshold bonus percentage for a particular withhold percentage may be calculated using the formula—Withhold % = −0.75 (Bonus %) + 25%.

(v) Capitation arrangements, if—

(A) The difference between the maximum potential payments and the minimum potential payments is more than 25 percent of the maximum potential payments;

(B) The maximum and minimum potential payments are not clearly explained in the contract with the physician or physician group.

(vi) Any other incentive arrangements that have the potential to hold a physician or physician group liable for more than 25 percent of potential payments.

(e) *Prohibition for private MA fee-for-service plans.* An MA fee-for-service plan may not operate a physician incentive plan.

(f) *Stop-loss protection requirements*—(1) *Basic rule.* The MA organization must assure that all physicians and physician groups at substantial financial risk have either aggregate or per-patient stop-loss protection in accordance with the following requirements:

(2) *Specific requirements.* (i) Aggregate stop-loss protection must cover 90 percent of the costs of referral services that exceed 25 percent of potential payments.

(ii) For per-patient stop-loss protection if the stop-loss protection provided is on a per-patient basis, the stop-loss limit (deductible) per patient must be determined based on the size of the patient panel and may be a combined policy or consist of separate policies for professional services and institutional services. In determining patient panel size, the patients may be pooled in accordance with paragraph (g) of this section.

(iii)(A) Stop-loss protection must cover at least 90 percent of costs of referral services above the deductible or an actuarial equivalent amount of the costs of referral services that exceed the per-patient deductible limit. The single combined deductible for the required stop-loss protection for the various panel sizes for contract years beginning on or after January 1, 2019 is determined using the Combined Stop-Loss Insurance Deductible Table (Table PIP–1). For panel sizes not shown on Table PIP–1 and for values not shown on Table PIP–2, linear interpolation (between the table values) may be used to identify the maximum deductible(s) for the required stop-loss coverage. Tables PIP–1 and PIP–2 apply to only multi-specialty physician groups in global capitation arrangements with per-patient stop-loss insurance. For all other physician incentive plan arrangements, the MA organization must assure that the physician or physician group entering into the physician incentive plan arrangement is covered by actuarially equivalent stop-loss protection that meets the requirements of this regulation.

(B) Using Table PIP–1, the deductible is identified for the panel size that is the number of risk patients plus non-risk patient equivalents. Non-risk patient equivalents may add a maximum of $100,000 to the deductible. The deductible for the stop-loss insurance required to be provided for the physician or physician group is then based on the lesser of:

(*1*) The deductible for the risk patient panel size plus $100,000; and

(*2*) The deductible for the panel size that is the total of the number of risk patients plus non-risk patient equivalents.

(iv) Table 1 is developed and updated by CMS using the methodology in this paragraph. CMS publishes Table PIP–1 in guidance (such as an attachment to the Rate Announcement issued under section 1853(b) of the Act) in advance of the bid due date for the upcoming year if CMS determines that an update would be prudent for that year.

(A) The stop-loss tables are calculated using claims data for a statistically valid sample of beneficiaries enrolled in Fee-for-Service Medicare Parts A and B from the most available recent year. The sample includes only claims for beneficiaries eligible for both Part A and Part B for whom Medicare is the primary insurer and excludes hospice claims. The estimate of medical group income is derived from payments for all Part A and Part B services (excluding hospice) in the sampled claims data (to emulate a multi-specialty practice). The central limit theorem is used to obtain the distribution of claim means for a multi-specialty group of any given panel size. The distribution of claim means is used to obtain, with 98 percent confidence, the point at which a multi-specialty group of a given panel size would, through referral services, lose no more than 25 percent of potential payments. This point is the deductible in Table PIP–1 for the given panel size.

(B) The 'net benefit premium' (NBP) column in Table PIP–1 is not used for computation of combined insurance but is used to determine the separate deductibles for professional services and institutional services in the *Separate Stop-Loss Insurance Deductible Table* (Table PIP–2).

(C) The NBP is computed by dividing the total amount of stop loss claims (90 percent of claims above the deductible) for that panel size by the panel size.

(v)(A) Insurance using separate deductibles for professional and institutional claims is permissible so long as the separate deductibles for institutional services and professional services are determined using Table 2 as described in paragraph (f)(2)(vi)(B) of this section. Table PIP–2 is developed and updated by CMS using the methodology in paragraph (f)(2)(vi). CMS publishes Table PIP–2 in guidance (such as an attachment to the Rate Announcement issued under section 1853(b) of the Act) in advance of the bid due date for the upcoming year if CMS determines that an update would be prudent for that year.

(B) The maximum deductibles for each category of services (institutional and professional claims) are identified by using the net benefit premium (NBP) determined in Table PIP–1 as the starting point in Table PIP–2. Any combination of institutional and professional attachment points for which the NBP in Table PIP–2 is greater than the NBP determined in Table PIP–1 is permissible. Interpolation may be used to find the NBP values in Table PIP–2 that are closest to the NBP identified in Table PIP–1.

(vi) Table PIP–2 is developed using a methodology similar to that for Table PIP–1.

(A) Claims data are obtained as described in paragraph (f)(2)(iv)(A).

(B) Professional and institutional claims are defined and categorized based on industry standards and based on payments for Part A and Part B services.

(C) The central limit theorem is used to obtain the distribution of claim means and deductibles are obtained at the 98 percent confidence level.

(3) *Special insurance.* If there is a different type of stop-loss policy obtained by the physician group, it must be actuarially equivalent to the coverage shown in Tables PIP–1 and PIP–2. Actuarially equivalent deductibles are acceptable if the insurance is actuarially certified by an attesting actuary who fulfills all of the following requirements:

(i) Develops the deductibles to be actuarially equivalent to those coverages in the Tables.

(ii) Makes the computations in accordance with generally accepted actuarial principles and practices.

(iii) Meets the qualification standards established by the American Academy of Actuaries and follow the practice standards established by the Actuarial Standards Board.

(g) *Pooling of patients.* Any entity that meets the pooling conditions of this section may pool commercial, Medicare, and Medicaid enrollees or the enrollees of several MA organizations with which a physician or physician group has contracts. The conditions for pooling are as follows:

(1) It is otherwise consistent with the relevant contracts governing the compensation arrangements for the physician or physician group.

(2) The physician or physician group is at risk for referral services with respect to each of the categories of patients being pooled.

(3) The terms of the compensation arrangements permit the physician or physician group to spread the risk across the categories of patients being pooled.

(4) The distribution of payments to physicians from the risk pool is not calculated separately by patient category.

(5) The terms of the risk borne by the physician or physician group are comparable for all categories of patients being pooled.

(h) *Sanctions.* An MA organization that fails to comply with the requirements of this section is subject to intermediate sanctions under subpart O of this part.

[63 FR 35085, June 26, 1998, as amended at 65 FR 40325, June 29, 2000; 70 FR 4724, Jan. 28, 2005; 70 FR 52026, Sept. 1, 2005; 83 FR 16731, Apr. 16, 2018; 83 FR 27914, June 15, 2018]

§ 422.210 Assurances to CMS.

(a) Assurances to CMS. Each organization will provide assurance satisfactory to the Secretary that the requirements of § 422.208 are met.

(b) Disclosure to Medicare Beneficiaries. Each MA organization must provide the following information to any Medicare beneficiary who requests it:

(1) Whether the MA organization uses a physician incentive plan that affects the use of referral services.

(2) The type of incentive arrangement.

(3) Whether stop-loss protection is provided.

[70 FR 52026, Sept. 1, 2005]

§ 422.212 Limitations on provider indemnification.

An MA organization may not contract or otherwise provide, directly or indirectly, for any of the following individuals, organizations, or entities to indemnify the organization against any civil liability for damage caused to an enrollee as a result of the MA organization's denial of medically necessary care:

(a) A physician or health care professional.

(b) Provider of services.

(c) Other entity providing health care services.

(d) Group of such professionals, providers, or entities.

§ 422.214 Special rules for services furnished by noncontract providers.

(a) *Services furnished by non-section 1861(u) providers.* (1) Any provider (other than a provider of services as defined in section 1861(u) of the Act) that does not have in effect a contract establishing payment amounts for services furnished to a beneficiary enrolled in an MA coordinated care plan, an MSA plan, or an MA private fee-for-service plan must accept, as payment in full, the amounts that the provider could collect if the beneficiary were enrolled in original Medicare.

(2) Any statutory provisions (including penalty provisions) that apply to payment for services furnished to a beneficiary not enrolled in an MA plan also apply to the payment described in paragraph (a)(1) of this section.

(b) Services furnished by section 1861(u) providers of service. Any provider of services as defined in section 1861(u) of the Act that does not have in effect a contract establishing payment amounts for services furnished to a beneficiary enrolled in an MA coordinated care plan, an MSA plan, or an MA private fee-for-service plan must accept, as payment in full, the amounts (less any payments under §§ 412.105(g) and 413.76 of this chapter) that it could collect if the beneficiary were enrolled in original Medicare. (Section 412.105(g) concerns indirect

medical education payment to hospitals for managed care enrollees. Section 413.76 concerns calculating payment for direct medical education costs.)

(c) *Deemed request for Medicare payment rate.* A noncontract section 1861(u) of the Act provider of services that furnishes services to MA enrollees and submits the same information that it would submit for payment under Original Medicare is deemed to be seeking to be paid the amount it would be paid under Original Medicare unless the provider expressly notifies the MA organization in writing that it is billing an amount less than such amount.

(d) *Regional PPO payments in non-network areas.* An MA Regional PPO must pay non-contract providers the Original Medicare payment rate in those portions of its service area where it is providing access to services by non-network means under § 422.111(b)(3)(ii) of this part.

[63 FR 35085, June 26, 1998, as amended at 65 FR 40325, June 29, 2000; 70 FR 4724, Jan. 28, 2005; 70 FR 47490, Aug. 12, 2005; 76 FR 21564, Apr. 15, 2011]

§ 422.216 Special rules for MA private fee-for-service plans.

(a) *Payment to providers*—(1) *Payment rate.* (i) The MA organization must establish payment rates for plan covered items and services that apply to deemed providers. The MA organization may vary payment rates for providers in accordance with § 422.4(a)(3).

(ii) Providers must be reimbursed on a fee-for-service basis.

(iii) The MA organization must make information on its payment rates available to providers that furnish services that may be covered under the MA private fee-for-service plan.

(2) *Noncontract providers.* The organization pays for services of noncontract providers in accordance with § 422.100(b)(2).

(3) *Services furnished by providers of service.* Any provider of services as defined in section 1861(u) of the Act that does not have in effect a contract establishing payment amounts for services furnished to a beneficiary enrolled in an MA private fee-for-service plan must receive, and accept as payment in full, at least the amount (less any payments under §§ 412.105(g) and 413.76 of this chapter) that it could collect if the beneficiary were enrolled in original Medicare.

(b) *Charges to enrollees*—(1) *Contract providers* (i) Contract providers and ''deemed'' contract providers may charge enrollees no more than the cost-sharing and, subject to the limit in paragraph (b)(1)(ii) of this section, balance billing amounts that are permitted under the plan, and these amounts must be the same for ''deemed'' contract providers as for those that have signed contracts in effect, unless access requirements with respect to a particular category of health care providers are met solely through § 422.114(a)(2)(ii) and the MA organization imposes higher beneficiary copayments as permitted under § 422.114(c).

(ii) The organization may permit balance billing no greater than 15 percent of the payment rate established under paragraph (a)(1) of this section.

(iii) The MA organization must specify the amount of cost-sharing and balance billing in its contracts with providers and these amounts must be the same for ''deemed'' contract providers as for those that have signed contracts in effect, unless access requirements with respect to a particular category of health care providers are met solely through § 422.114(a)(2)(ii) and the MA organization imposes higher beneficiary copayments as permitted under § 422.114(c).

(iv) The MA organization is subject to intermediate sanctions under § 422.752(a)(7), under the rules in subpart O of this part, if it fails to enforce the limit specified in paragraph (b)(1)(i) of this section.

(2) *Noncontract providers.* A noncontract provider may not collect from an enrollee more than the cost-sharing established by the MA private fee-for-service plan as specified in § 422.256(b)(3), unless the provider has opted out of Medicare as described in part 405, subpart D of this chapter.

(c) *Enforcement of limit*—(1) *Contract providers.* An MA organization that offers an MA fee-for-service plan must enforce the limit specified in paragraph (b)(1) of this section.

(2) *Noncontract providers.* An MA organization that offers an MA private fee-for-service plan must monitor the amount collected by noncontract providers to ensure that those amounts do not exceed the amounts permitted to be collected under paragraph (b)(2) of this section, unless the provider has opted out of Medicare as described in part 405, subpart D of this chapter. The MA organization must develop and document violations specified in instructions and must forward documented cases to CMS.

(d) *Information on enrollee liability*—(1) *General information.* An MA organization that offers an MA private fee-for-service plan must provide to plan enrollees, an appropriate explanation of benefits consistent with the requirements of §422.111(b)(12).

(2) *Advance notice for hospital services.* In its terms and conditions of payment to hospitals, the MA organization must require the hospital, if it imposes balance billing, to provide to the enrollee, before furnishing any services for which balance billing could amount to not less than $500—

(i) Notice that balance billing is permitted for those services;

(ii) A good faith estimate of the likely amount of balance billing, based on the enrollees presenting condition; and

(iii) The amount of any deductible, coinsurance, and copayment that may be due in addition to the balance billing amount.

(e) *Coverage determinations.* The MA organization must make coverage determinations in accordance with subpart M of this part.

(f) *Rules describing deemed contract providers.* Any provider furnishing health services, except for emergency services furnished in a hospital pursuant to §489.24 of this chapter, to an enrollee in an MA private fee-for-service plan, and who has not previously entered into a contract or agreement to furnish services under the plan, is treated as having a contract in effect and is subject to the limitations of this section that apply to contract providers if the following conditions are met:

(1) The services are covered under the plan and are furnished—

(i) To an enrollee of an MA fee-for-service plan; and

(ii) Provided by a provider including a provider of services (as defined in section 1861(u) of the Act) that does not have in effect a signed contract with the MA organization.

(2) Before furnishing the services, the provider—

(i) Was informed of the individual's enrollment in the plan; and

(ii) Was informed (or given a reasonable opportunity to obtain information) about the terms and conditions of payment under the plan, including the information described in §422.202(a)(1).

(3) The information was provided in a manner that was reasonably designed to effect informed agreement and met the requirements of paragraphs (g) and (h) of this section.

(g) *Enrollment information.* Enrollment information was provided by one of the following methods or a similar method:

(1) Presentation of an enrollment card or other document attesting to enrollment.

(2) Notice of enrollment from CMS, a Medicare intermediary or carrier, or the MA organization itself.

(h) *Information on payment terms and conditions.* Information on payment terms and conditions was made available through either of the following methods:

(1) The MA organization used postal service, electronic mail, FAX, or telephone to communicate the information to one of the following:

(i) The provider.

(ii) The employer or billing agent of the provider.

(iii) A partnership of which the provider is a member.

(iv) Any party to which the provider makes assignment or reassigns benefits.

(2) The MA organization has in effect a procedure under which—

(i) Any provider furnishing services to an enrollee in an MA private fee-for-service plan, and who has not previously entered into a contract or agreement to furnish services under the plan, can receive instructions on how to request the payment information;

(ii) The organization responds to the request before the entity furnishes the service; and

(iii) The information the organization provides includes the following:

(A) Billing procedures.

(B) The amount the organization will pay towards the service.

(C) The amount the provider is permitted to collect from the enrollee.

(D) The information described in § 422.202(a)(1).

(3) Announcements in newspapers, journals, or magazines or on radio or television are not considered communication of the terms and conditions of payment.

(i) *Provider credential requirements.* Contracts with providers must provide that, in order to be paid to provide services to plan enrollees, providers must meet the requirements specified in §§ 422.204(b)(1)(i) and (b)(3).

[63 FR 35085, June 26, 1998, as amended at 65 FR 40325, June 29, 2000; 70 FR 52056, Sept. 1, 2005; 70 FR 47490, Aug. 12, 2005; 70 FR 76197, Dec. 23, 2005; 73 FR 54250, Sept. 18, 2008; 77 FR 22167, Apr. 12, 2012]

§ 422.220 Exclusion of payment for basic benefits furnished under a private contract.

(a) Unless otherwise authorized in paragraph (b) or (c) of this section, an MA organization may not pay, directly or indirectly, on any basis, for basic benefits furnished to a Medicare enrollee by a physician (as defined in paragraphs (1), (2), (3), and (4) of section 1861(r) of the Act) or other practitioner (as defined in section 1842(b)(18)(C) of the Act) who has filed with the Medicare contractor an affidavit promising to furnish Medicare-covered services to Medicare beneficiaries only through private contracts under section 1802(b) of the Act with the beneficiaries.

(b) An MA organization must pay for emergency or urgently needed services furnished by a physician or practitioner described in paragraph (a) of this section who has not signed a private contract with the beneficiary.

(c) An MA organization may make payment to a physician or practitioner described in paragraph (a) of this section for services that are not basic benefits but are provided to a beneficiary as a supplemental benefit consistent with § 422.102.

[86 FR 6098, Jan. 19, 2021]

§ 422.222 Preclusion list for contracted and non-contracted individuals and entities.

(a)(1)(i) Except as provided in paragraph (a)(1)(ii) of this section, an MA organization must not make payment for a health care item, service, or drug that is furnished, ordered, or prescribed by an individual or entity that is included on the preclusion list, defined in § 422.2.

(ii) With respect to MA providers that have been added to an updated preclusion list but are not currently excluded by the OIG, the MA organization must do all of the following:

(A) No later than 30 days after the posting of this updated preclusion list, must provide an advance written notice to any beneficiary who has received or been prescribed an MA service, item, or drug from or by the individual or entity added to the preclusion list in this update.

(B)(*1*) Subject to paragraph (a)(1)(ii)(B)(*2*) of this section, must ensure that reasonable efforts are made to notify the individual or entity described in paragraph (a)(1)(ii) of this section of a beneficiary who was sent a notice under paragraph (a)(1)(ii)(A) of this section.

(*2*) Paragraph (a)(1)(ii)(B)(*1*) of this section applies only upon receipt of a claim from a precluded provider in Medicare Part C when—

(*i*) The MA organization has enough information on file to either copy the provider on the notification previously sent to the beneficiary or send a new notice informing the provider that they may not see plan beneficiaries due to their preclusion status; and

(*ii*) The claim is received after the claim denial or reject date in the preclusion file.

(C) Must not deny payment for a service, item, or drug furnished, ordered, or prescribed by the newly added individual or entity, solely on the ground that they have been included in the updated preclusion list, in the 60-day period after the date it sent the notice described in paragraph (a)(1)(ii)(A) of this section.

(2)(i) CMS sends written notice to the individual or entity via letter of their inclusion on the preclusion list. The notice must contain the reason for the inclusion and inform the individual or entity of their appeal rights. An individual or entity may appeal their inclusion on the preclusion list, defined in § 422.2, in accordance with part 498 of this chapter.

(ii) If the individual's or entity's inclusion on the preclusion list is based on a contemporaneous Medicare revocation under § 424.535 of this chapter:

(A) The notice described in paragraph (a)(2)(i) of this section must also include notice of the revocation, the reason(s) for the revocation, and a description of the individual's or entity's appeal rights concerning the revocation.

(B) The appeals of the individual's or entity's inclusion on the preclusion list and the individual's or entity's revocation must be filed jointly by the individual or entity and, as applicable, considered jointly under part 498 of this chapter.

(3)(i) Except as provided in paragraph (a)(3)(ii) of this section, an individual or entity will only be included on the preclusion list after the expiration of either of the following:

(A) If the individual or entity does not file a reconsideration request under § 498.5(n)(1) of this chapter, the individual or entity will be added to the preclusion list upon the expiration of the 60-day period in which the individual or entity may request a reconsideration; or

(B) If the individual or entity files a reconsideration request under § 498.5(n)(1) of this chapter, the individual or entity will be added to the preclusion list effective on the date on which CMS, if applicable, denies the individual's or entity's reconsideration.

(ii) An OIG excluded individual or entity is added to the preclusion list effective on the date of the exclusion.

(4) Payment denials based upon an individual's or entity's inclusion on the preclusion list are not appealable by beneficiaries.

(5)(i) Except as provided in paragraphs (a)(5)(iii) and (iv) of this section, an individual or entity that is revoked under § 424.535 of this chapter will be included on the preclusion list for the same length of time as the individual's or entity's reenrollment bar.

(ii) Except as provided in paragraphs (a)(5)(iii) and (iv) of this section, an individual or entity that is not enrolled in Medicare will be included on the preclusion list for the same length of time as the reenrollment bar that CMS could have imposed on the individual or entity had they been enrolled and then revoked.

(iii) Except as provided in paragraph (a)(5)(iv) of this section, an individual or entity, regardless of whether they are or were enrolled in Medicare, that is included on the preclusion list because of a felony conviction will remain on the preclusion list for a 10-year period, beginning on the date of the felony conviction, unless CMS determines that a shorter length of time is warranted. Factors that CMS considers in making such a determination are as follows:—

(A) The severity of the offense.

(B) When the offense occurred.

(C) Any other information that CMS deems relevant to its determination.

(iv) In cases where an individual or entity is excluded by the OIG, the individual or entity must remain on the preclusion list until the expiration of the CMS-imposed preclusion list period or reinstatement by the OIG, whichever occurs later.

(6) CMS has the discretion not to include a particular individual or entity on (or if warranted, remove the individual or entity from) the preclusion list should it determine that exceptional circumstances exist regarding beneficiary access to MA items, services, or drugs. In making a determination as to whether such circumstances exist, CMS takes into account:

(i) The degree to which beneficiary access to MA items, services, or drugs would be impaired; and

(ii) Any other evidence that CMS deems relevant to its determination.

(b) An MA organization that does not comply with paragraph (a) of this section may be subject to sanctions under § 422.750 and termination under § 422.510.

[83 FR 16733, Apr. 16, 2018, as amended at 84 FR 15831, Apr. 16, 2019]

§ 422.224 Payment to individuals and entities excluded by the OIG or included on the preclusion list.

(a) An MA organization may not pay, directly or indirectly, on any basis, for items or services furnished to a Medicare enrollee by any individual or entity that is excluded by the Office of the Inspector General (OIG) or is included on the preclusion list, defined in § 422.2.

(b) If an MA organization receives a request for payment by, or on behalf of, an individual or entity that is excluded by the OIG or an individual or entity that is included on the preclusion list, defined in § 422.2, the MA organization must notify the enrollee and the excluded individual or entity or the individual or entity included on the preclusion list in writing, as directed by contract or other direction provided by CMS, that payments will not be made. Payment may not be made to, or on behalf of, an individual or entity that is excluded by the OIG or is included on the preclusion list.

[83 FR 16733, Apr. 16, 2018]

Subpart F—Submission of Bids, Premiums, and Related Information and Plan Approval

SOURCE: 70 FR 4725, Jan. 28, 2005, unless otherwise noted.

§ 422.250 Basis and scope.

This subpart is based largely on section 1854 of the Act, but also includes provisions from sections 1853 and 1858 of the Act, and is also based on section 1106 of the Act. It sets forth the requirements for the Medicare Advantage bidding payment methodology, including CMS' calculation of benchmarks, submission of plan bids by Medicare Advantage (MA) organizations, establishment of beneficiary premiums and rebates through comparison of plan bids and benchmarks, negotiation and approval of bids by CMS, and the release of MA bid submission data.

[81 FR 80556, Nov. 15, 2016]

§ 422.252 Terminology.

Annual MA capitation rate means a county payment rate for an MA local area (county) for a calendar year. The terms ''per capita rate'' and ''capitation rate'' are used interchangeably to refer to the annual MA capitation rate.

Low enrollment contract means a contract that could not undertake Healthcare Effectiveness Data and Information Set (HEDIS) and Health Outcome Survey (HOS) data collections because of a lack of a sufficient number of enrollees to reliably measure the performance of the health plan.

MA local area means a payment area consisting of county or equivalent area specified by CMS.

MA monthly basic beneficiary premium means the premium amount (if any) an MA plan (except an MSA plan) charges an enrollee for basic benefits as defined in § 422.100(c)(1), and is calculated as described at § 422.262.

MA monthly MSA premium means the amount of the plan premium for coverage of basic benefits as defined in § 422.100(c)(1) through an MSA plan, as set forth at § 422.254(e).

MA monthly prescription drug beneficiary premium is the MA-PD plan base beneficiary premium, defined at section 1860D–13(a)(2) of the Act, as adjusted to reflect the difference between the plan's bid and the national average bid (as described in § 422.256(c)) less the amount of rebate the MA-PD plan elects to apply, as described at § 422.266(b)(2).

MA monthly supplemental beneficiary premium is the portion of the plan bid attributable to mandatory and/or optional supplemental health care benefits described under § 422.102, less the amount of beneficiary rebate the plan elects to apply to a mandatory supplemental benefit, as described at § 422.266(b)(1).

MA-PD plan means an MA local or regional plan that provides prescription drug coverage under Part D of Title XVIII of the Social Security Act.

Monthly aggregate bid amount means the total monthly plan bid amount for coverage of an MA eligible beneficiary with a nationally average risk profile for the factors described in § 422.308(c), and this amount is comprised of the following:

(1) The unadjusted MA statutory non-drug monthly bid amount for coverage of basic benefits as defined in § 422.100(c)(1).

(2) The amount for coverage of basic prescription drug benefits under Part D (if any).

(3) The amount for provision of supplemental health care benefits (if any).

New MA plan means a MA contract offered by a parent organization that has not had another MA contract in the previous 3 years. For purposes of 2022 quality bonus payments based on 2021 Star Ratings only, new MA plan means an MA contract offered by a parent organization that has not had another MA contract in the previous 4 years.

Plan basic cost sharing means cost sharing that would be charged by a plan for basic benefits as defined in § 422.100(c)(1) before any reductions resulting from mandatory supplemental benefits.

Unadjusted MA area-specific non-drug monthly benchmark amount means, for local MA plans serving one county, the county capitation rate CMS publishes annually that reflects the nationally average risk profile for the risk factors CMS applies to payment calculations as set forth at § 422.308(c) of this part, (that is, a standardized benchmark). For local MA plans serving multiple counties it is the weighted average of county rates in a plan's service area, weighted by the plan's projected enrollment per county. The rules for determining county capitation rates are specific to a time period, as set forth at § 422.258(a). Effective 2012, the MA area-specific non-drug monthly benchmark amount is called the blended benchmark amount, and is determined according to the rules set forth under § 422.258(d) of this part.

Unadjusted MA region-specific non-drug monthly benchmark amount means, for MA regional plans, the amount described at § 422.258(b).

Unadjusted MA statutory non-drug monthly bid amount means a plan's estimate of its average monthly required revenue to provide coverage of basic benefits as defined in § 422.100(c)(1) to an MA eligible beneficiary with a nationally average risk profile for the risk factors CMS applies to payment calculations as set forth at § 422.308(c).

[63 FR 35085, June 26, 1998, as amended at 70 FR 52026, Sept. 1, 2005; 76 FR 21564, Apr. 15, 2011; 84 FR 15832, Apr. 16, 2019; 85 FR 19290, Apr. 6, 2020; 86 FR 6098, Jan. 19, 2021; 87 FR 27895, May 9, 2022]

§ 422.254 Submission of bids.

(a) *General rules.* (1) Not later than the first Monday in June, each MA organization must submit to CMS an aggregate monthly bid amount for each MA plan (other than an MSA plan) the organization intends to offer in the upcoming year in the service area (or segment of such an area if permitted under § 422.262(c)(2)) that meets the requirements in paragraph (b) of this section. With each bid submitted, the MA organization must provide the information required in paragraph (c) of this section and, for plans with rebates as described at § 422.266(a), the MA organization must provide the information required in paragraph (d) of this section.

(2) CMS has the authority to determine whether and when it is appropriate to apply the bidding methodology described in this section to ESRD MA enrollees.

(3) If the bid submission described in paragraphs (a)(1) and (2) of this section is not complete, timely, or accurate, CMS has the authority to impose sanctions under subpart O of this part or may choose not to renew the contract.

(4) CMS may decline to accept any or every otherwise qualified bid submitted by an MA organization or potential MA organization.

(5) After an MA organization is permitted to begin marketing prospective plan year offerings for the following contract year (consistent with § 422.2263(a)), the MA organization must not change and must provide the benefits described in its CMS-approved plan benefit package (PBP) (as defined in § 422.162) for the following contract year without modification, except where a modification in benefits is required by law. This prohibition on changes applies to cost sharing and premiums as well as benefits.

(b) *Bid requirements.* (1) The monthly aggregate bid amount submitted by an MA organization for each plan is the

organization's estimate of the revenue required for the following categories for providing coverage to an MA eligible beneficiary with a national average risk profile for the factors described in § 422.308(c):

(i) The unadjusted MA statutory non-drug monthly bid amount, which is the MA plan's estimated average monthly required revenue for providing basic benefits as defined in § 422.100(c)(1).

(ii) The amount to provide basic prescription drug coverage, if any (defined at section 1860D–2(a)(3) of the Act).

(iii) The amount to provide supplemental health care benefits, if any.

(2) Each bid is for a uniform benefit package for the service area.

(3) Each bid submission must contain all estimated revenue required by the plan, including administrative costs and return on investment.

(i) MA plans offering additional telehealth benefits as defined in § 422.135(a) must exclude any capital and infrastructure costs and investments directly incurred or paid by the MA plan relating to such benefits from their bid submission for the unadjusted MA statutory non-drug monthly bid amount.

(ii) [Reserved]

(4) The bid amount is for plan payments only but must be based on plan assumptions about the amount of revenue required from enrollee cost-sharing. The estimate of plan cost-sharing for the unadjusted MA statutory non-drug monthly bid amount for coverage of basic benefits as defined in § 422.100(c)(1) must reflect the requirement that the level of cost sharing MA plans charge to enrollees must be actuarially equivalent to the level of cost sharing (deductible, copayments, or coinsurance) charged to beneficiaries under the original Medicare fee-for-service program option. The actuarially equivalent level of cost sharing reflected in a regional plan's unadjusted MA statutory non-drug monthly bid amount does not include cost sharing for out-of-network Medicare benefits, as described at § 422.101(d).

(5) *Actuarial valuation.* The bid must be prepared in accordance with CMS actuarial guidelines based on generally accepted actuarial principles.

(i) A qualified actuary must certify the plan's actuarial valuation (which may be prepared by others under his or her direction or review).

(ii) To be deemed a qualified actuary, the actuary must be a member of the American Academy of Actuaries.

(iii) Applicants may use qualified outside actuaries to prepare their bids.

(c) *Information required for coordinated care plans and MA private fee-for-service plans.* MA organizations' submission of bids for coordinated care plans, including regional MA plans and specialized MA plans for special needs beneficiaries (described at § 422.4(a)(1)(iv)), and for MA private fee-for-service plans must include the following information:

(1) The plan type for each plan.

(2) The monthly aggregate bid amount for the provision of all items and services under the plan, as defined in § 422.252 and discussed in paragraph (a) of this section.

(3) The proportions of the bid amount attributable to-

(i) The provision of basic benefits as defined in § 422.100(c)(1);

(ii) The provision of basic prescription drug coverage (as defined at section 1860D–2(a)(3) of the Act; and

(iii) The provision of supplemental health care benefits (as defined § 422.102).

(4) The projected number of enrollees in each MA local area used in calculation of the bid amount, and the enrollment capacity, if any, for the plan.

(5) The actuarial basis for determining the amount under paragraph (c)(2) of this section, the proportions under paragraph (c)(3) of this section, the amount under paragraph (b)(4) of this section, and additional information as CMS may require to verify actuarial bases and the projected number of enrollees.

(6) A description of deductibles, coinsurance, and copayments applicable under the plan and the actuarial value of the deductibles, coinsurance, and copayments.

(7) For qualified prescription drug coverage, the information required under section 1860D–11(b) of the Act with respect to coverage.

(8) For the purposes of calculation of risk corridors under § 422.458, MA organizations offering regional MA plans in

2006 and/or 2007 must submit the following information developed using the appropriate actuarial bases.

(i) Projected allowable costs (defined in § 422.458(a)).

(ii) The portion of projected allowable costs attributable to administrative expenses incurred in providing these benefits.

(iii) The total projected costs for providing rebatable integrated benefits (as defined in § 422.458(a)) and the portion of costs that is attributable to administrative expenses.

(9) For regional plans, as determined by CMS, the relative cost factors for the counties in a plan's service area, for the purposes of adjusting payment under § 422.308(d) for intra-area variations in an MA organization's local payment rates.

(d) *Beneficiary rebate information.* In the case of a plan required to provide a monthly rebate under § 422.266 for a year, the MA organization offering the plan must inform CMS how the plan will distribute the beneficiary rebate among the options described at § 422.266(b).

(e) *Information required for MSA plans.* MA organizations intending to offer MA MSA plans must submit—

(1) The enrollment capacity (if any) for the plan;

(2) The amount of the MA monthly MSA premium for basic benefits (as defined in § 422.252);

(3) The amount of the plan deductible; and

(4) The amount of the beneficiary supplemental premium, if any.

(f) Separate bids must be submitted for Part A and Part B enrollees and Part B-only enrollees for each MA plan offered.

[63 FR 35085, June 26, 1998, as amended at 70 FR 52026, Sept. 1, 2005; 75 FR 19806, Apr. 15, 2010; 76 FR 21564, Apr. 15, 2011; 83 FR 16733, Apr. 16, 2018; 84 FR 15833, Apr. 16, 2019; 89 FR 30822, Apr. 23, 2024]

§ 422.256 Review, negotiation, and approval of bids.

(a) *Authority.* Subject to paragraphs (a)(2), (d), and (e) of this section, CMS has the authority to review the aggregate bid amounts submitted under § 422.252 and conduct negotiations with MA organizations regarding these bids (including the supplemental benefits) and the proportions of the aggregate bid attributable to basic benefits, supplemental benefits, and prescription drug benefits and may decline to approve a bid if the plan sponsor proposes significant increases in cost sharing or decreases in benefits offered under the plan.

(1) When negotiating bid amounts and proportions, CMS has authority similar to that provided the Director of the Office of Personnel Management for negotiating health benefits plans under 5 U.S.C. chapter 89.

(2) *Noninterference.* (i) In carrying out Parts C and D under this title, CMS may not require any MA organization to contract with a particular hospital, physician, or other entity or individual to furnish items and services.

(ii) CMS may not require a particular price structure for payment under such a contract, with the exception of payments to Federally qualified health centers as set forth at § 422.316.

(b) *Standards of bid review.* Subject to paragraphs (d) and (e) of this section, CMS can only accept bid amounts or proportions described in paragraph (a) of this section if CMS determines the following standards have been met:

(1) The bid amount and proportions are supported by the actuarial bases provided by MA organizations under § 422.254.

(2) The bid amount and proportions reasonably and equitably reflects the plan's estimated revenue requirements for providing the benefits under that plan, as the term revenue requirements is used for purposes of section 1302(8) of the Public Health Service Act.

(3) *Limitation on enrollee cost sharing.* For coordinated care plans (including regional MA plans and specialized MA plans) and private fee-for-service plans:

(i) The actuarial value of plan basic cost sharing, reduced by any supplemental benefits, may not exceed—

(ii) The actuarial value of deductibles, coinsurance, and copayments that would be applicable for the benefits to individuals entitled to benefits under Part A and enrolled under Part B in the plan's service area with a national average risk profile for the factors described in § 422.308(c) if they

were not members of an MA organization for the year, except that cost sharing for non-network Medicare services in a regional MA plan is not counted under the amount described in paragraph (b)(2)(i) of this section.

(c) *Negotiation process.* The negotiation process may include the resubmission of information to allow MA organizations to modify their initial bid submissions to account for the outcome of CMS' regional benchmark calculations required under § 422.258(c) and the outcome of CMS' calculation of the national average monthly bid amount required under section 1860D–13(a)(4) of the Act.

(d) *Exception for private fee-for-service plans.* For private fee-for-service plans defined at § 422.4(a)(3), CMS will not review, negotiate, or approve the bid amount, proportions of the bid, or the amounts of the basic beneficiary premium and supplemental premium.

(e) *Exception for MSA plans.* CMS does not review, negotiate, or approve amounts submitted with respect to MA MSA plans, except to determine that the deductible does not exceed the statutory maximum, defined at § 422.103(d).

[63 FR 35085, June 26, 1998, as amended at 70 FR 52026, Sept. 1, 2005; 70 FR 76198, Dec. 23, 2005; 75 FR 19806, Apr. 15, 2010; 76 FR 21564, Apr. 15, 2011; 83 FR 16733, Apr. 16, 2018]

§ 422.258 Calculation of benchmarks.

(a) The term ''MA area-specific non-drug monthly benchmark amount'' means, for a month in a year:

(1) For MA local plans with service areas entirely within a single MA local area:

(i) For years before 2007, one-twelfth of the annual MA capitation rate (described at § 422.306) for the area, adjusted as appropriate for the purpose of risk adjustment.

(ii) For years 2007 through 2010, one-twelfth of the applicable amount determined under section 1853(k)(1) of the Act for the area for the year, adjusted as appropriate for the purpose of risk adjustment.

(iii) For 2011, one-twelfth of the applicable amount determined under 1853(k)(1) for the area for 2010.

(iv) Beginning with 2012, one-twelfth of the blended benchmark amount described in paragraph (d) of this section, subject to paragraph (d)(8) of this section and adjusted as appropriate for the purpose of risk adjustment.

(2) For MA local plans with service areas including more than one MA local area, an amount equal to the weighted average of amounts described in paragraph (a)(1) of this section for the year for each local area (county) in the plan's service area, using as weights the projected number of enrollees in each MA local area that the plan used to calculate the bid amount, and adjusted as appropriate for the purpose of risk adjustment.

(b) For MA regional plans, the term ''MA region-specific non-drug monthly benchmark amount'' is:

(1) The sum of two components: the statutory component (based on a weighted average of local benchmarks in the region, as described in paragraph (c)(3) of this section; and the plan bid component (based on a weighted average of regional plan bids in the region as described in paragraph (c)(4) of this section).

(2) Announced before November 15 of each year, but after CMS has received the plan bids.

(c) *Calculation of MA regional non-drug benchmark amount.* CMS calculates the monthly regional non-drug benchmark amount for each MA region as follows:

(1) *Reference month.* For all calculations that follow, CMS will determine the number of MA eligible individuals in each local area, in each region, and nationally as of the reference month, which is a month in the previous calendar year CMS identifies.

(2) *Statutory market share.* CMS will determine the statutory national market share percentage as the proportion of the MA eligible individuals nationally who were not enrolled in an MA plan.

(3) *Statutory component of the region-specific benchmark.* (i) CMS calculates the unadjusted region-specific non-drug amount by multiplying the amount determined under paragraph (a) of this section for the year by the county's share of the MA eligible individuals residing in the region (the number of MA eligible individuals in the county divided by the number of MA eligible individuals in the region),

and then adding all the enrollment-weighted county rates to a sum for the region.

(ii) CMS then multiplies the unadjusted region-specific non-drug amount from paragraph (c)(3)(i) of this section by the statutory market share to determine the statutory component of the regional benchmark.

(4) *Plan-bid component of the region-specific benchmark.* For each regional plan offered in a region, CMS will multiply the plan's unadjusted region-specific non-drug bid amount by the plan's share of enrollment (as determined under paragraph (c)(5) of this section) and then sum these products across all plans offered in the region. CMS then multiples this by 1 minus the statutory market share to determine the plan-bid component of the regional benchmark.

(5) *Plan's share of enrollment.* CMS will calculate the plan's share of MA enrollment in the region as follows:

(i) In the first year that any MA regional plan is being offered in an MA region, and more than one MA regional plan is being offered, CMS will determine each regional plan's share of enrollment based on one of two possible approaches. CMS may base this factor on equal division among plans, so that each plan's share will be 1 divided by the number of plans offered. Alternatively, CMS may base this factor on each regional plan's estimate of projected enrollment. Plan enrollment projections are subject to review and adjustment by CMS to assure reasonableness.

(ii) If two or more regional plans are offered in a region and were offered in the reference month: The plan's share of enrollment will be the number of MA eligible individuals enrolled in the plan divided by the number of MA eligible individuals enrolled in all of the plans in the region, as of the reference month.

(iii) If a single regional plan is being offered in the region: The plan's share of enrollment is equal to 1.

(d) *Determination of the blended benchmark amount*—(1) *General rules.* For the purpose of paragraphs (a) and (b) of this section, the term blended benchmark amount for an area for a year means the sum of two components: the applicable amount determined under section 1853(k)(1) of the Act and the specified amount determined under section 1853(n)(2) of Act. The weights for each component are based on the phase-in period assigned each area, as described in paragraphs (d)(8) and (d)(9) of this section. At the conclusion of an area's phase-in period, the blended benchmark for an area for a year equals the section 1853(n)(2) of the Act specified amount described in paragraph (d)(2) of this section. The blended benchmark amount for an area for a year (which takes into account paragraph (d)(8) of this section), cannot exceed the applicable amount described in paragraph (d)(2) of this section that would be in effect but for the application of this paragraph.

(2) *Applicable amount.* For the purpose of paragraphs (a) and (b) of this section, the applicable amount determined under section 1853(k)(1) of the Act for a year is—

(i) In a rebasing year (described at § 422.306(b)(2), an amount equal to the greater of the average FFS expenditure amount at § 422.306(b)(2) for an area for a year and the minimum percentage increase rate at § 422.306(a) for an area for a year.

(ii) In a year when the amounts at § 422.306(b)(2) are not rebased, the minimum percentage increase rate at § 422.306(a) for the area for the year.

(iii) In no case the blended benchmark amount for an area for a year, determined taking into account paragraph (d)(8) of this section, be greater than the applicable amount at paragraph (d)(2) of this section for an area for a year.

(iv) Paragraph (d) of this section does not apply to the PACE program under section 1894 of Act.

(3) *Specified amount.* For the purpose of paragraphs (a) and (b) of this section, the specified amount under section 1853(n)(2) of the Act is the product of the base payment amount for an area for a year (adjusted as required under § 422.306(c) and (d)) multiplied by the applicable percentage described in paragraph (d)(5) of this section for an area for a year.

(4) *Base payment amount.* The base payment amount is as follows:

(i) For 2012, the average FFS expenditure amount specified in § 422.306(b)(2), determined for 2012.

(ii) For subsequent years, the average FFS expenditure amount specified in § 422.306(b)(2).

(5) *Applicable percentage.* Subject to paragraph (d)(7) of this section, the applicable percentage is one of four values assigned to an area based on Secretary's determination of the quartile ranking of the area's average FFS expenditure amount (described at § 422.306(b)(2) and adjusted as required at § 422.306(c) and (d)), relative to this amount for all areas.

(i) For the 50 States or the District of Columbia, a county with an average FFS expenditure amount adjusted under § 422.306(c) and (d) that falls in the—

(A) Highest quartile of such rates for all areas for the previous year receives an applicable percentage of 95 percent;

(B) Second highest quartile of such rates for all areas for the previous year receives an applicable percentage of 100 percent;

(C) Third highest quartile of such rates for all areas for the previous year receives an applicable percentage of 107.5 percent; or

(D) Lowest quartile of such rates for all areas for the previous year receives an applicable percentage of 115 percent.

(ii) To determine the applicable percentages for a territory, the Secretary ranks such areas for a year based on the level of the area's § 422.306(b)(2) amount adjusted under § 422.306(c) and (d), relative to the quartile rankings computed under paragraph (d)(5)(i) of this section.

(6) *Additional rules for determining the applicable percentage.* (i) In a contract year when the average FFS expenditure amounts from the previous year were rebased (according to the periodic rebasing requirement at § 422.306(b)(2)), the Secretary must determine an area's applicable percentage based on a quartile ranking of the previous year's rebased FFS amounts adjusted under § 422.306(c) and (d).

(ii) If, for a year after 2012, there is a change in the quartile in which an area is ranked compared to the previous year's ranking, the applicable percentage for the area in the year must be the average of the applicable percentage for the previous year and the applicable percentage that would otherwise apply for the area for the year in the absence of this transitional provision.

(7) *Increases to the applicable percentage for quality.* Beginning with 2012, the blended benchmark under paragraphs (a) and (b) of this section will reflect the level of quality rating at the plan or contract level, as determined by the Secretary. The quality rating for a plan is determined by the Secretary according to a 5-star rating system (based on the data collected under section 1852(e) of the Act) specified in subpart D of this part 422. Specifically, the applicable percentage under paragraph (d)(5) of this section must be increased according to criteria in paragraphs (d)(7)(i) through (v) of this section if the plan or contract is determined to be a qualifying plan or a qualifying plan in a qualifying county for the year.

(i) *Qualifying plan.* Beginning with 2012, a qualifying plan means a plan that had a quality rating of 4 stars or higher based on the most recent data available for such year. For a qualifying plan, the applicable percentage at paragraph (d)(5) of this section must be increased as follows:

(A) For 2012, by 1.5 percentage points.

(B) For 2013, by 3.0 percentage points.

(C) For 2014 and subsequent years, by 5.0 percentage points.

(ii) *Qualifying county.* (A) A *qualifying county* means a county that meets the following three criteria:

(*1*) Has an MA capitation rate that, in 2004, was based on the amount specified in section 1853(c)(1)(B) of the Act for a Metropolitan Statistical Area with a population of more than 250,000.

(*2*) Of the MA-eligible individuals residing in the county, at least 25 percent of such individuals were enrolled in MA plans as of December 2009.

(*3*) Has per capita fee-for-service spending that is lower than the national monthly per capita cost for expenditures for individuals enrolled under the Original Medicare fee-for-service program for the year.

(B) Beginning with 2012, for a qualifying plan serving a qualifying county, the increase to the applicable percentage described at paragraph (d)(7)(i) of

this section must be doubled for the qualifying county.

(iii) MA organizations that fail to report data as required by the Secretary must be counted as having a rating of fewer than 3.5 stars at the plan or contract level, as determined by the Secretary.

(iv) *Application of applicable percentage increases to low enrollment contracts.* (A) For 2012, for an MA plan that the Secretary determines is unable to have a quality rating because of low enrollment, the Secretary treats this plan as a qualifying plan under paragraph (d)(7)(i) of this section.

(B) For 2013 and subsequent years, the Secretary develops a methodology to apply to MA plans with low enrollment (as defined by the Secretary) to determine whether a low enrollment contract is a qualifying plan.

(v) *Application of increases in applicable percentage to new MA plans.* A new MA plan (as defined at § 422.252) that meets criteria specified by the Secretary must be treated as a qualifying plan under paragraph (d)(7)(i) of this section, except that the applicable percentage must be increased as follows:

(A) For 2012, by 1.5 percentage points.

(B) For 2013, by 2.5 percentage points.

(C) For 2014 and subsequent years, by 3.5 percentage points.

(8) *Determination of phase-in period for the blended benchmark amount.* For 2012 through 2016, the blended benchmark amount for an area for a year depends on the phase-in period assigned to that area. The Secretary assigns one of three phase-in periods to each area: 2-year, 4 year, or 6 year. The phase-in period assigned to an area is based on the size of the difference between the 2010 applicable amount at paragraph (d)(2) of this section and the projected 2010 benchmark amount defined at paragraph (d)(8)(i) of this section.

(i) The projected 2010 benchmark amount is calculated once for the purpose of determining the phase-in period for an area. It is equal to one-half of the 2010 applicable amount at paragraph (d)(2) of this section and one-half of the specified amount at paragraph (d)(3) modified to apply to 2010 (as described in (d)(8)(ii) of this section).

(ii) To assign a phase-in period to an area, the specified amount is modified as if it applies to 2010, and is the product of—

(A) The 2010 base payment amount adjusted as required under § 422.306(c) of this part; and

(B) The applicable percentage determined as if the reference to the ''previous year'' at paragraph (d)(5) of this section were deemed a reference to 2010 and increased as follows:

(*1*) The increase at paragraph (d)(7)(i) of this section for a qualifying plan in the area is applied as if the reference to a qualifying plan for 2012 were deemed a reference for 2010; and

(*2*) The increase at paragraph (d)(7)(ii) of this section is applied as if the determination of a qualifying county were made for 2010.

(iii) *Two-year phase-in.* An area is assigned the 2-year phase-in period if the difference between the applicable amount at paragraph (d)(2) of this section and the projected 2010 benchmark amount at paragraph (d)(8)(i) of this section is less than $30.

(iv) *Four-year phase-in.* An area is assigned the 4-year phase-in period if the difference between the applicable amount at paragraph (d)(2) of this section and the projected 2010 benchmark amount at paragraph (d)(8)(i) of this section is at least $30 but less than $50.

(v) *Six-year phase-in.* An area is assigned the 6-year phase-in period if the difference between the applicable amount at paragraph (d)(2) of this section and the projected 2010 benchmark amount at paragraph (d)(8)(i) of this section is at least $50.

(9) *Impact of phase-in period on calculation of the blended benchmark amount*—(i) *Weighting for the 2-year phase-in.* (A) For 2012, the blended benchmark is the sum of one-half of the applicable amount at paragraph (d)(2) of this section and one-half of the specified amount at paragraph (d)(3) of this section.

(B) For 2013 and subsequent years, the blended benchmark equals the specified amount.

(ii) *Weighting for the 4-year phase-in.* The blended benchmark is the sum of the applicable amount at paragraph (d)(2) of this section and the specified amount at paragraph (d)(2) of this section in the following proportions:

(A) For 2012, three-fourths of the applicable amount for the area for the year and one-fourth of the specified amount for the area and year.

(B) For 2013, one-half of the applicable amount for the area for the year and one-half of the specified amount for the area and year.

(C) For 2014, one-fourth of the applicable amount for the area for the year and three-fourths of the specified amount for the area and year.

(D) For 2015 and subsequent years, the blended benchmark equals the specified amount for the area and year.

(iii) *Weighting for the 6-year phase-in.* The blended benchmark is the sum of the applicable amount at paragraph (d)(2) and the specified amount at paragraph (d)(3) of this section in the following proportions:

(A) For 2012, five-sixths of the applicable amount for the area and year and one-sixth of the specified amount for the area and year.

(B) For 2013, two-thirds of the applicable amount for the area and year and one-third of the specified amount for the area and year.

(C) For 2014, one-half of the applicable amount for the area and year and one-half of the specified amount for the area and for year.

(D) For 2015, one-third of the applicable amount for the area and year and two-thirds of the specified amount for the area and for year.

(E) For 2016, one-sixth of the applicable amount for the area and year and five-sixths of the specified amount for the area and for year.

(F) For 2017 and subsequent years, the blended benchmark equals the specified amount for the area and year.

[70 FR 4725, Jan. 28, 2005, as amended at 76 FR 21564, Apr. 15, 2011; 83 FR 16733, Apr. 16, 2018; 85 FR 33907, June 2, 2020]

§ 422.260 Appeals of quality bonus payment determinations.

(a) *Scope.* The provisions of this section pertain to the administrative review process to appeal quality bonus payment status determinations based on section 1853(o) of the Act. Such determinations are made based on the overall rating for MA–PDs and Part C summary rating for MA-only contracts for the contract assigned under subpart D of this part.

(b) *Definitions.* The following definitions apply to this section:

Quality bonus payment (QBP) means—

(i) Enhanced CMS payments to MA organizations based on the organization's demonstrated quality of its Medicare contract operations; or

(ii) Increased beneficiary rebate retention allowances based on the organization's demonstrated quality of its Medicare contract operations.

Quality bonus payment (QBP) determination methodology means the quality ratings system specified in subpart D of this part 422 for assigning quality ratings to provide comparative information about MA plans and evaluating whether MA organizations qualify for a QBP. (Low enrollment contracts and new MA plans are defined in § 422.252.)

Quality bonus payment (QBP) status means a MA organization's standing with respect to its qualification to—

(i) Receive a quality bonus payment, as determined by CMS; or

(ii) Retain a portion of its beneficiary rebates based on its quality rating, as determined by CMS.

(c) *Administrative review process for QBP status appeals.* (1) Reconsideration request. An MA organization may request reconsideration of its QBP status.

(i) The MA organization requesting reconsideration of its QBP status must do so by providing written notice to CMS within 10 business days of the release of its QBP status. The request must specify the given measure(s) in question and the basis for reconsideration such as a calculation error or incorrect data was used to determine the QBP status. Requests are limited to those circumstances where the error could impact an individual measure's value or the overall Star Rating. Based on any corrections, any applicable measure-level Star Ratings could go up, stay the same, or go down. The overall Star Rating also may go up, stay the same, or go down based on any corrections.

(ii) The reconsideration official's decision is final and binding unless a request for an informal hearing is filed in accordance with paragraph (2) of this section.

(2) *Informal hearing request.* An MA organization may request an informal hearing on the record following the reconsideration official's decision regarding its QBP status.

(i) The MA organization seeking an appeal of the reconsideration official's decision regarding its QBP status must do so by providing written notice to CMS within 10 business days of the issuance of the reconsideration decision. The notice must specify the errors the MA organization asserts that CMS made in making the QBP determination and how correction of those errors could result in the organization's qualification for a QBP or a higher QBP.

(ii) The MA organization may not request an informal hearing of its QBP status unless it has already requested and received a reconsideration decision in accordance with paragraph (c)(1) of this section.

(iii) The informal hearing request must pertain only to the measure(s) and value(s) in question that precipitated the request for reconsideration.

(iv) The informal hearing is conducted by a CMS hearing officer on the record. The hearing officer receives no testimony, but may accept written statements with exhibits from each party in support of their position in the matter.

(v) The MA organization must prove by a preponderance of evidence that CMS' calculations of the measure(s) and value(s) in question were incorrect. The burden of proof is on the MA organization to prove an error was made in the calculation of the QBP status.

(vi) The hearing officer issues the decision by electronic mail to the MA organization.

(vii) After the hearing officer's decision is issued to the MA organization and the CMS Administrator, the hearing officer's decision is subject to review and modification by the CMS Administrator within 10 business days of issuance. If the Administrator does not review and issue a decision within 10 business days, the hearing officer's decision is final and binding.

(3) *Limits to requesting an administrative review.* (i) CMS may limit the measures or bases for which a contract may request an administrative review of its QBP status.

(ii) An administrative review cannot be requested for the following: the methodology for calculating the star ratings (including the calculation of the overall star ratings); cut-off points for determining measure thresholds; the set of measures included in the star rating system; and the methodology for determining QBP determinations for low enrollment contracts and new MA plans.

(iii) The MA organization may not request a review based on data inaccuracy for the following data sources:

(A) HEDIS.

(B) CAHPS.

(C) HOS.

(D) Part C and D Reporting Requirements.

(E) PDE.

(F) Medicare Plan Finder pricing files.

(G) Data from the Medicare Beneficiary Database Suite of Systems.

(H) Medicare Advantage Prescription Drug (MARx) system.

(I) Other Federal data sources.

(4) *Designation of a hearing officer.* CMS designates a hearing officer to conduct the appeal of the QBP status. The officer must be an individual who did not directly participate in the initial QBP determination.

(d) *Reopening of QBP determinations.* CMS may, on its own initiative, revise an MA organization's QBP status at any time after the initial release of the QBP determinations through April 1 of each year. CMS may take this action on the basis of any credible information, including the information provided during the administrative review process by a different MA organization, that demonstrates that the initial QBP determination was incorrect. If a contract's QBP determination is reopened as a result of a systemic calculation issue that impacts more than the MA organization that submitted an appeal, the QBP rating for MA organizations that did not appeal will only be updated if it results in a higher QBP rating.

[76 FR 21566, Apr. 15, 2011, as amended at 83 FR 16733, Apr. 16, 2018; 89 FR 30822, Apr. 23, 2024]

§ 422.262 Beneficiary premiums.

(a) *Determination of MA monthly basic beneficiary premium.* (1) For an MA plan with an unadjusted statutory non-drug bid amount that is less than the relevant unadjusted non-drug benchmark amount, the basic beneficiary premium is zero.

(2) For an MA plan with an unadjusted statutory non-drug bid amount that is equal to or greater than the relevant unadjusted non-drug benchmark amount, the basic beneficiary premium is the amount by which (if any) the bid amount exceeds the benchmark amount. All approved basic premiums must be charged; they cannot be waived.

(b) *Consolidated monthly premiums.* Except as specified in paragraph (b)(2) of this section, MA organizations must charge enrollees a consolidated monthly MA premium.

(1) The consolidated monthly premium for an MA plan (other than a MSA plan) is the sum of the MA monthly basic beneficiary premium (if any), the MA monthly supplementary beneficiary premium (if any), and the MA monthly prescription drug beneficiary premium (if any).

(2) *Special rule for MSA plans.* For an individual enrolled in an MSA plan offered by an MA organization, the monthly beneficiary premium is the supplemental premium (if any).

(c) *Uniformity of premiums*—(1) *General rule.* Except as permitted for supplemental premiums pursuant to § 422.106(d), for MA contracts with employers and labor organizations, the MA monthly bid amount submitted under § 422.254, the MA monthly basic beneficiary premium, the MA monthly supplemental beneficiary premium, the MA monthly prescription drug premium, and the monthly MSA premium of an MA organization may not vary among individuals enrolled in an MA plan (or segment of the plan as provided for local MA plans under paragraph (c)(2) of this section). In addition, the MA organization cannot vary the level of cost-sharing charged for basic benefits or supplemental benefits (if any) among individuals enrolled in an MA plan (or segment of the plan).

(2) *Segmented service area option.* An MA organization may apply the uniformity requirements in paragraph (c)(1) of this section to segments of an MA local plan service area (rather than to the entire service area) as long as such a segment is composed of one or more MA payment areas. The information specified under § 422.254 is submitted separately for each segment. This provision does not apply to MA regional plans.

(d) *Monetary inducement prohibited.* An MA organization may not provide for cash or other monetary rebates as an inducement for enrollment or for any other reason or purpose.

(e) *Timing of payments.* The MA organization must permit payments of MA monthly basic and supplemental beneficiary premiums and monthly prescription drug beneficiary premiums on a monthly basis and may not terminate coverage for failure to make timely payments except as provided in § 422.74(b).

(f) *Beneficiary payment options.* An MA organization must permit each enrollee, at the enrollee's option, to make payment of premiums (if any) under this part to the organization through-

(1) Withholding from the enrollee's Social Security benefit payments, or benefit payments by the Railroad Retirement Board or the Office of Personnel Management, in the manner that the Part B premium is withheld;

(2) An electronic funds transfer mechanism (such as automatic charges of an account at a financial institution or a credit or debit card account);

(3) According to other means that CMS may specify, including payment by an employer or under employment-based retiree health coverage on behalf of an employee, former employee (or dependent), or by other third parties such as a State.

(i) Regarding the option in paragraph (f)(1) of this section, MA organizations may not impose a charge on beneficiaries for the election of this option.

(ii) An enrollee may opt to make a direct payment of premium to the plan.

(g) *Prohibition on improper billing of premiums.* MA organizations shall not bill an enrollee for a premium payment period if the enrollee has had the premium for that period withheld from his

or her Social Security, Railroad Retirement Board or Office of Personnel Management check.

(h) *Retroactive collection of premiums.* In circumstances where retroactive collection of premium amounts is necessary and the enrollee is without fault in creating the premium arrearage, the Medicare Advantage organization shall offer the enrollee the option of payment either by lump sum, by equal monthly installment spread out over at least the same period for which the premiums were due, or through other arrangements mutually acceptable to the enrollee and the Medicare Advantage organization. For monthly installments, for example, if 7 months of premiums are due, the member would have at least 7 months to repay.

[63 FR 18134, Apr. 14, 1998, as amended at 74 FR 1541, Jan. 12, 2009]

§ 422.264 Calculation of savings.

(a) *Computation of risk adjusted bids and benchmarks*—(1) *The risk adjusted MA statutory non-drug monthly bid amount* is the unadjusted MA statutory non-drug monthly bid amount (defined at § 422.254(b)(1)(i)), adjusted using the factors described in paragraph (c) of this section for local plans and paragraph (e) of this section for regional plans.

(2) The *risk adjusted MA area-specific non-drug monthly benchmark amount* is the unadjusted benchmark amount for coverage of basic benefits defined in § 422.100(c)(1) by a local MA plan, adjusted using the factors described in paragraph (c) of this section.

(3) The *risk adjusted MA region-specific non-drug monthly benchmark amount* is the unadjusted benchmark amount for coverage of basic benefits defined in § 422.100(c)(1) by a regional MA plan, adjusted using the factors described in paragraph (e) of this section.

(b) *Computation of savings for MA local plans.* The average per capita monthly savings for an MA local plan is 100 percent of the difference between the plan's risk-adjusted statutory non-drug monthly bid amount (described in paragraph (a)(1) of this section) and the plan's risk-adjusted area-specific non-drug monthly benchmark amount (described in paragraph (a)(2) of this section). Plans with bids equal to or greater than plan benchmarks will have zero savings.

(c) *Risk adjustment factors for determination of savings for local plans.* CMS will publish the first Monday in April before the upcoming calendar year the risk adjustment factors described in paragraph (c)(1) or (c)(2) of this section determined for the purpose of calculating savings amounts for MA local plans.

(1) For the purpose of calculating savings for MA local plans CMS has the authority to apply risk adjustment factors that are plan-specific average risk adjustment factors, Statewide average risk adjustment factors, or factors determined on a basis other than plan-specific factors or Statewide average factors.

(2) In the event that CMS applies Statewide average risk adjustment factors, the statewide factor for each State is the average of the risk factors calculated under § 422.308(c), based on all enrollees in MA local plans in that State in the previous year. In the case of a State in which no local MA plan was offered in the previous year, CMS will estimate an average and may base this average on average risk adjustment factors applied to comparable States or applied on a national basis.

(d) *Computation of savings for MA regional plans.* The average per capita monthly savings for an MA regional plan and year is 100 percent of the difference between the plan's risk-adjusted statutory non-drug monthly bid amount (described in paragraph (a)(1) of this section) and the plan's risk-adjusted region-specific non-drug monthly benchmark amount (described in paragraph (a)(3) of this section), using the risk adjustment factors described in paragraph (e) of this section. Plans with bids equal to or greater than plan benchmarks will have zero savings.

(e) *Risk adjustment factors for determination of savings for regional plans.* CMS will publish the first Monday in April before the upcoming calendar year the risk adjustment factors described in paragraph (e)(1)and (e)(2) of this section determined for the purpose of calculating savings amounts for MA regional plans.

(1) For the purpose of calculating savings for MA regional plans, CMS has

the authority to apply risk adjustment factors that are plan-specific average risk adjustment factors, Region-wide average risk adjustment factors, or factors determined on a basis other than MA regions.

(2) In the event that CMS applies region-wide average risk adjustment factors, the region-wide factor for each MA region is the average of the risk factors calculated under §422.308(c), based on all enrollees in MA regional plans in that region in the previous year. In the case of a region in which no regional plan was offered in the previous year, CMS will estimate an average and may base this average on average risk adjustment factors applied to comparable regions or applied on a national basis.

[70 FR 4725, Jan. 28, 2005, as amended at 84 FR 15833, Apr. 16, 2019]

§422.266 Beneficiary rebates.

(a) *Calculation of rebate.* (1) For 2006 through 2011, an MA organization must provide to the enrollee a monthly rebate equal to 75 percent of the average per capita savings (if any) described in §422.264(b) for MA local plans and §422.264(d) for MA regional plans.

(2) For 2012 and subsequent years, an MA organization must provide to the enrollee a monthly rebate equal to a specified percentage of the average per capita savings (if any) at §422.264(b) for MA local plans and §422.264(d) for MA regional plans. For 2012 and 2013, this percentage is based on a combination of the (a)(1) rule of 75 percent and the (a)(2)(ii) rules that set the percentage based on the plan's quality rating under a 5 star rating system, as determined by the Secretary under §422.258(d)(7). For 2014 and subsequent years, this percentage is determined based only on the paragraph (a)(2)(ii) of this section.

(i) *Applicable rebate percentage for 2012 and 2013.* Subject to paragraphs (a)(2)(iii) and (iv) of this section, the transitional applicable rebate percentage is, for a year, the sum of two amounts as follows:

(A) *For 2012.* Two-thirds of the old proportion of 75 percent of the average per capita savings; and one-third of the new proportion assigned the plan under paragraph (a)(2)(ii) of this section, based on the quality rating specified in §422.258(d)(7).

(B) *For 2013.* One-third of the old proportion of 75 percent of the average per capita savings; and two-thirds of the new proportion assigned the plan under paragraph (d)(2)(ii) of this section, based on the quality rating at §422.258(d)(7).

(ii) *Final applicable rebate percentage.* For 2014 and subsequent years, and subject to paragraphs (a)(2)(iii) and (iv) of this section, the final applicable rebate percentage is as follows:

(A) In the case of a plan with a quality rating under such system of at least 4.5 stars, 70 percent of the average per capita savings;

(B) In the case of a plan with a quality rating under such system of at least 3.5 stars and less than 4.5 stars, 65 percent of the average per capita savings.

(C) In the case of a plan with a quality rating under such system of less than 3.5 stars, 50 percent of the average per capita savings.

(iii) *Treatment of low enrollment contracts.* For 2012, in the case of a plan described at §422.258(d)(7)(iv), the plan must be treated as having a rating of 4.5 stars for the purpose of determining the beneficiary rebate amount.

(iv) *Treatment of new MA plans.* For 2012 or a subsequent year, a new MA plan defined at §422.252 that meets the criteria specified by the Secretary for purposes of §422.258(d)(7)(v) must be treated as a qualifying plan under §422.258(d)(7)(i), except that plan must be treated as having a rating of 3.5 stars for purposes of determining the beneficiary rebate amount.

(b) *Form of rebate.* The rebate required under this paragraph must be provided by crediting the rebate amount to one or more of the following:

(1) *Supplemental health care benefits.* MA organizations may apply all or some portion of the rebate for a plan toward payment for non-drug supplemental health care benefits for enrollees as described in §422.102, which may include the reduction of cost sharing for benefits under original Medicare and additional health care benefits that are not benefits under original Medicare. MA organizations also may

apply all or some portion of the rebate for a plan toward payment for supplemental drug coverage described at § 423.104(f)(1)(ii), which may include reduction in cost sharing and coverage of drugs not covered under Part D. The rebate, or portion of rebate, applied toward supplemental benefits may only be applied to a mandatory supplemental benefit, and cannot be used to fund an optional supplemental benefit.

(2) *Payment of premium for prescription drug coverage.* MA organizations that offer a prescription drug benefit may credit some or all of the rebate toward reduction of the MA monthly prescription drug beneficiary premium.

(3) *Payment toward Part B premium.* MA organizations may credit some or all of the rebate toward reduction of the Medicare Part B premium (determined without regard to the application of subsections (b), (h), and (i) of section 1839 of the Act).

(c) *Disclosure relating to rebates.* MA organizations must disclose to CMS information on the amount of the rebate provided, as required at § 422.254(d). MA organizations must distinguish, for each MA plan, the amount of rebate applied to enhance original Medicare benefits from the amount of rebate applied to enhance Part D benefits.≤[70 FR 4725, Jan. 28, 2005, as amended at 76 FR 21567, Apr. 15, 2011]

§ 422.270 Incorrect collections of premiums and cost-sharing.

(a) *Definitions.* As used in this section-

(1) Amounts incorrectly collected-

(i) Means amounts that-

(A) Exceed the limits approved under § 422.262;

(B) In the case of an MA private fee-for-service plan, exceed the MA monthly basic beneficiary premium or the MA monthly supplemental premium submitted under § 422.262; and

(C) In the case of an MA MSA plan, exceed the MA monthly beneficiary supplemental premium submitted under § 422.262, or exceed permissible cost sharing amounts after the deductible has been met per § 422.103; and

(ii) Includes amounts collected from an enrollee who was believed to be entitled to Medicare benefits but was later found not to be entitled.

(2) *Other amounts due* are amounts due for services that were—

(i) Emergency, urgently needed services, or other services obtained outside the MA plan; or

(ii) Initially denied but, upon appeal, found to be services the enrollee was entitled to have furnished by the MA organization.

(b) *Basic commitments.* An MA organization must agree to refund all amounts incorrectly collected from its Medicare enrollees, or from others on behalf of the enrollees, and to pay any other amounts due the enrollees or others on their behalf.

(c) *Refund methods*—(1) *Lump-sum payment.* The MA organization must use lump-sum payments for the following:

(i) Amounts incorrectly collected that were not collected as premiums.

(ii) Other amounts due.

(iii) All amounts due if the MA organization is going out of business or terminating its MA contract for an MA plan(s).

(2) *Premium adjustment or lump-sum payment, or both.* If the amounts incorrectly collected were in the form of premiums, or included premiums as well as other charges, the MA organization may refund by adjustment of future premiums or by a combination of premium adjustment and lump-sum payments.

(3) *Refund when enrollee has died or cannot be located.* If an enrollee has died or cannot be located after reasonable effort, the MA organization must make the refund in accordance with State law.

(d) *Reduction by CMS.* If the MA organization does not make the refund required under this section by the end of the contract period following the contract period during which an amount was determined to be due to an enrollee, CMS will reduce the premium the MA organization is allowed to charge an MA plan enrollee by the amounts incorrectly collected or otherwise due. In addition, the MA organization would be subject to sanction under subpart O of this part for failure to refund amounts incorrectly collected from MA plan enrollees.

§ 422.272 Release of MA bid pricing data.

(a) *Terminology*. For purposes of this section, the term ''MA bid pricing data'' means the following information that MA organizations must submit for each MA plan bid for the annual bid submission:

(1) The pricing-related information described at § 422.254(a)(1); and

(2) The information required for MSA plans, described at § 422.254(e).

(b) *Release of MA bid pricing data*. Subject to paragraph (c) of this section and to the annual timing identified in paragraph (d) of this section, CMS will release to the public MA bid pricing data for MA plan bids accepted or approved by CMS for a contract year under § 422.256. The annual release will contain MA bid pricing data from the final list of MA plan bids accepted or approved by CMS for a contract year that is at least 5 years prior to the upcoming calendar year.

(c) *Exclusions from release of MA bid pricing data*. For the purpose of this section, the following information is excluded from the data released under paragraph (b) of this section:

(1) For an MA plan bid that includes Part D benefits, the information described at § 422.254(b)(1)(ii), (c)(3)(ii), and (c)(7).

(2) Additional information that CMS requires to verify the actuarial bases of the bids for MA plans for the annual bid submission, as follows:

(i) Narrative information on base period factors, manual rates, cost-sharing methodology, optional supplement benefits, and other required narratives.

(ii) Supporting documentation.

(3) Any information that could be used to identify Medicare beneficiaries or other individuals.

(4) Bid review correspondence and reports.

(d) *Timing of data release*. CMS will release MA bid pricing data as provided in paragraph (b) of this section on an annual basis after the first Monday in October.

[81 FR 80556, Nov. 15, 2016]

Subpart G—Payments to Medicare Advantage Organizations

SOURCE: 70 FR 4729, Jan. 28, 2005, unless otherwise noted.

§ 422.300 Basis and scope.

This subpart is based on sections 1106, 1128J(d), 1852, 1853, 1854, and 1858 of the Act. It sets forth the requirements for making payments to MA organizations offering local and regional MA policies, including calculation of MA capitation rates and benchmarks, conditions under which payment is based on plan bids, adjustments to capitation rates (including risk adjustment), collection of risk adjustment data, conditions for use and disclosure of risk adjustment data, collection of improper payments and other payment rules. Section 422.458 specifies the requirements for risk sharing payments to MA regional organizations.

[88 FR 6665, Feb. 1, 2023]

§ 422.304 Monthly payments.

(a) *General rules*. Except as provided in paragraph (b) of this section, CMS makes advance monthly payments of the amounts determined under paragraphs (a)(1) and (a)(2) of this section for coverage of original fee-for-service benefits for an individual in an MA payment area for a month.

(1) *Payment of bid for plans with bids below benchmark*. For MA plans that have average per capita monthly savings (as described at § 422.264(b) for local plans and § 422.264(d) for regional plans), CMS pays:

(i) The unadjusted MA statutory nondrug monthly bid amount defined in § 422.252, risk-adjusted as described at § 422.308(c) and adjusted (if applicable) for variations in rates within the plan's service area (described at § 422.258(a)(2)) and for the effects of risk adjustment on beneficiary premiums under § 422.262; and

(ii) The amount (if any) of the rebate described in paragraph (a)(3) of this section.

(2) *Payment of benchmark for plans with bids at or above benchmark*. For MA plans that do not have average per capita monthly savings (as described at

§ 422.264(b) for local plans and § 422.264(d) for regional plans), CMS pays the unadjusted MA area-specific non-drug monthly benchmark amount specified at § 422.258, risk-adjusted as described at § 422.308(c) and adjusted (if applicable) for variations in rates within the plan's service area (described at § 422.258(a)(2)) and for the effects of risk adjustment on beneficiary premiums under § 422.262.

(3) *Payment of rebate for plans with bids below benchmarks.* The rebate amount under paragraph (a)(1)(ii) of this section is the amount of the monthly rebate computed under § 422.266(a) for that plan, less the amount (if any) applied to reduce the Part B premium, as provided under § 422.266(b)(3)).

(b) *Separate payment for Federal drug subsidies.* In the case of an enrollee in an MA-PD plan, defined at § 422.252, the MA organization offering such a plan also receives-

(1) Direct and reinsurance subsidy payments for qualified prescription drug coverage, described at section 1860D–15(a) and (b) of the Act (other than payments for fallback prescription drug plans described at section 1860D–11(g)(5) of the Act); and

(2) Reimbursement for premium and cost sharing reductions for low-income individuals, described at section 1860D–14 of the Act.

(c) *Special rules*—(1) *Enrollees with end-stage renal disease.* (i) For enrollees determined to have end-stage renal disease (ESRD), CMS establishes special rates that are actuarially equivalent to rates in effect before the enactment of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003.

(ii) CMS publishes annual changes in these capitation rates no later than the first Monday in April each year, as provided in § 422.312.

(iii) CMS applies appropriate adjustments when establishing the rates, including risk adjustment factors.

(iv) CMS reduces the payment rate for each renal dialysis treatment by the same amount that CMS is authorized to reduce the amount of each composite rate payment for each treatment as set forth in section 1881(b)(7) of the Act. These funds are to be used to help pay for the ESRD network program in the same manner as similar reductions are used in original Medicare.

(2) *MSA enrollees.* In the case of an MSA plan, CMS pays the unadjusted MA area-specific non-drug monthly benchmark amount for the service area, determined in accordance with § 422.314(c) and subject to risk adjustment as set forth at § 422.308(c), less 1/12 of the annual lump sum amount (if any) CMS deposits to the enrollee's MA MSA.

(3) *RFB plan enrollees.* For RFB plan enrollees, CMS adjusts the capitation payments otherwise determined under this subpart to ensure that the payment level is appropriate for the actuarial characteristics and experience of these enrollees. That adjustment can be made on an individual or organization basis.

(d) *Payment areas*—(1) *General rule.* Except as provided in paragraph (e) of this section—

(i) An MA payment area for an MA local plan is an MA local area defined at § 422.252.

(ii) An MA payment area for an MA regional plan is an MA region, defined at § 422.455(b)(1).

(2) *Special rule for ESRD enrollees.* For ESRD enrollees, the MA payment area is a State or other geographic area specified by CMS.

(e) *Geographic adjustment of payment areas for MA local plans*—(1) *Terminology.* ''Metropolitan Statistical Area'' and ''Metropolitan Division'' mean any areas so designated by the Office of Management and Budget in the Executive Office of the President.

(2) *State request.* A State's chief executive may request, no later than February 1 of any year, a geographic adjustment of the State's payment areas for MA local plans for the following calendar year. The chief executive may request any of the following adjustments to the payment area specified in paragraph (c)(1)(i) of this section:

(i) A single statewide MA payment area.

(ii) A metropolitan-based system in which all non-metropolitan areas within the State constitute a single payment area and any of the following constitutes a separate MA payment area:

(A) All portions of each single Metropolitan Statistical Area within the State.

(B) All portions of each Metropolitan Statistical Area within each Metropolitan Division within the State.

(iii) A consolidation of noncontiguous counties.

(3) *CMS response.* In response to the request, CMS makes the payment adjustment requested by the chief executive. This adjustment cannot be requested or made for payments to regional MA plans.

(4) *Budget neutrality adjustment for geographically adjusted payment areas.* If CMS adjusts a State's payment areas in accordance with paragraph (d)(2) of this section, CMS at that time, and each year thereafter, adjusts the capitation rates so that the aggregate Medicare payments do not exceed the aggregate Medicare payments that would have been made to all the State's payments areas, absent the geographic adjustment.

(f) *Separate payment for meaningful use of certified EHRs.* In the case of qualifying MA organizations, as defined in § 495.200 of this chapter, entitled to MA EHR incentive payments per § 495.204 of this chapter, such payments are made in accordance with sections 1853(l) and (m) of the Act and subpart C of part 495 of this chapter.

[70 FR 4729, Jan. 28, 2005, as amended at 75 FR 44564, July 28, 2010; 85 FR 72909, Nov. 16, 2020]

§ 422.306 Annual MA capitation rates.

Subject to adjustments at §§ 422.308(b) and (g), the annual capitation rate for each MA local area is determined under paragraph (a) of this section for 2005 and each succeeding year, except for years when CMS announces under § 422.312(b) that the annual capitation rates will be determined under paragraph (b) of this section, and is then adjusted to exclude the applicable phase-in percentage of the standardized costs for payments under section 1886(d)(5)(B) of the Act in the area for the year under paragraph (c) of this section and costs for kidney acquisitions in the area for the year under paragraph (d) of this section.

(a) *Minimum percentage increase rate.* The annual capitation rate for each MA local area is equal to the minimum percentage increase rate, which is the annual capitation rate for the area for the preceding year increased by the national per capita MA growth percentage (defined at § 422.308(a)) for the year, but not taking into account any adjustment under § 422.308(b) for a year before 2004.

(b) *Greater of the minimum percentage increase rate or local area fee-for-service costs.* The annual capitation rate for each MA local area is the greater of—

(1) The minimum percentage increase rate under paragraph (a) of this section; or

(2) The amount determined, no less frequently than every 3 years, to be the adjusted average per capita cost for the MA local area, as determined under section 1876(a)(4) of the Act, based on 100 percent of fee-for-service costs for individuals who are not enrolled in an MA plan for the year, with the following adjustments:

(i) Adjusted as appropriate for the purpose of risk adjustment;

(ii) Adjusted to exclude costs attributable to payments under section 1886(h) of the Act for the costs of direct graduate medical education;

(iii) Adjusted to include CMS' estimate of the amount of additional per capita payments that would have been made in the MA local area if individuals entitled to benefits under this title had not received services from facilities of the Department of Defense or the Department of Veterans Affairs; and

(iv) Adjusted to exclude costs attributable to payments under sections 1848(o) and 1886(n) of the Act of Medicare FFS incentive payments for meaningful use of electronic health records.

(c) *Phase-out of the indirect costs of medical education from MA capitation rates.* Beginning with 2010, after the annual capitation rate for each MA local area is determined under paragraph (a) or (b), the amount is adjusted in accordance with section 1853(k)(4) of the Act to exclude from such amount the phase-in percentage for the year of the estimated costs for payments under section 1886(d)(5)(B) of the Act in the area for the year.

(d) *Exclusion of costs for kidney acquisitions from MA capitation rates.* Beginning with 2021, after the annual capitation rate for each MA local area is determined under paragraph (a) or (b) of this section, the amount is adjusted in accordance with section 1853(k)(5) of the Act to exclude the Secretary's estimate of the standardized costs for payments for organ acquisitions for kidney transplants covered under this title (including expenses covered under section 1881(d) of the Act) in the area for the year.

[70 FR 4729, Jan. 28, 2005, as amended at 73 FR 54250, Sept. 18, 2008; 75 FR 19806, Apr. 15, 2010; 75 FR 44564, July 28, 2010; 85 FR 33907, June 2, 2020]

§ 422.308 Adjustments to capitation rates, benchmarks, bids, and payments.

CMS performs the following calculations and adjustments to determine rates and payments:

(a) *National per capita growth percentage.* (1) The national per capita growth percentage for a year, applied under § 422.306, is CMS' estimate of the rate of growth in per capita expenditures under this title for an individual entitled to benefits under Part A and enrolled under Part B. CMS may make separate estimates for aged enrollees, disabled enrollees, and enrollees who have ESRD.

(2) The amount calculated in paragraph (a)(1) of this section must exclude expenditures attributable to sections 1848(a)(7) and (o) and sections 1886(b)(3)(B)(ix) and (n) of the Act.

(b) *Adjustment for over or under projection of national per capita growth percentages.* CMS will adjust the minimum percentage increase rate at § 422.306(a)(2) and the adjusted average per capita cost rate at § 422.306(b)(2) for the previous year to reflect any differences between the projected national per capita growth percentages for that year and previous years, and the current estimates of those percentages for those years. CMS will not make this adjustment for years before 2004.

(c) *Risk adjustment*—(1) *General rule.* CMS will adjust the payment amounts under § 422.304(a)(1), (a)(2), and (a)(3) for age, gender, disability status, institutional status, and other factors CMS determines to be appropriate, including health status, in order to ensure actuarial equivalence. CMS may add to, modify, or substitute for risk adjustment factors if those changes will improve the determination of actuarial equivalence.

(2) *Risk adjustment: Health status*—(i) *Data collection.* To adjust for health status, CMS applies a risk factor based on data obtained in accordance with § 422.310.

(ii) *Implementation.* CMS applies a risk factor that incorporates inpatient hospital and ambulatory risk adjustment data. This factor is phased as follows:

(A) 100 percent of payments for ESRD MA enrollees in 2005 and succeeding years.

(B) 75 percent of payments for aged and disabled enrollees in 2006.

(C) 100 percent of payments for aged and disabled enrollees in 2007 and succeeding years.

(3) *Uniform application.* Except as provided for MA RFB plans under § 422.304(c)(3), CMS applies this adjustment factor to all types of plans.

(4) *Authority to apply frailty adjustment under PACE payment rules for certain specialized MA plans for special needs individuals.* (i) *Application of payment rules.* For plan year 2011 and subsequent plan years, in the case of a plan described in paragraph (c)(4)(ii) of this section, the Secretary may apply the payment rules under section 1894(d) of the Act (other than paragraph (3) of that section) rather than the payment rules that would otherwise apply under this part, but only to the extent necessary to reflect the costs of treating high concentrations of frail individuals.

(ii) *Plan described.* A plan described in this paragraph is a fully integrated dual-eligible special needs plan, as defined at § 422.2, and has a similar average level of frailty (as determined by the Secretary) as the PACE program.

(5) *Application of coding adjustment.* (i) In applying the adjustment under paragraph (c)(1) of this section for health status to payment amounts, the Secretary ensures that such adjustment

reflects changes in treatment and coding practices in the fee-for-service sector and reflects differences in coding patterns between MA plans and providers under Part A and B to the extent that the Secretary has identified such differences.

(ii) In order to ensure payment accuracy, the Secretary annually conducts an analysis of the differences described in paragraph (c)(5)(i) of this section.

(A) The Secretary completes such analysis by a date necessary to ensure that the results of such analysis are incorporated on a timely basis into the risk scores for 2008 and subsequent years.

(B) In conducting such analysis, the Secretary uses data submitted with respect to 2004 and subsequent years, as available and updated as appropriate.

(iii) In calculating each year's adjustment, the adjustment factor is as follows:

(A) For 2014, not less than the adjustment factor applied for 2010, plus 1.3 percentage points.

(B) For each of the years 2015 through 2018, not less than the adjustment factor applied for the previous year, plus 0.25 percentage points.

(C) For 2019 and each subsequent year, not less than 5.7 percent.

(iv) Such adjustment is applied to risk scores until the Secretary implements risk adjustment using MA diagnostic, cost, and use data.

(6) *Improvements to risk adjustment for special needs individuals with chronic health conditions*—(i) *General rule.* For 2011 and subsequent years, for purposes of the adjustment under paragraph (c)(1) of this section with respect to individuals described in paragraph (c)(6)(ii) of the section, the Secretary uses a risk score that reflects the known underlying risk profile and chronic health status of similar individuals. Such risk score is used instead of the default risk score for new enrollees in MA plans that are not specialized MA plans for special needs individuals (as defined in section 1859(b)(6) of the Act).

(ii) *Individuals described.* An individual described in this clause is a special needs individual described in section 1859(b)(6)(B)(iii) of the Act who enrolls in a specialized MA plan for special needs individuals on or after January 1, 2011.

(iii) *Evaluation.* For 2011 and periodically thereafter, the Secretary evaluates and revises the risk adjustment system under this paragraph in order to, as accurately as possible, account for—

(A) Higher medical and care coordination costs associated with frailty, individuals with multiple, comorbid chronic conditions, and individuals with a diagnosis of mental illness; and

(B) Costs that may be associated with higher concentrations of beneficiaries with the conditions specified in paragraph (c)(6)(iii)(A) of this section.

(iv) *Publication of evaluation and revisions.* The Secretary publishes, as part of an announcement under section 1853(b) of the Act, a description of any evaluation conducted under paragraph (c)(6)(iii) of this section during the preceding year and any revisions made under paragraph (c)(6)(iii) of this section as a result of such evaluation.

(d) *Adjustment for intra-area variations.* CMS makes the following adjustments to payments.

(1) *Intra-regional variations.* For payments for an MA regional plan for an MA region, CMS will adjust the payment amount specified at § 422.304(a)(1) and (a)(2) to take into account variations in local payment rates among the different MA local areas included in the region.

(2) *Intra-service area variations.* For payments to an MA local plan with a service area covering more than one MA local area (county), CMS will adjust the payment amount specified in § 422.304(a)(1) and (a)(2) to take into account variations in local payment rates among the different MA local areas included in the plan's service area.

(e) *Adjustment relating to risk adjustment: the government premium adjustment.* CMS will adjust payments to an MA plan as necessary to ensure that the sum of CMS' monthly payment made under § 422.304(a) and the plan's monthly basic beneficiary premium equals the unadjusted MA statutory non-drug bid amount, adjusted for risk and for intra-area or intra-regional payment variation.

(f) *Adjustment of payments to reflect number of Medicare enrollees*—(1) *General rule.* CMS adjusts payments retroactively to take into account any difference between the actual number of Medicare enrollees and the number on which it based an advance monthly payment.

(2) *Special rules for certain enrollees.* (i) Subject to paragraph (f)(2)(ii) of this section, CMS may make adjustments, for a period (not to exceed 90 days) that begins when a beneficiary elects a group health plan (as defined in §411.1010) offered by an MA organization, and ends when the beneficiary is enrolled in an MA plan offered by the MA organization.

(ii) CMS does not make an adjustment unless the beneficiary certifies that, at the time of enrollment under the MA plan, he or she received from the organization the disclosure statement specified in §422.111.

(g) *Adjustment for national coverage determination (NCD) services and legislative changes in benefits.* If CMS determines that the cost of furnishing an NCD service or legislative change in benefits is significant, as defined in §422.109, CMS will adjust capitation rates, or make other payment adjustments, to account for the cost of the service or legislative change in benefits. Until the new capitation rates are in effect, the MA organization will be paid for the significant cost NCD service or legislative change in benefits on a fee-for-service basis as provided under §422.109(b).

(h) *Adjustments to payments to regional MA plans for purposes of risk corridor payments.* For the purpose of calculation of risk corridors under §422.458, MA organizations offering regional MA plans in 2006 and/or 2007 must submit, after the end of a contract year and before a date CMS specifies, the following information:

(1) Actual allowable costs (defined in §422.458(a)) for the previous contract year.

(2) The portion of the costs attributable to administrative expenses incurred in providing these benefits.

(3) The total costs for providing rebatable integrated benefits (as defined in §422.458(a)) and the portion of the costs that is attributable to administrative expenses in addition to the administrative expenses described in paragraph (h)(2) of this section.

[70 FR 4729, Jan. 28, 2005, as amended at 75 FR 44564, July 28, 2010; 76 FR 21567, Apr. 15, 2011]

§422.310 Risk adjustment data.

(a) *Definition of risk adjustment data.* Risk adjustment data are all data that are used in the development and application of a risk adjustment payment model.

(b) *Data collection: Basic rule.* Each MA organization must submit to CMS (in accordance with CMS instructions) the data necessary to characterize the context and purposes of each item and service provided to a Medicare enrollee by a provider, supplier, physician, or other practitioner. CMS may also collect data necessary to characterize the functional limitations of enrollees of each MA organization.

(c) *Sources and extent of data.* (1) To the extent required by CMS, risk adjustment data must account for the following:

(i) Items and services covered under the original Medicare program.

(ii) Medicare covered items and services for which Medicare is not the primary payer.

(iii) Other additional or supplemental benefits that the MA organization may provide.

(2) The data must account separately for each provider, supplier, physician, or other practitioner that would be permitted to bill separately under the original Medicare program, even if they participate jointly in the same service.

(d) *Other data requirements.* (1) MA organizations must submit data that conform to CMS' requirements for data equivalent to Medicare fee-for-service data, when appropriate, and to all relevant national standards. CMS may specify abbreviated formats for data submission required of MA organizations.

(2) The data must be submitted electronically to the appropriate CMS contractor.

(3) MA organizations must obtain the risk adjustment data required by CMS from the provider, supplier, physician,

or other practitioner that furnished the item or service.

(4) MA organizations may include in their contracts with providers, suppliers, physicians, and other practitioners, provisions that require submission of complete and accurate risk adjustment data as required by CMS. These provisions may include financial penalties for failure to submit complete data.

(5) For data described in paragraph (d)(1) of this section as data equivalent to Medicare fee-for-service data, which is also known as MA encounter data, MA organizations must submit a NPI in a billing provider field on each MA encounter data record, per CMS guidance.

(e) *Validation of risk adjustment data.* MA organizations and their providers and practitioners are required to submit a sample of medical records for the validation of risk adjustment data, as required by CMS. There may be penalties for submission of false data. MA organizations must remit improper payments based on RADV audits, in a manner specified by CMS. For RADV audits, CMS may extrapolate RADV Contract-Level audit findings for payment year 2018 and subsequent payment years.

(f) *Use and release of data*—(1) *CMS use of data.* CMS may use the data described in paragraphs (a) through (d) of this section for the following purposes:

(i) To determine the risk adjustment factors used to adjust payments, as required under §§ 422.304(a) and (c);

(ii) To update risk adjustment models;

(iii) To calculate Medicare DSH percentages;

(iv) To conduct quality review and improvement activities;

(v) For Medicare coverage purposes;

(vi) To conduct evaluations and other analysis to support the Medicare and Medicaid programs (including demonstrations) and to support public health initiatives and other health care-related research;

(vii) For activities to support the administration of the Medicare and Medicaid programs;

(viii) For activities conducted to support program integrity; and

(ix) For purposes authorized by other applicable laws.

(2) *CMS release of data.* Regarding data described in paragraphs (a) through (d) of this section, CMS may release the minimum data it determines is necessary for one or more of the purposes listed in paragraph (f)(1) of this section to other HHS agencies, other Federal executive branch agencies, States, and external entities in accordance with the following:

(i) Applicable Federal laws;

(ii) CMS data sharing procedures;

(iii) Subject to the protection of beneficiary identifier elements and beneficiary confidentiality, including—

(A) A prohibition against public disclosure of beneficiary identifying information;

(B) Release of beneficiary identifying information to other HHS agencies, other Federal executive branch agencies, and States only when such information is needed; and

(C) Release of beneficiary identifying information to external entities only to the extent needed to link datasets.

(iv) Subject to the aggregation of dollar amounts reported for the associated encounter to protect commercially sensitive data.

(v) Risk adjustment data other than data described in paragraphs (f)(2)(iii) and (f)(2)(iv) of this section will be released without the redaction or aggregation described in paragraphs (f)(2)(iii) and (f)(2)(iv) of this section, respectively.

(3) Risk adjustment data will not become available for release under this paragraph (f) unless—

(i) The risk adjustment reconciliation for the applicable payment year has been completed;

(ii) CMS determines that data release is necessary under paragraph (f)(1)(vi) of this section for emergency preparedness purposes before reconciliation; or

(iii) CMS determines that extraordinary circumstances exist to release the data before reconciliation.

(iv) CMS determines that releasing aggregated data before reconciliation is necessary and appropriate to support activities or authorized uses under paragraph (f)(1)(vii) of this section.

(v) CMS determines that releasing data to State Medicaid agencies before

reconciliation for the purpose of coordinating care for dually eligible individuals is necessary and appropriate to support activities or authorized uses under paragraph (f)(1)(vii) of this section.

(g) *Deadlines for submission of risk adjustment data.* Risk adjustment factors for each payment year are based on risk adjustment data submitted for items and services furnished during the 12-month period before the payment year that is specified by CMS. As determined by CMS, this 12-month period may include a 6-month data lag that may be changed or eliminated as appropriate. CMS may adjust these deadlines, as appropriate.

(1) The annual deadline for risk adjustment data submission is the first Friday in September for risk adjustment data reflecting items and services furnished during the 12-month period ending the prior June 30, and the first Friday in March for data reflecting services furnished during the 12-month period ending the prior December 31.

(2) After the payment year is completed, CMS recalculates the risk factors for affected individuals to determine if adjustments to payments are necessary.

(i) Prior to calculation of final risk factors for a payment year, CMS allows a reconciliation process to account for risk adjustment data submitted after the March deadline until the final risk adjustment data submission deadline in the year following the payment year.

(ii) After the final risk adjustment data submission deadline, which is a date announced by CMS that is no earlier than January 31 of the year following the payment year, an MA organization can submit data to correct overpayments but cannot submit diagnoses for additional payment.

(3) Submission of corrected risk adjustment data in accordance with overpayments after the final risk adjustment data submission deadline, as described in paragraph (g)(2) of this section, must be made as provided in § 422.326.

[73 FR 48757, Aug. 19, 2008, as amended at 79 FR 29956, May 23, 2014; 79 FR 50358, Aug. 22, 2014; 80 FR 7960, Feb. 12, 2015; 83 FR 16733, Apr. 16, 2018; 88 FR 6665, Feb. 1, 2023; 88 FR 79539, Nov. 16, 2023; 89 FR 30822, Apr. 23, 2024]

§ 422.311 RADV audit dispute and appeal processes.

(a) *Risk adjustment data validation (RADV) audits.* In accordance with §§ 422.2 and 422.310(e), the Secretary conducts RADV audits to ensure risk-adjusted payment integrity and accuracy.

(1) Recovery of improper payments from MA organizations is conducted in accordance with the Secretary's payment error extrapolation and recovery methodologies.

(2) CMS may apply extrapolation to audits for payment year 2018 and subsequent payment years.

(b) *RADV audit results.* (1) MA organizations that undergo RADV audits will be issued an audit report post medical record review that describes the results of the RADV audit as follows:

(i) Detailed enrollee-level information relating to confirmed enrollee HCC discrepancies.

(ii) The contract-level RADV payment error estimate in dollars.

(iii) The contract-level payment adjustment amount to be made in dollars.

(iv) An approximate timeframe for the payment adjustment.

(v) A description of the MA organization's RADV audit appeal rights.

(2) *Compliance date.* The compliance date for meeting RADV medical record submission requirements for the validation of risk adjustment data is the due date when MA organizations selected for RADV audit must submit medical records to the Secretary.

(c) *RADV audit appeals*—(1) *Appeal rights.* MA organizations that do not agree with their RADV audit results may appeal.

(2) *Issues eligible for RADV appeals*—(i) *General rules.* MA organizations may appeal RADV medical record review determinations and the Secretary's RADV payment error calculation. In order to be eligible for RADV appeal, MA organizations must adhere to the following:

(A) Established RADV audit procedures and requirements.

(B) RADV appeals procedures and requirements.

(ii) *Failure to follow RADV rules.* Failure to follow the Secretary's RADV audit procedures and requirements and the Secretary's RADV appeals procedures and requirements will render the MA organization's request for appeal invalid.

(iii) *RADV appeal rules.* The MA organization's written request for medical record review determination appeal must specify the following:

(A) The audited HCC(s) that the Secretary identified as being in error.

(B) A justification in support of the audited HCC selected for appeal.

(iv) *Number of medical records eligible for appeal.* For each audited HCC, MA organizations may appeal one medical record that has undergone RADV review. If an attestation was submitted to cure a signature or credential-related error, the attestation may be included in the HCC appeal.

(v) *Selection of medical record for appeal.* The MA organization must select the medical record that undergoes appeal.

(vi) *Written request for RADV payment error calculation appeal.* The written request for RADV payment error calculation appeal must clearly specify the following:

(A) The MA organization's own RADV payment error calculation.

(B) Where the Secretary's RADV payment error calculation was erroneous.

(3) *Issues ineligible for RADV appeals.* (i) MA organizations' request for appeal may not include HCCs, medical records or other documents beyond the audited HCC, RADV-reviewed medical record, and any accompanying attestation that the MA organization chooses for appeal.

(ii) MA organizations may not appeal the Secretary's medical record review determination methodology or RADV payment error calculation methodology.

(iii) As part of the RADV payment error calculation appeal— MA organizations may not appeal RADV medical record review-related errors.

(iv) MA organizations may not appeal RADV errors that result from an MA organization's failure to submit a medical record.

(4) *Burden of proof.* The MA organization bears the burden of proof by a preponderance of the evidence in demonstrating that the Secretary's medical record review determination(s) or payment error calculation was incorrect.

(5) *Manner and timing of a request for RADV appeal.* (i) At the time the Secretary issues its RADV audit report, the Secretary notifies audited MA organizations of the following:

(A) That they may appeal RADV HCC errors that are eligible for medical record review determination appeal.

(B) That they may appeal the Secretary's RADV payment error calculation.

(ii) MA organizations have 60 days from date of issuance of the RADV audit report to file a written request with CMS for RADV appeal. This request for RADV appeal must specify one of the following:

(A) Whether the MA organization requests medical record review determination appeal, the issues with which the MA organization disagrees, and the reasons for the disagreements.

(B) Whether the MA organization requests a payment error calculation appeal, the issues with which the MA organization disagrees, and the reasons for the disagreements. MA organizations will forgo their medical record review determination appeal if they choose to file only a payment error calculation appeal because medical record review determinations need to be final prior to adjudicating a payment error calculation appeal.

(iii) For MA organizations that intend to appeal both the medical record review determination and the RADV payment error calculation, an MA organization's request for appeal of its RADV payment error calculation may not be filed and will not be adjudicated until—

(A) The administrative appeal process for the RADV medical record review determinations filed by the MA organization has been exhausted; or

(B) The MA organization does not timely request a RADV medical record review determination appeal at the

hearing stage and/or the CMS Administrator review stage, as applicable.

(iv) An MA organization whose medical record review determination appeal has been completed as described in paragraph (c)(5)(iii) of this section has 60 days from the date of issuance of a revised RADV audit report, based on the final medical record review determination, to file a written request with CMS for a RADV payment error calculation appeal. This request for RADV payment error calculation appeal must clearly specify where the Secretary's RADV payment error calculation was erroneous, what the MA organization disagrees with, and the reasons for the disagreements.

(6) *Reconsideration stage*—(i) *Written request for medical record review reconsideration.* A MA organization's written request for medical record review determination reconsideration must specify the following:

(A) Any and all HCC(s) that the Secretary identified as being in error that the MA organization wishes to appeal.

(B) A justification in support of the audited HCC chosen for appeal.

(ii) *Written request for payment error calculation.* The MA organization's written request for payment error calculation reconsideration—

(A) Must include the MA organization's own RADV payment error calculation that clearly specifies where the Secretary's RADV payment error calculation was erroneous; and

(B) May include additional documentary evidence pertaining to the calculation of the payment error that the MA organization wishes the reconsideration official to consider.

(iii) *Conduct of the reconsideration.* (A) For medical record review determination reconsideration, a medical record review professional who was not involved in the initial medical record review determination of the disputed audited HCCs does the following:

(*1*) Reviews the medical record and accompanying dispute justification.

(*2*) Reconsiders the initial audited medical record review determination.

(B) For payment error calculation reconsideration, CMS ensures that a third party not involved in the initial RADV payment error calculation does the following:

(*1*) Reviews the Secretary's RADV payment error calculation.

(*2*) Reviews the MA organization's RADV payment error calculation;

(*3*) Recalculates the payment error in accordance with CMS's RADV payment error calculation procedures.

(iv) *Effect of the reconsideration official's decision.* (A) The reconsideration official issues a written reconsideration decision to the MA organization.

(B) The reconsideration official's decision is final unless it is reversed or modified by a final decision of the hearing officer as defined at §422.311(c)(7)(x).

(C) If the MA organization disagrees with the reconsideration official's decision, they may request a hearing in accordance with paragraph (c)(7) of this section.

(v) *Computations based on reconsideration official's decision.* (A) Once the reconsideration official's medical record review determination decision is considered final in accordance with paragraph (c)(6)(iv)(B) of this section, the Secretary recalculates the MA organization's RADV payment error and issues a revised RADV audit report superseding all prior RADV audit reports to the appellant MA organization.

(B) For MA organizations appealing the RADV payment error calculation only, once the reconsideration official's payment error calculation decision is considered final in accordance with paragraph (c)(6)(iv)(B) of this section, the Secretary recalculates the MA organization's RADV payment error and issues a revised RADV audit report superseding all prior RADV audit reports to the appellant MA organization.

(7) *Hearing stage*—(i) *Errors eligible for hearing.* At the time the reconsideration official issues his or her reconsideration determination to the MA organization, the reconsideration official notifies the MA organization of any RADV HCC errors or payment error-calculations that are eligible for RADV hearing.

(ii) *General hearing rules.* A MA organization that requests a RADV hearing must do so in writing in accordance with procedures established by CMS.

(iii) *Written request for hearing.* The written request for a hearing must be

filed with the Hearing Officer within 60 days of the date the MA organization receives the reconsideration officer's written reconsideration decision.

(A) If the MA organization appeals medical record review reconsideration determination, the written request for RADV hearing must—

(*1*) Include a copy of the written decision of the reconsideration official;

(*2*) Specify the audited HCCs that the reconsideration official confirmed as being in error; and

(*3*) Specify a justification why the MA organization disputes the reconsideration official's determination.

(B) If the MA organization appeals the RADV payment error calculation reconsideration determination, the written request for RADV hearing must include the following:

(*1*) A copy of the written decision of the reconsideration official.

(*2*) The MA organization's own RADV payment error calculation that clearly specifies where the Secretary's payment error calculation was erroneous.

(iv) *Designation of hearing officer*. A hearing officer will conduct the RADV hearing.

(v) *Disqualification of the hearing officer*. (A) A hearing officer may not conduct a hearing in a case in which he or she is prejudiced or partial to any party or has any interest in the matter pending for decision.

(B) A party to the hearing who objects to the designated hearing officer must notify that officer in writing at the earliest opportunity.

(C) The hearing officer must consider the objections, and may, at his or her discretion, either proceed with the hearing or withdraw.

(D) If the hearing officer withdraws, another hearing officer conducts the hearing.

(E) If the hearing officer does not withdraw, the objecting party may, after the hearing, present objections and request that the officer's decision be revised or a new hearing be held before another hearing officer. The objections must be submitted in writing to the Secretary.

(vi) *Hearing Officer review*. The hearing officer reviews the following:

(A) For a medical record review determination appeal, the hearing officer reviews all of the following:

(*1*) The RADV-reviewed medical record and any accompanying attestation that the MA organization selected for review.

(*2*) The reconsideration official's written determination.

(*3*) The written brief submitted by the MA organization or the Secretary in response to the reconsideration official's determination.

(B) For a payment error calculation appeal, the hearing officer reviews all of the following:

(*1*) The reconsideration official's written determination.

(*2*) Briefs addressing the reconsideration decision.

(vii) *Hearing procedures*—(A) *Authority of the Hearing Officer*. The hearing officer has full power to make rules and establish procedures, consistent with the law, regulations, and the Secretary rulings. These powers include the authority to dismiss the appeal with prejudice and take any other action which the hearing officer considers appropriate, including for failure to comply with such rules and procedures.

(B) *The hearing is on the record*. (*1*) Except as specified in paragraph (c)(viii)(B)(*2*) of this section, the hearing officer is limited to the review of the record.

(*2*)(*i*) Subject to the hearing officer's full discretion, the parties may request a live or telephonic hearing regarding some or all of the disputed medical records.

(*ii*) The hearing officer may, on his or her own-motion, schedule a live or telephonic hearing.

(*3*) The record is comprised of the following:

(*i*) *Written decisions* described at paragraphs (c)(6)(iv) and (7)(vi) of this section.

(*ii*) Written briefs from the MA organization explaining why they believe the reconsideration official's determination was incorrect.

(*iii*) The Secretary's optional brief that responds to the MA organization's brief—

(*4*) The hearing officer neither receives testimony nor accepts any new evidence that is not part of the record.

(*5*) Either the MA organization or the Secretary may ask the hearing officer to rule on a motion for summary judgment.

(viii) *Hearing Officer decision.* The hearing officer decides whether to uphold or overturn the reconsideration official's decision, and sends a written determination to CMS and the MA organization, explaining the basis for the decision.

(ix) *Computations based on Hearing Officer's decision.* (A) Once the hearing officer's medical record review determination decision is considered final in accordance with paragraph (c)(7)(x) of this section, the Secretary recalculates the MA organization's RADV payment error and issues a revised RADV audit report superseding all prior RADV audit reports to the appellant MA organization.

(B) For MA organizations appealing the RADV payment error calculation only, once the hearing officer's payment error calculation decision is considered final in accordance with paragraph (c)(7)(x) of this section, the Secretary recalculates the MA organization's RADV payment error and issues a revised RADV audit report superseding all prior RADV audit reports to the appellant MA organization.

(x) *Effect of the Hearing Officer's decision.* The hearing officer's decision is final unless the decision is reversed or modified by the CMS Administrator.

(8) *CMS Administrator review stage.* (i) A request for CMS Administrator review must be made in writing and filed with the CMS Administrator.

(ii) CMS or a MA organization that has received a hearing officer's decision and requests review by the CMS Administrator must do so within 60 days of receipt of the hearing officer's decision.

(iii) After reviewing a request for review, the CMS Administrator has the discretion to elect to review the hearing officer's decision or to decline to review the hearing officer's decision. If the CMS Administrator does not decline to review or does not elect to review within 90 days of receipt of either the MA organization or CMS's timely request for review (whichever is later), the hearing officer's decision becomes final.

(iv) If the CMS Administrator elects to review the hearing decision—

(A) The CMS Administrator acknowledges the decision to review the hearing decision in writing and notifies CMS and the MA organization of their right to submit comments within 15 days of the date of the issuance of the notification that the Administrator has elected to review the hearing decision; and

(B) [Reserved]

(v) The CMS Administrator renders his or her final decision in writing within 60 days of the date of the issuance of the notice acknowledging his or her decision to elect to review the hearing officer's decision.

(vi) The decision of the hearing officer is final if the CMS Administrator—

(A) Declines to review the hearing officer's decision; or

(B) Does not decline to review or elect to review within 90 days of the date of the receipt of either the MA organization or CMS's request for review (whichever is later); or

(C) Does not make a decision within 60 days of the date of the issuance of the notice acknowledging his or her decision to elect to review the hearing officer's decision.

(vii) *Computations based on CMS Administrator decision.* (A) Once the CMS Administrator's medical record review determination decision is considered final in accordance with paragraph (c)(8)(vi) of this section, the Secretary recalculates the MA organization's RADV payment error and issues a revised RADV audit report superseding all prior RADV audit reports to the appellant MA organization.

(B) For MA organizations appealing the RADV payment error calculation only, once the CMS Administrator's payment error calculation decision is considered final in accordance with paragraph (c)(8)(vi) of this section, the Secretary recalculates the MA organization's RADV payment error and issues a revised and final RADV audit report superseding all prior RADV audit reports to the appellant MA organization.

(9) *Final agency action.* In cases when an MA organization files a payment error calculation appeal subsequent to a medical record review determination

appeal that has completed the administrative appeals process, the medical record review determination appeal final decision and the payment error calculation appeal final decision will not be considered a final agency action until the payment error calculation appeal has completed the administrative appeals process and a final revised audit report superseding all prior RADV audit reports has been issued to the appellant MA organization.

[75 FR 19806, Apr. 15, 2010; 75 FR 32859, June 10, 2010; as amended at 79 FR 29956, May 23, 2014; 88 FR 6665, Feb. 1, 2023; 89 FR 30822, Apr. 23, 2024]

§ 422.312 Announcement of annual capitation rate, benchmarks, and methodology changes.

(a) *Capitation rates*—(1) *Initial announcement.* Not later than the first Monday in April each year, CMS announces to MA organizations and other interested parties the following information for each MA payment area for the following calendar year:

(i) The annual MA capitation rate.

(ii) The risk and other factors to be used in adjusting those rates under § 422.308 for payments for months in that year.

(2) CMS includes in the announcement an explanation of assumptions used and a description of the risk and other factors.

(3) *Regional benchmark announcement.* Before the beginning of each annual, coordinated election period under § 422.62(a)(2), CMS will announce to MA organizations and other interested parties the MA region-specific non-drug monthly benchmark amount for the year involved for each MA region and each MA regional plan for which a bid was submitted under § 422.256.

(b) *Advance notice of changes in methodology.* (1) No later than 60 days before making the announcement under paragraph (a)(1) of this section, CMS notifies MA organizations of changes it proposes to make in the factors and the methodology it used in the previous determination of capitation rates.

(2) The MA organizations have 30 days to comment on the proposed changes.

[70 FR 4729, Jan. 28, 2005, as amended at 85 FR 33908, June 2, 2020]

§ 422.314 Special rules for beneficiaries enrolled in MA MSA plans.

(a) *Establishment and designation of medical savings account (MSA).* A beneficiary who elects coverage under an MA MSA plan—

(1) Must establish an MA MSA with a trustee that meets the requirements of paragraph (b) of this section; and

(2) If he or she has more than one MA MSA, designate the particular account to which payments under the MA MSA plan are to be made.

(b) *Requirements for MSA trustees.* An entity that acts as a trustee for an MA MSA must—

(1) Register with CMS;

(2) Certify that it is a licensed bank, insurance company, or other entity qualified, under sections 408(a)(2) or 408(h) of the Internal Revenue Code of 1986, to act as a trustee of individual retirement accounts;

(3) Agree to comply with the MA MSA provisions of section 138 of the Internal Revenue Code of 1986; and

(4) Provide any other information that CMS may require.

(c) *Deposit in the MA MSA.* (1) The payment is calculated as follows:

(i) The monthly MA MSA premium is compared with 1/12 of the annual capitation rate applied under this section for the.

(ii) If the monthly MA MSA premium is less than 1/12 of the annual capitation rate applied under this section for the area, the difference is the amount to be deposited in the MA MSA for each month for which the beneficiary is enrolled in the MSA plan.

(2) CMS deposits the full amount to which a beneficiary is entitled under paragraph (c)(1)(ii) of this section for the calendar year, beginning with the month in which MA MSA coverage begins.

(3) If the beneficiary's coverage under the MA MSA plan ends before the end of the calendar year, CMS recovers the amount that corresponds to the remaining months of that year.

[70 FR 4729, Jan. 28, 2005, as amended at 70 FR 52027, Sept. 1, 2005]

§ 422.316 Special rules for payments to Federally qualified health centers.

If an enrollee in an MA plan receives a service from a Federally qualified

health center (FQHC) that has a written agreement with the MA organization offering the plan concerning the provision of this service (including the agreement required under section 1857(e)(3) of the Act and as codified in § 422.527)—

(a) CMS will pay the amount determined under section 1833(a)(3)(B) of the Act directly to the FQHC at a minimum on a quarterly basis, less the amount the FQHC would receive for the MA enrollee from the MA organization (which includes the cost sharing amount the FQHC may charge an enrollee, as established in the contract between the FQHC and the MA organization); and

(b) CMS will not reduce the amount of the monthly payments under this section as a result of the application of paragraph (a) of this section.

[70 FR 4729, Jan. 28, 2005, as amended at 70 FR 76198, Dec. 23, 2005]

§ 422.318 Special rules for coverage that begins or ends during an inpatient hospital stay.

(a) *Applicability*. This section applies to inpatient services in a ''subsection (d) hospital'' as defined in section 1886(d)(1)(B) of the Act, a psychiatric hospital described in section 1886(d)(1)(B)(i) of the act, a rehabilitation hospital described in section 1886(d)(1)(B)(ii) of the Act, a distinct part rehabilitation unit described in the matter following clause (v) of section 1886(d)(1)(B) of the Act, or a long-term care hospital (described in section 1886(d)(1)(B)(iv)).

(b) *Coverage that begins during an inpatient stay*. If coverage under an MA plan offered by an MA organization begins while the beneficiary is an inpatient in one of the facilities described in paragraph (a) of this section—

(1) Payment for inpatient services until the date of the beneficiary's discharge is made by the previous MA organization or original Medicare, as appropriate;

(2) The MA organization offering the newly-elected MA plan is not responsible for the inpatient services until the date after the beneficiary's discharge; and

(3) The MA organization offering the newly-elected MA plan is paid the full amount otherwise payable under this subpart.

(c) *Coverage that ends during an inpatient stay*. If coverage under an MA plan offered by an MA organization ends while the beneficiary is an inpatient in one of the facilities described in paragraph (a) of this section—

(1) The MA organization is responsible for the inpatient services until the date of the beneficiary's discharge;

(2) Payment for those services during the remainder of the stay is not made by original Medicare or by any succeeding MA organization offering a newly-elected MA plan; and

(3) The MA organization that no longer provides coverage receives no payment for the beneficiary for the period after coverage ends.

§ 422.320 Special rules for hospice care.

(a) *Information*. An MA organization that has a contract under subpart K of this part must inform each Medicare enrollee eligible to select hospice care under § 418.24 of this chapter about the availability of hospice care (in a manner that objectively presents all available hospice providers, including a statement of any ownership interest in a hospice held by the MA organization or a related entity) if—

(1) A Medicare hospice program is located within the plan's service area; or

(2) It is common practice to refer patients to hospice programs outside that area.

(b) *Enrollment status*. Unless the enrollee disenrolls from the MA plan, a beneficiary electing hospice continues his or her enrollment in the MA plan and is entitled to receive, through the MA plan, any benefits other than those that are the responsibility of the Medicare hospice.

(c) *Payment*. (1) No payment is made to an MA organization on behalf of a Medicare enrollee who has elected hospice care under § 418.24 of this chapter, except for the portion of the payment attributable to the beneficiary rebate for the MA plan, described in § 422.266(b)(1) plus the amount of the monthly prescription drug payment described in § 423.315 (if any). This no-payment rule is effective from the first day of the month following the month

of election to receive hospice care, until the first day of the month following the month in which the election is terminated.

(2) During the time the hospice election is in effect, CMS' monthly capitation payment to the MA organization is reduced to the sum of—

(i) An amount equal to the beneficiary rebate for the MA plan, as described in § 422.304(a)(3) or to zero for plans with no beneficiary rebate, described at § 422.304(a)(2); and

(ii) The amount of the monthly prescription drug payment described in § 423.315 (if any).

(3) In addition, CMS pays through the original Medicare program (subject to the usual rules of payment)—

(i) The hospice program for hospice care furnished to the Medicare enrollee; and

(ii) The MA organization, provider, or supplier for other Medicare-covered services to the enrollee.

[70 FR 4729, Jan. 28, 2005, as amended at 70 FR 52027, Sept. 1, 2005]

§ 422.322 Source of payment and effect of MA plan election on payment.

(a) *Source of payments.* (1) Payments under this subpart for original fee-for-service benefits to MA organizations or MA MSAs are made from the Federal Hospital Insurance Trust Fund or the Supplementary Medical Insurance Trust Fund. CMS determines the proportions to reflect the relative weight that benefits under Part A, and benefits under Part B represents of the actuarial value of the total benefits under title XVIII of the Act.

(2) Payments to MA-PD organizations for statutory drug benefits provided under this title are made from the Medicare Prescription Drug Account in the Federal Supplementary Medical Insurance Trust Fund.

(3) Payments under subpart C of part 495 of this chapter for meaningful use of certified EHR technology are made from the Federal Hospital Insurance Trust Fund or the Supplementary Medical Insurance Trust Fund. In applying section 1848(o) of the Act under sections 1853(l) and 1886(n)(2)of the Act under section 1853(m) of the Act, CMS determines the amount to the extent feasible and practical to be similar to the estimated amount in the aggregate that would be payable for services furnished by professionals and hospitals under Parts B and A, respectively, under title XVIII of the Act.

(b) *Payments to the MA organization.* Subject to §§ 412.105(g), 413.76, and 495.204 of this chapter and §§ 422.109, 422.316, and 422.320, CMS' payments under a contract with an MA organization (described in § 422.304) with respect to an individual electing an MA plan offered by the organization are instead of the amounts which (in the absence of the contract) would otherwise be payable under original Medicare for items and services furnished to the individual.

(c) *Only the MA organization entitled to payment.* Subject to §§ 422.314, 422.316, 422.318, 422.320, and 422.520 and sections 1886(d)(11) and 1886(h)(3)(D) of the Act, only the MA organization is entitled to receive payment from CMS under title XVIII of the Act for items and services furnished to the individual.

(d) *FFS payment for expenses for kidney acquisitions.* Paragraphs (b) and (c) of this section do not apply with respect to expenses for organ acquisitions for kidney transplants described in section 1852(a)(1)(B)(i) of the Act.

[70 FR 4729, Jan. 28, 2005, as amended at 70 FR 52027, Sept. 1, 2005; 75 FR 44654, July 28, 2010; 85 FR 33908, June 2, 2020; 85 FR 72909, Nov. 16, 2020]

§ 422.324 Payments to MA organizations for graduate medical education costs.

(a) MA organizations may receive direct graduate medical education payments for the time that residents spend in non-hospital provider settings such as freestanding clinics, nursing homes, and physicians' offices in connection with approved programs.

(b) MA organizations may receive direct graduate medical education payments if all of the following conditions are met:

(1) The resident spends his or her time assigned to patient care activities.

(2) The MA organization incurs ''all or substantially all'' of the costs for the training program in the non-hospital setting as defined in § 413.75(b) of this chapter.

(3) There is a written agreement between the MA organization and the non-hospital site that indicates the MA organization will incur the costs of the resident's salary and fringe benefits and provide reasonable compensation to the non-hospital site for teaching activities.

(c) An MA organization's allowable direct graduate medical education costs, subject to the redistribution and community support principles specified in § 413.85(c) of this chapter, consist of—

(1) Residents' salaries and fringe benefits (including travel and lodging where applicable); and

(2) Reasonable compensation to the non-hospital site for teaching activities related to the training of medical residents.

(d) The direct graduate medical education payment is equal to the product of—

(1) The lower of—

(i) The MA organization's allowable costs per resident as defined in paragraph (c) of this section; or

(ii) The national average per resident amount; and

(2) Medicare's share, which is equal to the ratio of the number of Medicare beneficiaries enrolled to the total number of individuals enrolled in the MA organization.

(e) Direct graduate medical education payments made to MA organizations under this section are made from the Federal Supplementary Medical Insurance Trust Fund.

[70 FR 4729, Jan. 28, 2005, as amended at 85 FR 72909, Nov. 16, 2020]

§ 422.326 Reporting and returning of overpayments.

(a) *Terminology*. For purposes of this section—

Applicable reconciliation occurs on the date of the annual final deadline for risk adjustment data submission described at § 422.310(g), which is announced by CMS each year.

Funds means any payment that an MA organization has received that is based on data submitted by the MA organization to CMS for payment purposes, including § 422.308(f) and § 422.310.

Overpayment means any funds that an MA organization has received or retained under title XVIII of the Act to which the MA organization, after applicable reconciliation, is not entitled under such title.

(b) *General rule*. If an MA organization has identified that it has received an overpayment, the MA organization must report and return that overpayment in the form and manner set forth in this section.

(c) *Identified overpayment*. The MA organization has identified an overpayment when the MA organization knowingly receives or retains an overpayment. The term ''knowingly'' has the meaning set forth in 31 U.S.C. 3729(b)(1)(A).

(d) *Reporting and returning of an overpayment*. An MA organization must report and return any overpayment it received no later than 60 days after the date on which it identified it received an overpayment, unless otherwise directed by CMS for purposes of § 422.311.

(1) *Reporting*. An MA organization must notify CMS, of the amount and reason for the overpayment, using a notification process determined by CMS.

(2) *Returning*. An MA organization must return identified overpayments in a manner specified by CMS.

(e) *Enforcement*. Any overpayment retained by an MA organization is an obligation under 31 U.S.C. 3729(b)(3) if not reported and returned in accordance with paragraph (d) of this section.

(f) *Look-back period*. An MA organization must report and return any overpayment identified for the 6 most recent completed payment years.

[79 FR 29958, May 23, 2014, as amended at 89 FR 98565, Dec. 9, 2024]

§ 422.330 CMS-identified overpayments associated with payment data submitted by MA organizations.

(a) *Definitions*. For purposes of this section—

Applicable reconciliation date occurs on the date of the annual final deadline for risk adjustment data submission described at § 422.310(g)(2)(ii).

Erroneous payment data means payment data that should not have been submitted either because the data submitted are inaccurate or because the data are inconsistent with Medicare Part C requirements.

Payment data means data submitted by an MA organization to CMS and used for payment purposes, including enrollment data and data submitted under § 422.310.

(b) *Request to correct payment data.* (1) When CMS identifies erroneous payment data submitted by an MA organization (other than an error identified through the process described in § 422.311), CMS may send a data correction notice to the MA organization requesting that the MA organization correct the payment data.

(2) The notice will include or make reference to the specific payment data that need to be corrected, the reason why CMS believes that the payment data are erroneous, and the timeframe for correcting the payment data.

(c) *Payment offset.* (1) If the MA organization fails to submit the corrected payment data within the timeframe as requested in accordance with paragraph (b) of this section, CMS will conduct a payment offset against payments made to the MA organization if—

(i) The payment error affects payments for any of the 6 most recently completed payment years; and

(ii) The payment error for a particular payment year is identified after the applicable reconciliation date for that payment year.

(2) CMS will calculate the payment offset amount using the correct payment data and a payment algorithm that applies the payment rules for the applicable year.

(d) *Payment offset notification.* CMS will issue a payment offset notice to the MA organization that includes at least the following:

(1) The dollar amount of the offset from plan payments.

(2) An explanation of how the erroneous data were identified and used to calculate the payment offset amount.

(3) An explanation that, if the MA organization disagrees with the payment offset, it may request an appeal within 30 days of issuance of the payment offset notification.

(e) *Appeals process.* If an MA organization does not agree with the payment offset described in paragraph (c) of this section, it may appeal under the following three-level appeal process:

(1) *Reconsideration.* An MA organization may request reconsideration of the payment offset described in paragraph (c) of this section, according to the following process:

(i) *Manner and timing of request.* A written request for reconsideration must be filed within 30 days from the date that CMS issued the payment offset notice to the MA organization.

(ii) *Content of request.* The written request for reconsideration must specify the findings or issues with which the MA organization disagrees and the reasons for its disagreement. As part of its request for reconsideration, the MA organization may include any additional documentary evidence in support of its position. Any additional evidence must be submitted with the request for reconsideration. Additional information submitted after this time will be rejected as untimely.

(iii) *Conduct of reconsideration.* In conducting the reconsideration, the CMS reconsideration official reviews the underlying data that were used to determine the amount of the payment offset and any additional documentary evidence timely submitted by the MA organization.

(iv) *Reconsideration decision.* The CMS reconsideration official informs the MA organization of its decision on the reconsideration request.

(v) *Effect of reconsideration decision.* The decision of the CMS reconsideration official is final and binding unless a timely request for an informal hearing is filed in accordance with paragraph (e)(2) of this section.

(2) *Informal hearing.* An MA organization dissatisfied with CMS' reconsideration decision made under paragraph (e)(1) of this section is entitled to an informal hearing as provided for under paragraphs (e)(2)(i) through (e)(2)(v) of this section.

(i) *Manner and timing for request.* A request for an informal hearing must be made in writing and filed with CMS within 30 days of the date of CMS' reconsideration decision.

(ii) *Content of request.* The request for an informal hearing must include a copy of the reconsideration decision and must specify the findings or issues

in the decision with which the MA organization disagrees and the reasons for its disagreement.

(iii) *Informal hearing procedures.* The informal hearing will be conducted in accordance with the following:

(A) CMS provides written notice of the time and place of the informal hearing at least 30 days before the scheduled date.

(B) The informal hearing is conducted by a CMS hearing officer who neither receives testimony nor accepts any new evidence that was not timely presented with the reconsideration request. The CMS hearing officer is limited to the review of the record that was before the CMS reconsideration official when CMS made its reconsideration determination.

(C) The CMS hearing officer will review the proceeding before the CMS reconsideration official on the record made before the CMS reconsideration official using the clearly erroneous standard of review.

(iv) *Decision of the CMS hearing officer.* The CMS hearing officer decides the case and sends a written decision to the MA organization explaining the basis for the decision.

(v) *Effect of hearing officer's decision.* The hearing officer's decision is final and binding, unless the decision is reversed or modified by the Administrator in accordance with paragraph (e)(3) of this section.

(3) *Review by the Administrator.* The Administrator review will be conducted in the following manner:

(i) An MA organization that has received a hearing officer's decision may request review by the Administrator within 30 days of the date of issuance of the hearing officer's decision under paragraph (e)(2)(iv) of this section. The MA organization may submit written arguments to the Administrator for review.

(ii) After receiving a request for review, the Administrator has the discretion to elect to review the hearing officer's determination in accordance with paragraph (e)(3)(iv) of this section or to decline to review the hearing officer's decision.

(iii) If the Administrator declines to review the hearing officer's decision, the hearing officer's decision is final and binding.

(iv) If the Administrator elects to review the hearing officer's decision, the Administrator will review the hearing officer's decision, as well as any information included in the record of the hearing officer's decision and any written argument submitted by the MA organization, and determine whether to uphold, reverse, or modify the hearing officer's decision.

(v) The Administrator's determination is final and binding.

(f) *Matters subject to appeal and burden of proof.* (1) The MA organization's appeal is limited to CMS' finding that the payment data submitted by the MA organization are erroneous.

(2) The MA organization bears the burden of proof by a preponderance of the evidence in demonstrating that CMS' finding that the payment data were erroneous was incorrect or otherwise inconsistent with applicable program requirements.

(g) *Applicability of appeals process.* The appeals process under paragraph (e) of this section applies only to payment offsets under paragraph (c) of this section.

[79 FR 67031, Nov. 10, 2014]

Subpart H—Provider-Sponsored Organizations

EDITORIAL NOTE: Nomenclature changes to subpart H of part 422 appear at 63 FR 35098, 35099, June 26, 1998.

§ 422.350 Basis, scope, and definitions.

(a) *Basis and scope.* This subpart is based on sections 1851 and 1855 of the Act which, in part,—

(1) Authorize provider sponsored organizations, (PSOs), to contract as a MA plan;

(2) Require that a PSO meet certain qualifying requirements; and

(3) Provide for waiver of State licensure for PSOs under specified conditions.

(b) *Definitions.* As used in this subpart (unless otherwise specified)—

Capitation payment means a fixed per enrollee per month amount paid for contracted services without regard to

the type, cost, or frequency of services furnished.

Cash equivalent means those assets excluding accounts receivable that can be exchanged on an equivalent basis as cash, or converted into cash within 90 days from their presentation for exchange.

Control means that an individual, group of individuals, or entity has the power, directly or indirectly, to direct or influence significantly the actions or policies of an organization or institution.

Current ratio means total current assets divided by total current liabilities.

Deferred acquisition costs are those costs incurred in starting or purchasing a business. These costs are capitalized as intangible assets and carried on the balance sheet as deferred charges since they benefit the business for periods after the period in which the costs were incurred.

Engaged in the delivery of health care services means—

(1) For an individual, that the individual directly furnishes health care services, or

(2) For an entity, that the entity is organized and operated primarily for the purpose of furnishing health care services directly or through its provider members or entities.

Generally accepted accounting principles (GAAP) means broad rules adopted by the accounting profession as guides in measuring, recording, and reporting the financial affairs and activities of a business to its owners, creditors and other interested parties.

Guarantor means an entity that—

(1) Has been approved by CMS as meeting the requirements to be a guarantor; and

(2) Obligates its resources to a PSO to enable the PSO to meet the solvency requirements required to contract with CMS as an MA organization.

Health care delivery assets (HCDAs) means any tangible assets that are part of a PSO's operation, including hospitals and other medical facilities and their ancillary equipment, and such property as may be reasonably required for the PSO's principal office or for such other purposes as the PSO may need for transacting its business.

Insolvency means a condition in which the liabilities of the debtor exceed the fair valuation of its assets.

Net worth means the excess of total assets over total liabilities, excluding fully subordinated debt or subordinated liabilities.

Provider-sponsored organization (PSO) means a public or private entity that—

(1) Is established or organized, and operated, by a provider or group of affiliated providers;

(2) Provides a substantial proportion (as defined in §422.352) of the health care services under the MA contract directly through the provider or affiliated group of providers; and

(3) When it is a group, is composed of affiliated providers who—

(i) Share, directly or indirectly, substantial financial risk, as determined under §422.356, for the provision of services that are the obligation of the PSO under the MA contract; and

(ii) Have at least a majority financial interest in the PSO.

Qualified actuary means a member in good standing of the American Academy of Actuaries or a person recognized by the Academy as qualified for membership, or a person who has otherwise demonstrated competency in the field of actuarial determination and is satisfactory to CMS.

Statutory accounting practices means those accounting principles or practices prescribed or permitted by the domiciliary State insurance department in the State that PSO operates.

Subordinated debt means an obligation that is owed by an organization, that the creditor of the obligation, by law, agreement, or otherwise, has a lower repayment rank in the hierarchy of creditors than another creditor. The creditor would be entitled to repayment only after all higher ranking creditors' claims have been satisfied. A debt is fully subordinated if it has a lower repayment rank than all other classes of creditors.

Subordinated liability means claims liabilities otherwise due to providers that are retained by the PSO to meet net worth requirements and are fully subordinated to all other creditors.

Uncovered expenditures means those expenditures for health care services

that are the obligation of an organization, for which an enrollee may also be liable in the event of the organization's insolvency and for which no alternative arrangements have been made that are acceptable to CMS. They include expenditures for health care services for which the organization is at risk, such as out-of-area services, referral services and hospital services. However, they do not include expenditures for services when a provider has agreed not to bill the enrollee.

[63 FR 18134, Apr. 14, 1998, as amended at 63 FR 25376, May 7, 1998; 63 FR 35098, June 26, 1998]

§ 422.352 Basic requirements.

(a) *General rule.* An organization is considered a PSO for purposes of a MA contract if the organization—

(1) Has obtained a waiver of State licensure as provided for under § 422.370;

(2) Meets the definition of a PSO set forth in § 422.350 and other applicable requirements of this subpart; and

(3) Is effectively controlled by the provider or, in the case of a group, by one or more of the affiliated providers that established and operate the PSO.

(b) *Provision of services.* A PSO must demonstrate to CMS's satisfaction that it is capable of delivering to Medicare enrollees the range of services required under a contract with CMS. Each PSO must deliver a substantial proportion of those services directly through the provider or the affiliated providers responsible for operating the PSO. Substantial proportion means—

(1) For a non-rural PSO, not less than 70% of Medicare services covered under the contract.

(2) For a rural PSO, not less than 60% of Medicare services covered under the contract.

(c) *Rural PSO.* To qualify as a rural PSO, a PSO must—

(1) Demonstrate to CMS that—

(i) It has available in the rural area, as defined in § 412.62(f) of this chapter, routine services including but not limited to primary care, routine specialty care, and emergency services; and

(ii) The level of use of providers outside the rural area is consistent with general referral patterns for the area; and

(2) Enroll Medicare beneficiaries, the majority of which reside in the rural area the PSO serves.

[63 FR 18134, Apr. 14, 1998, as amended at 63 FR 35098, June 26, 1998; 65 FR 40327, June 29, 2000]

§ 422.354 Requirements for affiliated providers.

A PSO that consists of two or more providers must demonstrate to CMS'S satisfaction that it meets the following requirements:

(a) The providers are affiliated. For purposes of this subpart, providers are affiliated if, through contract, ownership, or otherwise—

(1) One provider, directly or indirectly, controls, is controlled by, or is under common control with another;

(2) Each provider is part of a lawful combination under which each shares substantial financial risk in connection with the PSO's operations;

(3) Both, or all, providers are part of a controlled group of corporations under section 1563 of the Internal Revenue Code of 1986; or

(4) Both, or all, providers are part of an affiliated service group under section 414 of that Code.

(b) Each affiliated provider of the PSO shares, directly or indirectly, substantial financial risk for the furnishing of services the PSO is obligated to provide under the contract.

(c) Affiliated providers, as a whole or in part, have at least a majority financial interest in the PSO.

(d) For purposes of paragraph(a)(1) of this section, control is presumed to exist if one party, directly or indirectly, owns, controls, or holds the power to vote, or proxies for, not less than 51 percent of the voting rights or governance right of another.

[63 FR 18134, Apr. 14, 1998, as amended at 63 FR 35098, June 26, 1998]

§ 422.356 Determining substantial financial risk and majority financial interest.

(a) *Determining substantial financial risk.* The PSO must demonstrate to CMS's satisfaction that it apportions a significant part of the financial risk of the PSO enterprise under the MA contract to each affiliated provider. The

PSO must demonstrate that the financial arrangements among its affiliated providers constitute ''substantial'' risk in the PSO for each affiliated provider. The following mechanisms may constitute risk-sharing arrangements, and may have to be used in combination to demonstrate substantial financial risk in the PSO enterprise.

(1) Agreement by a provider to accept capitation payment for each Medicare enrollee.

(2) Agreement by a provider to accept as payment a predetermined percentage of the PSO premium or the PSO's revenue.

(3) The PSO's use of significant financial incentives for its affiliated providers, with the aim of achieving utilization management and cost containment goals. Permissible methods include the following:

(i) Affiliated providers agree to a withholding of a significant amount of the compensation due them, to be used for any of the following:

(A) To cover losses of the PSO.

(B) To cover losses of other affiliated providers.

(C) To be returned to the affiliated provider if the PSO meets its utilization management or cost containment goals for the specified time period.

(D) To be distributed among affiliated providers if the PSO meets its utilization management or cost-containment goals for the specified time period.

(ii) Affiliated providers agree to preestablished cost or utilization targets for the PSO and to subsequent significant financial rewards and penalties (which may include a reduction in payments to the provider) based on the PSO's performance in meeting the targets.

(4) Other mechanisms that demonstrate significant shared financial risk.

(b) *Determining majority financial interest.* Majority financial interest means maintaining effective control of the PSO.

[63 FR 18134, Apr. 14, 1998, as amended at 63 FR 35098, June 26, 1998]

§ 422.370 Waiver of State licensure.

For an organization that seeks to contract to offer an MA plan under this subpart, CMS may waive the State licensure requirement of section 1855(a)(1) of the Act if—

(a) The organization requests a waiver no later than November 1, 2002; and

(b) CMS determines there is a basis for a waiver under § 422.372.

[63 FR 25376, May 7, 1998, as amended at 63 FR 35098, June 26, 1998]

§ 422.372 Basis for waiver of State licensure.

(a) *General rule.* Subject to this section and to paragraphs (a) and (e) of § 422.374, CMS may waive the State licensure requirement if the organization has applied (except as provided in paragraph (b)(4) of this section) for the most closely appropriate State license or authority to conduct business as an MA plan.

(b) *Basis for waiver of State licensure.* Any of the following may constitute a basis for CMS's waiver of State licensure.

(1) *Failure to act timely on application.* The State failed to complete action on the licensing application within 90 days of the date the State received a substantially complete application.

(2) *Denial of application based on discriminatory treatment.* The State has—

(i) Denied the license application on the basis of material requirements, procedures, or standards (other than solvency requirements) not generally applied by the State to other entities engaged in a substantially similar business; or

(ii) Required, as a condition of licensure that the organization offer any product or plan other than an MA plan.

(3) *Denial of application based on different solvency requirements.* (i) The State has denied the application, in whole or in part, on the basis of the organization's failure to meet solvency requirements that are different from those set forth in §§ 422.380 through 422.390; or

(ii) CMS determines that the State has imposed, as a condition of licensure, any documentation or information requirements relating to solvency or other material requirements, procedures, or standards relating to solvency that are different from the requirements, procedures, or standards

set forth by CMS to implement, monitor, and enforce §§ 422.380 through 422.390.

(4) *State declines to accept licensure application.* The appropriate State licensing authority has given the organization written notice that it will not accept its licensure application.

[63 FR 35098, June 26, 1998]

§ 422.374 Waiver request and approval process.

(a) *Substantially complete waiver request.* The organization must submit a substantially complete waiver request that clearly demonstrates and documents its eligibility for a waiver under § 422.372.

(b) CMS gives the organization written notice of granting or denial of waiver within 60 days of receipt of a substantially complete waiver request.

(c) *Subsequent waiver requests.* An organization that has had a waiver request denied, may submit subsequent waiver requests until November 1, 2002.

(d) *Effective date.* A waiver granted under § 422.370 will be effective on the effective date of the organization's MA contract.

(e) *Consistency in application.* CMS reserves the right to revoke waiver eligibility if it subsequently determines that the organization's MA application is significantly different from the application submitted by the organization to the State licensing authority.

[63 FR 25377, May 7, 1998, as amended at 63 FR 35098, June 26, 1998]

§ 422.376 Conditions of the waiver.

A waiver granted under this section is subject to the following conditions:

(a) *Limitation to State.* The waiver is effective only for the particular State for which it is granted and does not apply to any other State. For each State in which the organization wishes to operate without a State license, it must submit a waiver request and receive a waiver.

(b) *Limitation to 36-month period.* The waiver is effective for 36 months or through the end of the calendar year in which the 36 month period ends unless it is revoked based on paragraph (c) of this section.

(c) *Mid-period revocation.* During the waiver period (set forth in paragraph (b) of this section), the waiver is automatically revoked upon—

(1) Termination of the MA contract;

(2) The organization's compliance with the State licensure requirement of section 1855(a)(1) of the Act; or

(3) The organization's failure to comply with § 422.378.

[63 FR 25377, May 7, 1998]

§ 422.378 Relationship to State law.

(a) *Preemption of State law.* Any provisions of State law that relate to the licensing of the organization and that prohibit the organization from providing coverage under a contract as specified in this subpart, are superseded.

(b) *Consumer protection and quality standards.* (1) A waiver of State licensure granted under this subpart is conditioned upon the organization's compliance with all State consumer protection and quality standards that—

(i) Would apply to the organization if it were licensed under State law;

(ii) Generally apply to other MA organizations and plans in the State; and

(iii) Are consistent with the standards established under this part.

(2) The standards specified in paragraph (b)(1) of this section do not include any standard preempted under section 1856(b)(3)(B) of the Act.

(c) *Incorporation into contract.* In contracting with an organization that has a waiver of State licensure, CMS incorporates into the contract the requirements specified in paragraph (b) of this section.

(d) *Enforcement.* CMS may enter into an agreement with a State for the State to monitor and enforce compliance with the requirements specified in paragraph (b) of this section by an organization that has obtained a waiver under this subpart.

[63 FR 25377, May 7, 1998]

§ 422.380 Solvency standards.

General rule. A PSO or the legal entity of which the PSO is a component that has been granted a waiver under

§ 422.370 must have a fiscally sound operation that meets the requirements of §§ 422.382 through 422.390.

[63 FR 25377, May 7, 1998]

§ 422.382 Minimum net worth amount.

(a) At the time an organization applies to contract with CMS as a PSO under this part, the organization must have a minimum net worth amount, as determined under paragraph (c) of this section, of:

(1) At least $1,500,000, except as provided in paragraph (a)(2) of this section.

(2) No less than $1,000,000 based on evidence from the organization's financial plan (under § 422.384) demonstrating to CMS's satisfaction that the organization has available to it an administrative infrastructure that CMS considers appropriate to reduce, control or eliminate start-up administrative costs.

(b) After the effective date of a PSO's MA contract, a PSO must maintain a minimum net worth amount equal to the greater of—

(1) One million dollars;

(2) Two percent of annual premium revenues as reported on the most recent annual financial statement filed with CMS for up to and including the first $150,000,000 of annual premiums and 1 percent of annual premium revenues on premiums in excess of $150,000,000;

(3) An amount equal to the sum of three months of uncovered health care expenditures as reported on the most recent financial statement filed with CMS; or

(4) Using the most recent financial statement filed with CMS, an amount equal to the sum of—

(i) Eight percent of annual health care expenditures paid on a non-capitated basis to non-affiliated providers; and

(ii) Four percent of annual health care expenditures paid on a capitated basis to non-affiliated providers plus annual health care expenditures paid on a non-capitated basis to affiliated providers.

(iii) Annual health care expenditures that are paid on a capitated basis to affiliated providers are not included in the calculation of the net worth requirement (regardless of downstream arrangements from the affiliated provider) under paragraphs (a) and (b)(4) of this section.

(c) *Calculation of the minimum net worth amount*—(1) *Cash requirement.* (i) At the time of application, the organization must maintain at least $750,000 of the minimum net worth amount in cash or cash equivalents.

(ii) After the effective date of a PSO's MA contract, a PSO must maintain the greater of $750,000 or 40 percent of the minimum net worth amount in cash or cash equivalents.

(2) *Intangible assets.* An organization may include intangible assets, the value of which is based on Generally Accepted Accounting Principles (GAAP), in the minimum net worth amount calculation subject to the following limitations—

(i) *At the time of application.* (A) Up to 20 percent of the minimum net worth amount, provided at least $1,000,000 of the minimum net worth amount is met through cash or cash equivalents; or

(B) Up to 10 percent of the minimum net worth amount, if less than $1,000,000 of the minimum net worth amount is met through cash or cash equivalents, or if CMS has used its discretion under paragraph (a)(2) of this section.

(ii) *From the effective date of the contract.* (A) Up to 20 percent of the minimum net worth amount if the greater of $1,000,000 or 67 percent of the minimum net worth amount is met by cash or cash equivalents; or

(B) Up to ten percent of the minimum net worth amount if the greater of $1,000,000 or 67 percent of the minimum net worth amount is not met by cash or cash equivalents.

(3) *Health care delivery assets.* Subject to the other provisions of this section, a PSO may apply 100 percent of the GAAP depreciated value of health care delivery assets (HCDAs) to satisfy the minimum net worth amount.

(4) *Other assets.* A PSO may apply other assets not used in the delivery of health care provided that those assets are valued according to statutory accounting practices (SAP) as defined by the State.

(5) *Subordinated debts and subordinated liabilities.* Fully subordinated

debt and subordinated liabilities are excluded from the minimum net worth amount calculation.

(6) *Deferred acquisition costs.* Deferred acquisition costs are excluded from the calculation of the minimum net worth amount.

[63 FR 25377, May 7, 1998, as amended at 64 FR 71678, Dec. 22, 1999]

§ 422.384 Financial plan requirement.

(a) *General rule.* At the time of application, an organization must submit a financial plan acceptable to CMS.

(b) *Content of plan.* A financial plan must include—

(1) A detailed marketing plan;

(2) Statements of revenue and expense on an accrual basis;

(3) Cash-flow statements;

(4) Balance sheets;

(5) Detailed justifications and assumptions in support of the financial plan including, where appropriate, certification of reserves and actuarial liabilities by a qualified actuary; and

(6) If applicable, statements of the availability of financial resources to meet projected losses.

(c) *Period covered by the plan.* A financial plan must—

(1) Cover the first 12 months after the estimated effective date of a PSO's MA contract; or

(2) If the PSO is projecting losses, cover 12 months beyond the end of the period for which losses are projected.

(d) *Funding for projected losses.* Except for the use of guarantees, LOC, and other means as provided in § 422.384(e), (f) and (g), an organization must have the resources for meeting projected losses on its balance sheet in cash or a form that is convertible to cash in a timely manner, in accordance with the PSO's financial plan.

(e) *Guarantees and projected losses.* Guarantees will be an acceptable resource to fund projected losses, provided that a PSO—

(1) Meets CMS's requirements for guarantors and guarantee documents as specified in § 422.390; and

(2) Obtains from the guarantor cash or cash equivalents to fund the projected losses timely, as follows—

(i) Prior to the effective date of a PSO's MA contract, the amount of the projected losses for the first two quarters;

(ii) During the first quarter and prior to the beginning of the second quarter of a PSO's MA contract, the amount of projected losses through the end of the third quarter; and

(iii) During the second quarter and prior to the beginning of the third quarter of a PSO's MA contract, the amount of projected losses through the end of the fourth quarter.

(3) If the guarantor complies with the requirements in paragraph (e)(2) of this section, the PSO, in the third quarter, may notify CMS of its intent to reduce the period of advance funding of projected losses. CMS will notify the PSO within 60 days of receiving the PSO's request if the requested reduction in the period of advance funding will not be accepted.

(4) If the guarantee requirements in paragraph (e)(2) of this section are not met, CMS may take appropriate action, such as requiring funding of projected losses through means other than a guarantee. CMS retains discretion to require other methods or timing of funding, considering factors such as the financial condition of the guarantor and the accuracy of the financial plan.

(f) *Letters of credit.* Letters of credit are an acceptable resource to fund projected losses, provided they are irrevocable, unconditional, and satisfactory to CMS. They must be capable of being promptly paid upon presentation of a sight draft under the letters of credt without further reference to any other agreement, document, or entity.

(g) *Other means.* If satisfactory to CMS, and for periods beginning one year after the effective date of a PSO's MA contract, a PSO may use the following to fund projected losses—

(1) Lines of credit from regulated financial institutions;

(2) Legally binding agreements for capital contributions; or

(3) Legally binding agreements of a similar quality and reliability as permitted in paragraphs (g)(1) and (2) of this section.

(h) *Application of guarantees, Letters of credit or other means of funding projected losses.* Notwithstanding any other provision of this section, a PSO may use

guarantees, letters of credit and, beginning one year after the effective date of a PSO's MA contract, other means of funding projected losses, but only in a combination or sequence that CMS considers appropriate.

[63 FR 25378, May 7, 1998, as amended at 63 FR 35098, June 26, 1998; 64 FR 71678, Dec. 22, 1999]

§ 422.386 Liquidity.

(a) A PSO must have sufficient cash flow to meet its financial obligations as they become due and payable.

(b) To determine whether the PSO meets the requirement in paragraph (a) of this section, CMS will examine the following—

(1) The PSO's timeliness in meeting current obligations;

(2) The extent to which the PSO's current ratio of assets to liabilities is maintained at 1:1 including whether there is a declining trend in the current ratio over time; and

(3) The availability of outside financial resources to the PSO.

(c) If CMS determines that a PSO fails to meet the requirement in paragraph (b)(1) of this section, CMS will require the PSO to initiate corrective action and pay all overdue obligations.

(d) If CMS determines that a PSO fails to meet the requirement of paragraph (b)(2) of this section, CMS may require the PSO to initiate corrective action to—

(1) Change the distribution of its assets;

(2) Reduce its liabilities; or

(3) Make alternative arrangements to secure additional funding to restore the PSO's current ratio to 1:1.

(e) If CMS determines that there has been a change in the availability of outside financial resources as required by paragraph (b)(3) of this section, CMS requires the PSO to obtain funding from alternative financial resources.

[63 FR 25378, May 7, 1998, as amended at 64 FR 71678, Dec. 22, 1999]

§ 422.388 Deposits.

(a) *Insolvency deposit.* (1) At the time of application, an organization must deposit $100,000 in cash or securities (or any combination thereof) into an account in a manner that is acceptable to CMS.

(2) The deposit must be restricted to use in the event of insolvency to help assure continuation of services or pay costs associated with receivership or liquidation.

(3) At the time of the PSO's application for an MA contract and, thereafter, upon CMS's request, a PSO must provide CMS with proof of the insolvency deposit, such proof to be in a form that CMS considers appropriate.

(b) *Uncovered expenditures deposit.* (1) If at any time uncovered expenditures exceed 10 percent of a PSO's total health care expenditures, then the PSO must place an uncovered expenditures deposit into an account with any organization or trustee that is acceptable to CMS.

(2) The deposit must at all times have a fair market value of an amount that is 120 percent of the PSO's outstanding liability for uncovered expenditures for enrollees, including incurred, but not reported claims.

(3) The deposit must be calculated as of the first day of each month required and maintained for the remainder of each month required.

(4) If a PSO is not otherwise required to file a quarterly report, it must file a report within 45 days of the end of the calendar quarter with information sufficient to demonstrate compliance with this section.

(5) The deposit required under this section is restricted and in trust for CMS's use to protect the interests of the PSO's Medicare enrollees and to pay the costs associated with administering the insolvency. It may be used only as provided under this section.

(c) A PSO may use the deposits required under paragraphs (a) and (b) of this section to satisfy the PSO's minimum net worth amount required under § 422.382(a) and (b).

(d) All income from the deposits or trust accounts required under paragraphs (a) and (b) of this section, are considered assets of the PSO. Upon CMS's approval, the income from the deposits may be withdrawn.

(e) On prior written approval from CMS, a PSO that has made a deposit under paragraphs (a) or (b) of this section, may withdraw that deposit or any part thereof if—

(1) A substitute deposit of cash or securities of equal amount and value is made;

(2) The fair market value exceeds the amount of the required deposit; or

(3) The required deposit under paragraphs (a) or (b) of this section is reduced or eliminated.

[63 FR 25379, May 7, 1998]

§ 422.390 Guarantees.

(a) *General policy.* A PSO, or the legal entity of which the PSO is a component, may apply to CMS to use the financial resources of a guarantor for the purpose of meeting the requirements in § 422.384. CMS has the discretion to approve or deny approval of the use of a guarantor.

(b) *Request to use a guarantor.* To apply to use the financial resources of a guarantor, a PSO must submit to CMS—

(1) Documentation that the guarantor meets the requirements for a guarantor under paragraph (c) of this section; and

(2) The guarantor's independently audited financial statements for the current year-to-date and for the two most recent fiscal years. The financial statements must include the guarantor's balance sheets, profit and loss statements, and cash flow statements.

(c) *Requirements for guarantor.* To serve as a guarantor, an organization must meet the following requirements:

(1) Be a legal entity authorized to conduct business within a State of the United States.

(2) Not be under Federal or State bankruptcy or rehabilitation proceedings.

(3) Have a net worth (not including other guarantees, intangibles and restricted reserves) equal to three times the amount of the PSO guarantee.

(4) If the guarantor is regulated by a State insurance commissioner, or other State official with authority for risk-bearing entities, it must meet the net worth requirement in § 422.390(c)(3) with all guarantees and all investments in and loans to organizations covered by guarantees excluded from its assets.

(5) If the guarantor is not regulated by a State insurance commissioner, or other similar State official it must meet the net worth requirement in § 422.390(c)(3) with all guarantees and all investments in and loans to organizations covered by a guarantee and to related parties (subsidiaries and affiliates) excluded from its assets.

(d) *Guarantee document.* If the guarantee request is approved, a PSO must submit to CMS a written guarantee document signed by an appropriate authority of the guarantor. The guarantee document must—

(1) State the financial obligation covered by the guarantee;

(2) Agree to—

(i) Unconditionally fulfill the financial obligation covered by the guarantee; and

(ii) Not subordinate the guarantee to any other claim on the resources of the guarantor;

(3) Declare that the guarantor must act on a timely basis, in any case not more than 5 business days, to satisfy the financial obligation covered by the guarantee; and

(4) Meet other conditions as CMS may establish from time to time.

(e) *Reporting requirement.* A PSO must submit to CMS the current internal financial statements and annual audited financial statements of the guarantor according to the schedule, manner, and form that CMS requests.

(f) *Modification, substitution, and termination of a guarantee.* A PSO cannot modify, substitute or terminate a guarantee unless the PSO—

(1) Requests CMS's approval at least 90 days before the proposed effective date of the modification, substitution, or termination;

(2) Demonstrates to CMS's satisfaction that the modification, substitution, or termination will not result in insolvency of the PSO; and

(3) Demonstrates how the PSO will meet the requirements of this section.

(g) *Nullification.* If at any time the guarantor or the guarantee ceases to meet the requirements of this section, CMS will notify the PSO that it ceases to recognize the guarantee document. In the event of this nullification, a PSO must—

(1) Meet the applicable requirements of this section within 15 business days; and

(2) If required by CMS, meet a portion of the applicable requirements in less than the time period granted in paragraph (g)(1) of this section.

[63 FR 25379, May 7, 1998]

Subpart I—Organization Compliance With State Law and Preemption by Federal Law

SOURCE: 63 FR 35099, June 26, 1998, unless otherwise noted.

§ 422.400 State licensure requirement.

Except in the case of a PSO granted a waiver under subpart H of this part, each MA organization must—

(a) Be licensed under State law, or otherwise authorized to operate under State law, as a risk-bearing entity (as defined in § 422.2) eligible to offer health insurance or health benefits coverage in each State in which it offers one or more MA plans;

(b) If not commercially licensed, obtain certification from the State that the organization meets a level of financial solvency and such other standards as the State may require for it to operate as an MA organization; and

(c) Demonstrate to CMS that—

(1) The scope of its license or authority allows the organization to offer the type of MA plan or plans that it intends to offer in the State; and

(2) If applicable, it has obtained the State certification required under paragraph (b) of this section.

§ 422.402 Federal preemption of State law.

The standards established under this part supersede any State law or regulation (other than State licensing laws or State laws relating to plan solvency) with respect to the MA plans that are offered by MA organizations.

[70 FR 4733, Jan. 28, 2005]

§ 422.404 State premium taxes prohibited.

(a) *Basic rule.* No premium tax, fee, or other similar assessment may be imposed by any State, the District of Columbia, the Commonwealth of Puerto Rico, the Virgin Islands, Guam, and American Samoa, or any of their political subdivisions or other governmental authorities with respect to any payment CMS makes on behalf of MA enrollees under subpart G of this part, or with respect to any payment made to MA plans by beneficiaries, or payment to MA plans by a third party on a beneficiary's behalf.

(b) *Construction.* Nothing in this section shall be construed to exempt any MA organization from taxes, fees, or other monetary assessments related to the net income or profit that accrues to, or is realized by, the organization from business conducted under this part, if that tax, fee, or payment is applicable to a broad range of business activity.

[63 FR 35099, June 26, 1998, as amended at 70 FR 4733, Jan. 28, 2005]

Subpart J—Special Rules for MA Regional Plans

SOURCE: 70 FR 4733, Jan. 28, 2005, unless otherwise noted.

§ 422.451 Moratorium on new local preferred provider organization plans.

CMS will not approve the offering of a local preferred provider organization plan during 2006 or 2007 in a service area unless the MA organization seeking to offer the plan was offering a local preferred provider organization plan in the service area before December 31, 2005.

§ 422.455 Special rules for MA Regional Plans.

(a) *Coverage of entire MA region.* The service area for an MA regional plan will consist of an entire MA region established under paragraph (b) of this section, and an MA region may not be segmented as described in § 422.262(c)(2).

(b) *Establishment of MA regions*—(1) *MA region.* The term ''MA region'' means a region within the 50 States and the District of Columbia as established by CMS under this section.

(2) *Establishment*—(i) *Initial establishment.* By January 1, 2005, CMS will establish and publish the MA regions.

(ii) *Periodic review and revision of service areas.* CMS may periodically review MA regions and may revise the regions if it determines the revision to be appropriate.

(3) *Requirements for MA regions.* CMS will establish, and may revise, MA regions in a manner consistent with the following:

(i) *Number of regions.* There will be no fewer than 10 regions, and no more than 50 regions.

(ii) *Maximizing availability of plans.* The main purpose of the regions is to maximize the availability of MA regional plans to all MA eligible individuals without regard to health status, or geographic location, especially those residing in rural areas.

(4) *Market survey and analysis.* Before establishing MA regions, CMS will conduct a market survey and analysis, including an examination of current insurance markets, to assist CMS in determining how the regions should be established.

(c) *National plan.* An MA regional plan can be offered in more than one MA region (including all regions).

§422.458 Risk sharing with regional MA organizations for 2006 and 2007.

(a) *Terminology.* For purposes of this section—

Allowable costs means, with respect to an MA regional plan offered by an organization for a year, the total amount of costs that the organization incurred in providing benefits covered under the original Medicare fee-for-service program option for all enrollees under the plan in the region in the year and in providing rebatable integrated benefits, as defined in this paragraph, reduced by the portion of those costs attributable to administrative expenses incurred in providing these benefits.

Rebatable integrated benefits means those non-drug supplemental benefits that are funded through beneficiary rebates (described at §422.266(b)(1)) and that CMS determines are additional health benefits not covered under the original Medicare program option and that require expenditures by the plan. For purposes of the calculation of risk corridors, these are the only supplemental benefits that count toward allowable costs.

Target amount means, with respect to an MA regional plan offered by an organization in a year, the total amount of payments made to the organization for enrollees in the plan for the year (which includes payments attributable to benefits under the original Medicare fee-for-service program option as defined in §422.100(c)(1), the total of the MA monthly basic beneficiary premium collectible for those enrollees for the year, and the total amount of rebatable integrated benefits), reduced by the amount of administrative expenses assumed in the portion of the bid attributable to benefits under original Medicare fee-for-service program option or to rebatable integrated benefits.

(b) *Application of risk corridors for benefits covered under original fee-for-service Medicare*—(1) *General rule.* This section will only apply to MA regional plans offered during 2006 or 2007.

(2) *Notification of allowable costs under the plan.* In the case of an MA organization that offers an MA regional plan in an MA region in 2006 or 2007, the organization must notify CMS, before that date in the succeeding year as CMS specifies, of—

(i) Its total amount of costs that the organization incurred in providing benefits covered under the original Medicare fee-for-service program option for all enrollees under the plan (as described in paragraph (a) of this section).

(ii) Its total amount of costs that the organization incurred in providing rebatable integrated benefits for all enrollees under the plan (as described in paragraph (a) of this section), and, with respect to those benefits, the portion of those costs that is attributable to administrative expenses that is in addition to the administrative expense incurred in provision of benefits under the original Medicare fee-for-service program option.

(c) *Adjustment of payment*—(1) *No adjustment if allowable costs within 3 percent of target amount.* If the allowable costs for the plan for the year are at least 97 percent, but do not exceed 103 percent, of the target amount for the plan and year, there will be no payment adjustment under this section for the plan and year.

(2) *Increase in payment if allowable costs above 103 percent of target amount*—(i) *Costs between 103 and 108 percent of target amount.* If the allowable costs for the plan for the year are greater than

103 percent, but not greater than 108 percent, of the target amount for the plan and year, CMS will increase the total of the monthly payments made to the organization offering the plan for the year under § 422.302(a) (section 1853(a) of the Act) by an amount equal to 50 percent of the difference between those allowable costs and 103 percent of that target amount.

(ii) *Costs above 108 percent of target amount.* If the allowable costs for the plan for the year are greater than 108 percent of the target amount for the plan and year, CMS will increase the total of the monthly payments made to the organization offering the plan for the year under section 1853(a) of the Act by an amount equal to the sum of—

(A) 2.5 percent of that target amount; and

(B) 80 percent of the difference between those allowable costs and 108 percent of that target amount.

(3) *Reduction in payment if allowable costs below 97 percent of target amount*—(i) *Costs between 92 and 97 percent of target amount.* If the allowable costs for the plan for the year are less than 97 percent, but greater than or equal to 92 percent, of the target amount for the plan and year, CMS will reduce the total of the monthly payments made to the organization offering the plan for the year under § 422.302(a) (section 1853(a) of the Act) by an amount (or otherwise recover from the plan an amount) equal to 50 percent of the difference between 97 percent of the target amount and those allowable costs.

(ii) *Costs below 92 percent of target amount.* If the allowable costs for the plan for the year are less than 92 percent of the target amount for the plan and year, CMS will reduce the total of the monthly payments made to the organization offering the plan for the year under § 422.302(a) (section 1853(a)of the Act) by an amount (or otherwise recover from the plan an amount) equal to the sum of-

(A) 2.5 percent of that target amount; and

(B) 80 percent of the difference between 92 percent of that target amount and those allowable costs.

(d) *Disclosure of information*—(1) *General rule.* Each MA organization offering an MA regional plan must provide CMS with information as CMS determines is necessary to implement this section; and

(2) According to § 422.504(d)(1)(iii), CMS has the right to inspect and audit any books and records of the organization that pertain to the information regarding costs provided to CMS under paragraph (b)(2) of this section.

(3) *Restriction on use of information.* Information disclosed or obtained for the purposes of this section may be used by officers, employees, and contractors of DHHS only for the purposes of, and to the extent necessary in, implementing this section.

(e) *Organizational and financial requirements*—(1) *General rule.* Regional MA plans offered by MA organizations must be licensed under State law, or otherwise authorized under State law, as a risk-bearing entity (as defined in § 422.2) eligible to offer health insurance or health benefits coverage in each State in which it offers one or more plans. However, as provided for under this section, MA organizations offering MA regional plans may obtain a temporary waiver of State licensure. In the case of an MA organization that is offering an MA regional plan in an MA region, and is not licensed in each State in which it offers such an MA regional plan, the following rules apply:

(i) The MA organization must be licensed to bear risk in at least one State of the region.

(ii) For the other States in a region in which the organization is not licensed to bear risk, if it demonstrates to CMS that it has filed the necessary application to meet those requirements, CMS may temporarily waive the licensing requirement with respect to each State for a period of time as CMS determines appropriate for the timely processing of the application by the State or States.

(iii) If the State licensing application or applications are denied, CMS may extend the licensing waiver through the end of the plan year or as CMS determines appropriate to provide for a transition.

(2) *Selection of appropriate State.* In the case of an MA organization to which CMS grants a waiver and that is

licensed in more than one State in a region, the MA organization will select one of the States, the rules of which shall apply in States where the organization is not licensed for the period of the waiver.

[70 FR 4732, Jan. 28, 2005, as amended at 70 FR 52027, Sept. 1, 2005; 76 FR 21568, Apr. 15, 2011]

Subpart K—Application Procedures and Contracts for Medicare Advantage Organizations

SOURCE: 63 FR 35099, June 26, 1998, unless otherwise noted.

§ 422.500 Scope and definitions.

(a) *Scope.* This subpart sets forth application requirements for entities seeking a contract as a Medicare organization offering an MA plan, including MA organizations offering a specialized MA plan for special needs individuals. MA organizations offering prescription drug plans must, in addition to the requirements of this part, follow the requirements of part 423 of this chapter specifically related to the prescription drug benefit.

(b) *Definitions.* For purposes of this subpart, the following definitions apply:

Business transaction means any of the following kinds of transactions:

(1) Sale, exchange, or lease of property.

(2) Loan of money or extension of credit.

(3) Goods, services, or facilities furnished for a monetary consideration, including management services, but not including—

(i) Salaries paid to employees for services performed in the normal course of their employment; or

(ii) Health services furnished to the MA organization's enrollees by hospitals and other providers, and by MA organization staff, medical groups, or independent practice associations, or by any combination of those entities.

Clean claim means—

(1) A claim that has no defect, impropriety, lack of any required substantiating documentation (consistent with § 422.310(d)) or particular circumstance requiring special treatment that prevents timely payment; and

(2) A claim that otherwise conforms to the clean claim requirements for equivalent claims under original Medicare.

Downstream entity means any party that enters into an acceptable written arrangement below the level of the arrangement between an MA organization (or contract applicant) and a first tier entity. These written arrangements continue down to the level of the ultimate provider of both health and administrative services.

Final settlement adjustment period means the period of time between when the contract terminates and the date the MA organization is issued a notice of the final settlement amount.

Final settlement amount is the final payment amount that CMS owes and ultimately pays to an MA organization, or that an MA organization owes and ultimately pays to CMS, with respect to an MA contract that has consolidated, nonrenewed, or terminated. The final settlement amount is calculated by summing final retroactive payment adjustments for a specific contract that accumulated after that contract ceases operation but before the calculation of the final settlement amount and the following applicable reconciliation amounts that have been completed as of the date the notice of final settlement has been issued, without accounting for any data submitted after the data submission deadlines for calculating these reconciliation amounts:

(1) Risk adjustment reconciliation (described in § 422.310);

(2) Part D annual reconciliation (described in § 423.343);

(3) Coverage Gap Discount Program annual reconciliation (described in § 423.2320) and;

(4) MLR remittances (described in §§ 422.2470 and 423.2470).

Final settlement process means for a contract that has been consolidated, nonrenewed, or terminated, the process by which CMS calculates the final settlement amount, issues the final settlement amount along with supporting documentation in the notice of final

settlement to the MA organization, receives responses from the MA organization requesting an appeal of the final settlement amount, and takes final actions to adjudicate an appeal (if requested) and make payments to or receive payments from the MA organization. The final settlement amount is calculated after all applicable reconciliations have occurred after a contract has been consolidated, nonrenewed, or terminated.

First tier entity means any party that enters into an acceptable written arrangement with an MA organization or contract applicant to provide administrative services or health care services for a Medicare eligible individual.

Fraud hotline tip is a complaint or other communications that are submitted through a fraud reporting phone number or a website intended for the same purpose, such as the Federal Government's HHS OIG Hotline or a health plan's fraud hotline.

Inappropriate prescribing means that, after consideration of all the facts and circumstances of a particular situation identified through investigation or other information or actions taken by MA organizations and Part D plan sponsors, there is an established pattern of potential fraud, waste, and abuse related to prescribing of opioids, as reported by the plan sponsors. Beneficiaries with cancer and sickle-cell disease, as well as those patients receiving hospice and long term care (LTC) services are excluded, when determining inappropriate prescribing. Plan sponsors may consider any number of factors including, but not limited to the following:

(1) Documentation of a patient's medical condition.

(2) Identified instances of patient harm or death.

(3) Medical records, including claims (if available).

(4) Concurrent prescribing of opioids with an opioid potentiator in a manner that increases risk of serious patient harm.

(5) Levels of morphine milligram equivalent (MME) dosages prescribed.

(6) Absent clinical indication or documentation in the care management plan or in a manner that may indicate diversion.

(7) State-level prescription drug monitoring program (PDMP) data.

(8) Geography, time, and distance between a prescriber and the patient.

(9) Refill frequency and factors associated with increased risk of opioid overdose.

Party in interest includes the following:

(1) Any director, officer, partner, or employee responsible for management or administration of an MA organization.

(2) Any person who is directly or indirectly the beneficial owner of more than 5 percent of the organization's equity; or the beneficial owner of a mortgage, deed of trust, note, or other interest secured by and valuing more than 5 percent of the organization.

(3) In the case of an MA organization organized as a nonprofit corporation, an incorporator or member of such corporation under applicable State corporation law.

(4) Any entity in which a person described in paragraph (1), (2), or (3) of this definition:

(i) Is an officer, director, or partner; or

(ii) Has the kind of interest described in paragraphs (1), (2), or (3) of this definition.

(5) Any person that directly or indirectly controls, is controlled by, or is under common control with, the MA organization.

(6) Any spouse, child, or parent of an individual described in paragraph (1), (2), or (3) of this definition.

Related entity means any entity that is related to the MA organization by common ownership or control and—

(1) Performs some of the MA organization's management functions under contract or delegation;

(2) Furnishes services to Medicare enrollees under an oral or written agreement; or

(3) Leases real property or sells materials to the MA organization at a cost of more than $2,500 during a contract period.

Significant business transaction means any business transaction or series of transactions of the kind specified in the above definition of ''business transaction'' that, during any fiscal year of the MA organization, have a total

value that exceeds $25,000 or 5 percent of the MA organization's total operating expenses, whichever is less.

Substantiated or suspicious activities of fraud, waste, or abuse means and includes, but is not limited to, allegations that a provider of services (including a prescriber) or supplier—

(1) Engaged in a pattern of improper billing;

(2) Submitted improper claims with suspected knowledge of their falsity;

(3) Submitted improper claims with reckless disregard or deliberate ignorance of their truth or falsity; or

(4) Is the subject of a fraud hotline tip verified by further evidence.

[63 FR 35099, June 26, 1998, as amended at 65 FR 40327, June 29, 2000; 70 FR 4736, Jan. 28, 2005; 70 FR 52027, Sept. 1, 2005; 77 FR 22167, Apr. 12, 2012; 86 FR 6098, Jan. 19, 2021; 89 FR 30823, Apr. 23, 2024]

§ 422.501 Application requirements.

(a) *Scope.* This section sets forth application requirements for entities that seek a contract as an MA organization offering an MA plan and additional application requirements for MA organizations seeking to offer a Specialized MA Plan for Special Needs Individuals.

(b) *Completion of a notice of intent to apply.* (1) An organization submitting an application under this section for a particular contract year must first submit a completed Notice of Intent to Apply by the date established by CMS. CMS will not accept applications from organizations that do not first submit a timely Notice of Intent to Apply.

(2) Submitting a Notice of Intent to Apply does not bind that organization to submit an application for the applicable contract year.

(3) An organization's decision not to submit an application after submitting a Notice of Intent To Apply will not form the basis of any action taken against the organization by CMS.

(c) *Completion of an application.* (1) In order to obtain a determination on whether it meets the requirements to become an MA organization and is qualified to provide a particular type of MA plan, an entity, or an individual authorized to act for the entity (the applicant) must fully complete all parts of a certified application, in the form and manner required by CMS, including the following:

(i) Documentation of appropriate State licensure or State certification that the entity is able to offer health insurance or health benefits coverage that meets State-specified standards applicable to MA plans, and is authorized by the State to accept prepaid capitation for providing, arranging, or paying for the comprehensive health care services to be offered under the MA contract.

(ii) For regional plans, documentation of application for State licensure in any State in the region that the organization is not already licensed.

(iii) For Specialized MA Plans for Special Needs Individuals, documentation that the entity meets the requirements of §§ 422.2; 422.4(a)(1)(iv); 422.101(f); 422.107, if applicable; and 422.152(g) of this part.

(iv) Documentation that payment for health care services or items is not being and will not be made to individuals and entities included on the preclusion list, defined in § 422.2.

(2) The authorized individual must thoroughly describe how the entity and MA plan meet, or will meet, all the requirements described in this part, including providing documentation that payment for health care services or items is not being and will not be made to individuals and entities included on the preclusion list, defined in § 422.2.

(d) *Responsibility for making determinations.* (1) CMS is responsible for determining whether an entity qualifies as an MA organization and whether proposed MA plans meet the requirements of this part.

(2) A CMS determination that an entity is qualified to act as an MA organization is distinct from the bid negotiation that occurs under subpart F of this part and such negotiation is not subject to the appeals provisions included in subpart N of this part.

(e) *Resubmittal of an application.* An application that has been denied by CMS for a particular contract year may not be resubmitted until the beginning of the application cycle for the following contract year.

(f) *Disclosure of application information under the Freedom of Information Act.* An applicant submitting material that

he or she believes is protected from disclosure under 5 U.S.C. 552, the Freedom of Information Act, or because of exemptions provided in 45 CFR part 5 (the Department's regulations providing exceptions to disclosure), must label the material ''privileged'' and include an explanation of the applicability of an exception described in 45 CFR part 5. Any final decisions as to whether material is privileged is the final decision of the Secretary.

[70 FR 4736, Jan. 28, 2005, as amended at 75 FR 19809, Apr. 15, 2010; 77 FR 22167, Apr. 12, 2012; 81 FR 80557, Nov. 15, 2016; 83 FR 16733, Apr. 16, 2018]

§ 422.502 Evaluation and determination procedures.

(a) *Basis for evaluation and determination.* (1) *Information used to evaluate applications.* With the exception of evaluations conducted under paragraph (b) of this section, CMS evaluates an application for an MA contract or for a Specialized MA Plan for Special Needs Individuals solely on the basis of information contained in the application itself and any additional information that CMS obtains through other means such as on-site visits.

(2) *Issuing application determination.* After evaluating all relevant information, CMS determines whether the applicant's application meets all the requirements described in this part.

(3) *Substantially incomplete applications.* (i) CMS does not evaluate or issue a notice of determination described in § 422.502(c) when an organization submits a substantially incomplete application.

(ii) An application is substantially incomplete when the submission as of the deadline for applications established by CMS is missing content or responsive materials for one or more sections of the application form required by CMS.

(iii) A determination that an application is substantially incomplete is not a contract determination as defined in § 422.641 and a determination that an organization submitted a substantially incomplete application is not subject to the appeals provisions of subpart N of this part.

(b) *Use of information from a current or prior contract.* (1) Except as provided in paragraphs (b)(2) through (4) of this section, if an MA organization fails during the 12 months preceding the deadline established by CMS for the submission of contract qualification applications to comply with the requirements of the Part C program under any current or prior contract with CMS under title XVIII of the Act, CMS may deny an application based on the applicant's failure to comply with the requirements of the Part C program under any current or prior contract with CMS even if the applicant currently meets all of the requirements of this part.

(i) An applicant may be considered to have failed to comply with a contract for purposes of an application denial under paragraph (b)(1) of this section if during the applicable review period the applicant does any of the following:

(A) Was under intermediate sanction under subpart O of this part or a determination by CMS to prohibit the enrollment of new enrollees in accordance with § 422.2410(c), with the exception of a sanction imposed under § 422.752(d).

(B) Failed to maintain a fiscally sound operation consistent with the requirements of § 422.504(a)(14).

(C) Filed for or is currently in federal or state bankruptcy proceedings.

(D) Received any combination of Part C or D summary ratings of 2.5 or less in both of the two most recent Star Rating periods, as identified in § 422.166.

(E) Met or exceeded 13 points for compliance actions for any one contract.

(*1*) CMS determines the number of points each MA organization accumulated during the performance period for compliance actions based on the following point values:

(*i*) Each corrective action plan issued during the performance period under § 422.504(m) counts for 6 points.

(*ii*) Each warning letter issued during the performance period under § 422.504(m) counts for 3 points.

(*iii*) Each notice of noncompliance issued during the performance period under § 422.504(m) counts for 1 point.

(*2*) CMS adds all the point values for each MA organization to determine if any organization meets CMS' identified threshold.

(ii) CMS may deny an application submitted by an organization that does not hold a Part C contract at the time of the submission when the applicant's parent organization or another subsidiary of the parent organization meets the criteria for denial stated in paragraph (b)(1)(i) of this section. This paragraph does not apply when the parent organization completed the acquisition of the subsidiary that meets the criteria within the 24 months preceding the application submission deadline.

(2) In the absence of 12 months of performance history, CMS may deny an application based on a lack of information available to determine an applicant's capacity to comply with the requirements of the MA program.

(3) If CMS has terminated, under § 422.510, or non-renewed, under § 422.506(b), an MA organization's contract, effective within the 38 months preceding the deadline established by CMS for the submission of contract qualification applications, CMS may deny an application for a new contract or service area expansion based on the applicant's substantial failure to comply with the requirements of the Part C program even if the applicant currently meets all of the requirements of this part.

(4) During the same 38-month period as specified in (b)(3) of this section, CMS may deny an application where the applicant's covered persons also served as covered persons for the terminated or non-renewed contract. A ''covered person'' as used in this paragraph means one of the following:

(i) All owners of terminated organizations who are natural persons, other than shareholders who have an ownership interest of less than 5 percent.

(ii) An owner in whole or part interest in any mortgage, deed of trust, note or other obligation secured (in whole or in part) by the organization, or any of the property or assets thereof, which whole or part interest is equal to or exceeds 5 percent of the total property, and assets of the organization.

(iii) A member of the board of directors or board of trustees of the entity, if the organization is organized as a corporation.

(c) *Notice of determination.* Within timeframes determined by CMS, it notifies each applicant that applies for an MA contract or to be designated a Specialized MA Plan for Special Needs Individuals under this part of its determination and the basis for the determination. The determination is one of the following:

(1) *Approval of application.* If CMS approves the application, it gives written notice to the applicant, indicating that it qualifies to contract as an MA organization.

(2) *Intent to deny.* (i) If CMS finds that the applicant does not appear to be able to meet the requirements for an MA organization or Specialized MA Plan for Special Needs Individuals, CMS gives the applicant notice of intent to deny the application for an MA contract or for a Specialized MA Plan for Special Needs Individuals a summary of the basis for this preliminary finding.

(ii) Within 10 days from the intent to deny, the applicant must respond in writing to the issues or other matters that were the basis for CMS' preliminary finding and must revise its application to remedy any defects CMS identified.

(iii) If CMS does not receive a revised application within 10 days from the date of the notice, or if after timely submission of a revised application, CMS still finds that the applicant does not appear qualified or has not provided CMS enough information to allow CMS to evaluate the application, CMS will deny the application.

(3) *Denial of application.* If CMS denies the application, it gives written notice to the contract applicant indicating—

(i) That the applicant is not qualified to contract as an MA organization under Part C of title XVIII of the Act and/or is not qualified to offer a Specialized MA Plan for Special Needs Individuals;

(ii) The reasons why the applicant is not qualified; and

(iii) The applicant's right to request a hearing in accordance with the procedures specified in subpart N of this part.

[70 FR 4736, Jan. 28, 2005, as amended at 75 FR 19809, Apr. 15, 2010; 76 FR 21568, Apr. 15, 2011; 77 FR 22167, Apr. 12, 2012; 80 FR 7960, Feb. 12, 2015; 83 FR 16733, Apr. 16, 2018; 86 FR 6099, Jan. 19, 2021; 87 FR 27896, May 9, 2022; 89 FR 30824, Apr. 23, 2024]

§ 422.503 General provisions.

(a) *Basic rule.* In order to qualify as an MA organization, enroll beneficiaries in any MA plans it offers, and be paid on behalf of Medicare beneficiaries enrolled in those plans, an MA organization must enter into a contract with CMS.

(b) *Conditions necessary to contract as an MA organization.* Any entity seeking to contract as an MA organization must:

(1) Complete an application as described in § 422.501.

(2) Be licensed by the State as a risk bearing entity in each State in which it seeks to offer an MA plan as defined in § 422.2.

(3) Meet the minimum enrollment requirements of § 422.514, unless waived under § 422.514(b).

(4) Have administrative and management arrangements satisfactory to CMS, as demonstrated by at least the following:

(i) A policy making body that exercises oversight and control over the MA organization's policies and personnel to ensure that management actions are in the best interest of the organization and its enrollees.

(ii) Personnel and systems sufficient for the MA organization to organize, implement, control, and evaluate financial and communication activities, the furnishing of services, the quality improvement program, and the administrative and management aspects of the organization.

(iii) At a minimum, an executive manager whose appointment and removal are under the control of the policy making body.

(iv) A fidelity bond or bonds, procured and maintained by the MA organization, in an amount fixed by its policymaking body but not less than $100,000 per individual, covering each officer and employee entrusted with the handling of its funds. The bond may have reasonable deductibles, based upon the financial strength of the MA organization.

(v) Insurance policies or other arrangements, secured and maintained by the MA organization and approved by CMS to insure the MA organization against losses arising from professional liability claims, fire, theft, fraud, embezzlement, and other casualty risks.

(vi) Adopt and implement an effective compliance program, which must include measures that prevent, detect, and correct non-compliance with CMS' program requirements as well as measures that prevent, detect, and correct fraud, waste, and abuse. The compliance program must, at a minimum, include the following core requirements:

(A) Written policies, procedures, and standards of conduct that—

(*1*) Articulate the organization's commitment to comply with all applicable Federal and State standards;

(*2*) Describe compliance expectations as embodied in the standards of conduct;

(*3*) Implement the operation of the compliance program;

(*4*) Provide guidance to employees and others on dealing with potential compliance issues;

(*5*) Identify how to communicate compliance issues to appropriate compliance personnel;

(*6*) Describe how potential compliance issues are investigated and resolved by the organization; and

(*7*) Include a policy of non-intimidation and non-retaliation for good faith participation in the compliance program, including but not limited to reporting potential issues, investigating issues, conducting self-evaluations, audits and remedial actions, and reporting to appropriate officials.

(B) The designation of a compliance officer and a compliance committee who report directly and are accountable to the organization's chief executive or other senior management.

(*1*) The compliance officer, vested with the day-to-day operations of the compliance program, must be an employee of the MA organization, parent organization or corporate affiliate. The

compliance officer may not be an employee of the MA organization's first tier, downstream or related entity.

(*2*) The compliance officer and the compliance committee must periodically report directly to the governing body of the MA organization on the activities and status of the compliance program, including issues identified, investigated, and resolved by the compliance program.

(*3*) The governing body of the MA organization must be knowledgeable about the content and operation of the compliance program and must exercise reasonable oversight with respect to the implementation and effectiveness of the compliance programs.

(C)(*1*) Each MA organization must establish and implement effective training and education for its compliance officer and organization employees, the MA organization's chief executive and other senior administrators, managers and governing body members.

(*2*) Such training and education must occur at a minimum annually and must be made a part of the orientation for a new employee and new appointment to a chief executive, manager, or governing body member.

(D) Establishment and implementation of effective lines of communication, ensuring confidentiality, between the compliance officer, members of the compliance committee, the MA organization's employees, managers and governing body, and the MA organization's first tier, downstream, and related entities. Such lines of communication must be accessible to all and allow compliance issues to be reported including a method for anonymous and confidential good faith reporting of potential compliance issues as they are identified.

(E) Well-publicized disciplinary standards through the implementation of procedures which encourage good faith participation in the compliance program by all affected individuals. These standards must include policies that—

(*1*) Articulate expectations for reporting compliance issues and assist in their resolution,

(*2*) Identify noncompliance or unethical behavior; and

(*3*) Provide for timely, consistent, and effective enforcement of the standards when noncompliance or unethical behavior is determined.

(F) Establishment and implementation of an effective system for routine monitoring and identification of compliance risks. The system should include internal monitoring and audits and, as appropriate, external audits, to evaluate the MA organization, including first tier entities', compliance with CMS requirements and the overall effectiveness of the compliance program.

(G) Establishment and implementation of procedures and a system for promptly responding to compliance issues as they are raised, investigating potential compliance problems as identified in the course of self-evaluations and audits, correcting such problems promptly and thoroughly to reduce the potential for recurrence, and ensure ongoing compliance with CMS requirements.

(*1*) If the MA organization discovers evidence of misconduct related to payment or delivery of items or services under the contract, it must conduct a timely, reasonable inquiry into that conduct.

(*2*) The MA organization must conduct appropriate corrective actions (for example, repayment of overpayments, disciplinary actions against responsible employees) in response to the potential violation referenced in paragraph (b)(4)(vi)(G)(1) of this section.

(*3*) The MA organization should have procedures to voluntarily self-report potential fraud or misconduct related to the MA program to CMS or its designee.

(*4*) The MA organization must have procedures to identify, and must report to CMS or its designee either of the following, in the manner described in paragraphs (b)(4)(vi)(G)(*4*) through (*6*) of this section:

(*i*) Any payment suspension implemented by a plan, pending investigation of credible allegations of fraud by a pharmacy, which must be implemented in the same manner as the Secretary does under section 1862(o)(1) of the Act.

(*ii*) Any information concerning investigations, credible evidence of suspicious activities of a provider of services (including a prescriber) or supplier, and other actions taken by the plan related to the inappropriate prescribing of opioids.

(*5*) The MA organization must submit data, as specified in this section, in the program integrity portal when reporting payment suspensions pending investigations of credible allegations of fraud by pharmacies; information related to the inappropriate prescribing of opioids and concerning investigations and credible evidence of suspicious activities of a provider of services (including a prescriber) or supplier, and other actions taken by the MA organization; or if the plan reports a referral, through the portal, of substantiated or suspicious activities of a provider of services (including a prescriber) or a supplier related to fraud, waste, or abuse to initiate or assist with investigations conducted by CMS, or its designee, a Medicare program integrity contractor, or law enforcement partners. The data categories, as applicable, include referral information and actions taken by the MA organization on the referral.

(*6*)(*i*) The MA organization is required to notify the Secretary, or its designee, of a payment suspension described in paragraph (b)(4)(vi)(G)(*4*)(*i*) of this section 7 days prior to implementation of the payment suspension. The MA organization may request an exception to the 7-day prior notification to the Secretary, or its designee, if circumstances warrant a reduced reporting time frame, such as potential beneficiary harm.

(*ii*) The MA organization is required to submit the information described in paragraph (b)(4)(vi)(G)(*4*)(*ii*) of this section no later than January 30, April 30, July 30, and October 30 of each year for the preceding periods, respectively, of October 1 through December 31, January 1 through March 31, April 1 through June 30, and July 1 through September 30. For the first reporting period (January 30, 2022), the reporting will reflect the data gathered and analyzed for the previous quarter in the calendar year (October 1–December 31).

(*7*)(*i*) CMS will provide MA organizations with data report(s) or links to the information described in paragraphs (b)(4)(vi)(G)(*4*)(*i*) and (*ii*) of this section no later than April 15, July 15, October 15, and January 15 of each year based on the information in the portal, respectively, as of the preceding October 1 through December 31, January 1 through March 31, April 1 through June 30, and July 1 through September 30.

(*ii*) Include administrative actions, pertinent information related to opioid overprescribing, and other data determined appropriate by the Secretary in consultation with stakeholders.

(*iii*) Are anonymized information submitted by plans without identifying the source of such information.

(*iv*) For the first quarterly report (April 15, 2022), that the report reflect the data gathered and analyzed for the previous quarter submitted by the plan sponsors on January 30, 2022.

(5) Not accept new enrollees under a section 1876 reasonable cost contract in any area in which it seeks to offer an MA plan.

(i) Not accept, or share a corporate parent organization owning a controlling interest in an entity that accepts, new enrollees under a section 1876 reasonable cost contract in any area in which it seeks to offer an MA plan that is not a dual eligible special needs plan.

(ii) Not accept, or be either the parent organization owning a controlling interest of or subsidiary of an entity that accepts, new enrollees under a section 1876 reasonable cost contract in any area in which it seeks to offer an MA plan that is not a dual eligible special needs plan.

(6) The MA organization's contract must not have been non-renewed under § 422.506 within the past 2 years unless—

(i) During the 6-month period beginning on the date the organization notified CMS of the intention to non-renew the most recent previous contract, there was a change in the statute or regulations that had the effect of increasing MA payments in the payment area or areas at issue; or

(ii) CMS has otherwise determined that circumstances warrant special consideration.

(7) Not have terminated a contract by mutual consent under which, as a condition of the consent, the MA organization agreed that it was not eligible to apply for new contracts or service area expansions for a period of 2 years per § 422.508(c) of this subpart.

(8) Not newly offer a dual eligible special needs plan that would result in noncompliance with § 422.514(h).

(c) *Contracting authority.* Under the authority of section 1857(c)(5) of the Act, CMS may enter into contracts under this part without regard to Federal and Departmental acquisition regulations set forth in title 48 of the CFR and provisions of law or other regulations relating to the making, performance, amendment, or modification of contracts of the United States if CMS determines that those provisions are inconsistent with the efficient and effective administration of the Medicare program.

(d) *Protection against fraud and beneficiary protections.* (1) CMS annually audits the financial records (including data relating to Medicare utilization, costs, and computation of the bid) of at least one-third of the MA organizations offering MA plans. These auditing activities are subject to monitoring by the Comptroller General.

(2) Each contract under this section must provide that CMS, or any person or organization designated by CMS has the right to:

(i) Inspect or otherwise evaluate the quality, appropriateness, and timeliness of services performed under the MA contract;

(ii) Inspect or otherwise evaluate the facilities of the organization when there is reasonable evidence of some need for such inspection; and

(iii) Audit and inspect any books, contracts, and records of the MA organization that pertain to—

(A) The ability of the organization or its first tier or downstream providers to bear the risk of potential financial losses; or

(B) Services performed or determinations of amounts payable under the contract.

(iv) CMS may require that the MA organization hire an independent auditor to provide CMS with additional information to determine if deficiencies found during an audit or inspection have been corrected and are not likely to recur. The independent auditor must work in accordance with CMS specifications and must be willing to attest that a complete and full independent review has been performed.

(e) *Severability of contracts.* The contract must provide that, upon CMS's request—

(1) The contract will be amended to exclude any MA plan, MA plan segment, or State-licensed entity specified by CMS; and

(2) A separate contract for any such excluded plan, segment, or entity will be deemed to be in place when such a request is made.

[63 FR 35099, June 26, 1998, as amended at 65 FR 40327, June 29, 2000. Redesignated at 70 FR 4736, Jan. 28, 2005, and amended at 70 FR 4737, Jan. 28, 2005; 70 FR 52027, Sept. 1, 2005; 70 FR 76198, Dec. 23, 2005; 72 FR 68722, Dec. 5, 2007; 75 FR 19809, Apr. 15, 2010; 79 FR 29958, May 23, 2014; 80 FR 7960, Feb. 12, 2015; 83 FR 16733, Apr. 16, 2018; 86 FR 6099, Jan. 19, 2021; 87 FR 27896, May 9, 2022; 88 FR 22334, Apr. 12, 2023; 89 FR 30824, Apr. 23, 2024]

§ 422.504 Contract provisions.

The contract between the MA organization and CMS must contain the following provisions:

(a) *Agreement to comply with regulations and instructions.* The MA organization agrees to comply with all the applicable requirements and conditions set forth in this part and in general instructions. Compliance with the terms of this paragraph (a) is material to the performance of the MA contract. The MA organization agrees—

(1) To accept new enrollments, make enrollments effective, process voluntary disenrollments, and limit involuntary disenrollments, as provided in subpart B of this part.

(2) That it will comply with the prohibition in § 422.110 on discrimination in beneficiary enrollment.

(3) To provide—

(i) The basic benefits as required under § 422.101 and, to the extent applicable, supplemental benefits under § 422.102; and

(ii) Access to benefits as required under subpart C of this part;

(iii) In a manner consistent with professionally recognized standards of

health care, all benefits covered by Medicare.

(4) To disclose information to beneficiaries in the manner and the form prescribed by CMS as required under § 422.111;

(5) To operate a quality assurance and performance improvement program and have an agreement for external quality review as required under subpart D of this part;

(6) To comply with all applicable provider and supplier requirements in subpart E of this part, including provider certification requirements, anti-discrimination requirements, provider participation and consultation requirements, the prohibition on interference with provider advice, limits on provider indemnification, rules governing payments to providers, limits on physician incentive plans, and the preclusion list requirements in §§ 422.222 and 422.224.

(7) To comply with all requirements in subpart M of this part governing coverage determinations, grievances, and appeals;

(8) To comply with the reporting requirements in § 422.516 and the requirements in § 422.310 for submitting data to CMS;

(9) That it will be paid under the contract in accordance with the payment rules in subpart G of this part;

(10) To develop its annual bid, and submit all required information on premiums, benefits, and cost-sharing by not later than the first Monday in June, as provided in subpart F of this part;

(11) That its contract may not be renewed or may be terminated in accordance with this subpart and subpart N of this part.

(12) To comply with all requirements that are specific to a particular type of MA plan, such as the special rules for private fee-for-service plans in §§ 422.114 and 422.216 and the MSA requirements in §§ 422.56, 422.103, and 422.262; and

(13) To comply with the confidentiality and enrollee record accuracy requirements in § 422.118.

(14) Maintain a fiscally sound operation by at least maintaining a positive net worth (total assets exceed total liabilities).

(15) As described in § 422.125 of this part, address and resolve complaints received by CMS against the MA organization in the Complaints Tracking Module.

(16) To maintain administrative and management capabilities sufficient for the organization to organize, implement, and control the financial, marketing, benefit administration, and quality improvement activities related to the delivery of Part C services.

(17) To maintain a Part C summary plan rating score of at least 3 stars under the 5-star rating system specified in subpart D of this part. A Part C summary plan rating is calculated as provided in § 422.166.

(18) To comply with the requirements for access to health data and plan information under §§ 422.119 and 422.120 of this chapter.

(19) Not to establish a segment of an MA plan that meets the criteria in § 422.514(d), as determined in the procedures described in § 422.514(e)(3), with the addition of the newly enrolled individuals.

(20) To comply with the requirements established in § 422.514(h).

(21) Not to establish additional MA plans that are not facility based I–SNPs to contracts described in § 422.116(f)(3).

(b) *Communication with CMS.* The MA organization must have the capacity to communicate with CMS electronically.

(c) *Prompt payment.* The MA organization must comply with the prompt payment provisions of § 422.520 and with instructions issued by CMS, as they apply to each type of plan included in the contract.

(d) *Maintenance of records.* The MA organization agrees to maintain for 10 years books, records, documents, and other evidence of accounting procedures and practices that—

(1) Are sufficient to do the following:

(i) Accommodate periodic auditing of the financial records (including data related to Medicare utilization, costs, and computation of the bid) of MA organizations.

(ii) Enable CMS to inspect or otherwise evaluate the quality, appropriateness and timeliness of services performed under the contract, and the facilities of the organization.

(iii) Enable CMS to audit and inspect any books and records of the MA organization that pertain to the ability of the organization to bear the risk of potential financial losses, or to services performed or determinations of amounts payable under the contract.

(iv) Properly reflect all direct and indirect costs claimed to have been incurred and used in the preparation of the bid proposal.

(v) Establish component rates of the bid for determining additional and supplementary benefits.

(vi) Determine the rates utilized in setting premiums for State insurance agency purposes and for other government and private purchasers; and

(2) Include at least records of the following:

(i) Ownership and operation of the MA organization's financial, medical, and other record keeping systems.

(ii) Financial statements for the current contract period and 10 prior periods.

(iii) Federal income tax or informational returns for the current contract period and 10 prior periods.

(iv) Asset acquisition, lease, sale, or other action.

(v) Agreements, contracts, and subcontracts.

(vi) Franchise, marketing, and management agreements.

(vii) Schedules of charges for the MA organization's fee-for-service patients.

(viii) Matters pertaining to costs of operations.

(ix) Amounts of income received by source and payment.

(x) Cash flow statements.

(xi) Any financial reports filed with other Federal programs or State authorities.

(e) *Access to facilities and records.* The MA organization agrees to the following:

(1) HHS, the Comptroller General, or their designee may evaluate, through inspection, audit, or other means—

(i) The quality, appropriateness, and timeliness of services furnished to Medicare enrollees under the contract;

(ii) Compliance with CMS requirements for maintaining the privacy and security of protected health information and other personally identifiable information of Medicare enrollees;

(iii) The facilities of the MA organization to include computer and other electronic systems; and

(iv) The enrollment and disenrollment records for the current contract period and 10 prior periods.

(2) HHS, the Comptroller General, or their designees may audit, evaluate, or inspect any books, contracts, medical records, patient care documentation, and other records of the MA organization, related entity, contractor, subcontractor, or its transferee that pertain to any aspect of services performed, reconciliation of benefit liabilities, and determination of amounts payable under the contract, or as the Secretary may deem necessary to enforce the contract.

(3) The MA organization agrees to make available, for the purposes specified in paragraph (d) of this section, its premises, physical facilities and equipment, records relating to its Medicare enrollees, and any additional relevant information that CMS may require.

(4) HHS, the Comptroller General, or their designee's right to inspect, evaluate, and audit extends through 10 years from the end of the final contract period or completion of audit, whichever is later unless—

(i) CMS determines there is a special need to retain a particular record or group of records for a longer period and notifies the MA organization at least 30 days before the normal disposition date;

(ii) There has been a termination, dispute, or allegation of fraud or similar fault by the MA organization, in which case the retention may be extended to 6 years from the date of any resulting final resolution of the termination, dispute, fraud, or similar fault; or

(iii) CMS determines that there is a reasonable possibility of fraud or similar fault, in which case CMS may inspect, evaluate, and audit the MA organization at any time.

(f) *Disclosure of information.* The MA organization agrees to submit—

(1) To CMS, certified financial information that must include the following:

(i) Such information as CMS may require demonstrating that the organization has a fiscally sound operation.

(ii) Such information as CMS may require pertaining to the disclosure of ownership and control of the MA organization.

(2) To CMS, all information that is necessary for CMS to administer and evaluate the program and to simultaneously establish and facilitate a process for current and prospective beneficiaries to exercise choice in obtaining Medicare services. This information includes, but is not limited to:

(i) The benefits covered under an MA plan;

(ii) The MA monthly basic beneficiary premium and MA monthly supplemental beneficiary premium, if any, for the plan or in the case of an MSA plan, the MA monthly MSA premium.

(iii) The service area and continuation area, if any, of each plan and the enrollment capacity of each plan;

(iv) Plan quality and performance indicators for the benefits under the plan including—

(A) Disenrollment rates for Medicare enrollees electing to receive benefits through the plan for the previous 2 years;

(B) Information on Medicare enrollee satisfaction;

(C) Information on health outcomes;

(D) The recent record regarding compliance of the plan with requirements of this part, as determined by CMS; and

(E) Other information determined by CMS to be necessary to assist beneficiaries in making an informed choice among MA plans and traditional Medicare;

(v) Information about beneficiary appeals and their disposition;

(vi) Information regarding all formal actions, reviews, findings, or other similar actions by States, other regulatory bodies, or any other certifying or accrediting organization;

(vii) To CMS, any other information deemed necessary by CMS for the administration or evaluation of the Medicare program.

(3) To its enrollees all informational requirements under § 422.64 and, upon an enrollee's, request the financial disclosure information required under § 422.516.

(g) *Beneficiary financial protections.* The MA organization agrees to comply with the following requirements:

(1) Effective January 1, 2010, each MA organization must adopt and maintain arrangements satisfactory to CMS to protect its enrollees from incurring liability (for example, as a result of an organization's insolvency or other financial difficulties) for payment of any fees that are the legal obligation of the MA organization. To meet this requirement, the MA organization must—

(i) Ensure that all contractual or other written arrangements with providers prohibit the organization's providers from holding any enrollee liable for payment of any such fees;

(ii) Indemnify the enrollee for payment of any fees that are the legal obligation of the MA organization for services furnished by providers that do not contract, or that have not otherwise entered into an agreement with the MA organization, to provide services to the organization's enrollees; and

(iii) For all MA organizations with enrollees eligible for both Medicare and Medicaid, specify in contracts with providers that such enrollees will not be held liable for Medicare Part A and B cost sharing when the State is responsible for paying such amounts, and inform providers of Medicare and Medicaid benefits, and rules for enrollees eligible for Medicare and Medicaid. The MA plans may not impose cost-sharing that exceeds the amount of cost-sharing that would be permitted with respect to the individual under title XIX if the individual were not enrolled in such a plan. The contracts must state that providers will—

(A) Accept the MA plan payment as payment in full, or

(B) Bill the appropriate State source.

(iv) Ensure that the enrollee does not have any financial liability for services, items, or drugs furnished, ordered, or prescribed to the enrollee by an MA contracted individual or entity on the preclusion list, as defined in § 422.2 and as described in § 422.222.

(v) Ensure that the plan's provider agreement contains a provision stating that after the expiration of the 60-day period specified in § 422.222:

(A) The provider will no longer be eligible for payment from the plan and will be prohibited from pursuing payment from the beneficiary as stipulated by the terms of the contract between CMS and the plan per § 422.504(g)(1)(iv); and

(B) The provider will hold financial liability for services, items, and drugs that are furnished, ordered, or prescribed after this 60-day period, at which point the provider and the beneficiary will have already received notification of the preclusion.

(2) The MA organization must provide for continuation of enrollee health care benefits—

(i) For all enrollees, for the duration of the contract period for which CMS payments have been made; and

(ii) For enrollees who are hospitalized on the date its contract with CMS terminates, or, in the event of an insolvency, through discharge.

(3) In meeting the requirements of this paragraph, other than the provider contract requirements specified in paragraph (g)(1)(i) of this section, the MA organization may use—

(i) Contractual arrangements;

(ii) Insurance acceptable to CMS;

(iii) Financial reserves acceptable to CMS; or

(iv) Any other arrangement acceptable to CMS.

(h) *Requirements of other laws and regulations.* The MA organization agrees to comply with-

(1) Federal laws and regulations designed to prevent or ameliorate fraud, waste, and abuse, including, but not limited to, applicable provisions of Federal criminal law, the False Claims Act (31 U.S.C. 3729 et. seq.), and the anti-kickback statute (section 1128B(b)) of the Act); and

(2) HIPAA administrative simplification rules at 45 CFR parts 160, 162, and 164.

(i) *MA organization relationship with first tier, downstream, and related entities.* (1) Notwithstanding any relationship(s) that the MA organization may have with first tier, downstream, and related entities, the MA organization maintains ultimate responsibility for adhering to and otherwise fully complying with all terms and conditions of its contract with CMS.

(2) The MA organization agrees to require all first tier, downstream, and related entities to agree that—

(i) HHS, the Comptroller General, or their designees have the right to audit, evaluate, collect, and inspect any books, contracts, computer or other electronic systems, including medical records and documentation of the first tier, downstream, and entities related to CMS' contract with the MA organization.

(ii) HHS, the Comptroller General, or their designees have the right to audit, evaluate, collect, and inspect any records under paragraph (i)(2)(i) of this section directly from any first tier, downstream, or related entity.

(iii) For records subject to review under paragraph (i)(2)(ii) of this section, except in exceptional circumstances, CMS will provide notification to the MA organization that a direct request for information has been initiated.

(iv) HHS', the Comptroller General's, or their designee's right to inspect, evaluate, and audit any pertinent information for any particular contract period will exist through 10 years from the final date of the contract period or from the date of completion of any audit, whichever is later.

(v) They will ensure that payments are not made to individuals and entities included on the preclusion list, defined in § 422.2.

(3) All contracts or written arrangements between MA organizations and first tier, downstream, and related entities must contain the following:

(i) Enrollee protection provisions that provide, consistent with paragraph (g)(1) of this section, arrangements that prohibit providers from holding an enrollee liable for payment of any fees that are the obligation of the MA organization.

(ii) Accountability provisions that indicate that the MA organization may only delegate activities or functions to a first tier, downstream, or related entity, in a manner consistent with the requirements set forth at paragraph (i)(4) of this section.

(iii) A provision requiring that any services or other activity performed by a first tier, downstream, and related entity in accordance with a contract

are consistent and comply with the MA organization's contractual obligations.

(4) If any of the MA organizations' activities or responsibilities under its contract with CMS are delegated to other parties, the following requirements apply to any first tier, downstream and related entity:

(i) Each and every contract must specify delegated activities and reporting responsibilities.

(ii) Each and every contract must either provide for revocation of the delegation activities and reporting requirements or specify other remedies in instances where CMS or the MA organization determine that such parties have not performed satisfactorily.

(iii) Each and every contract must specify that the performance of the parties is monitored by the MA organization on an ongoing basis.

(iv) Each and every contract must specify that either—

(A) The credentials of medical professionals affiliated with the party or parties will be either reviewed by the MA organization; or

(B) The credentialing process will be reviewed and approved by the MA organization and the MA organization must audit the credentialing process on an ongoing basis.

(v) All contracts or written arrangements must specify that the related entity, contractor, or subcontractor must comply with all applicable Medicare laws, regulations, and CMS instructions.

(5) If the MA organization delegates selection of the providers, contractors, or subcontractor to another organization, the MA organization's contract with that organization must state that the CMS-contracting MA organization retains the right to approve, suspend, or terminate any such arrangement.

(j) *Additional contract terms.* The MA organization agrees to include in the contract such other terms and conditions as CMS may find necessary and appropriate in order to implement requirements in this part.

(k) *Severability of contracts.* The contract must provide that, upon CMS's request—

(1) The contract will be amended to exclude any MA plan or State-licensed entity specified by CMS; and

(2) A separate contract for any such excluded plan or entity will be deemed to be in place when such a request is made.

(l) *Certification of data that determine payment.* As a condition for receiving a monthly payment under subpart G of this part, the MA organization agrees that its chief executive officer (CEO), chief financial officer (CFO), or an individual delegated the authority to sign on behalf of one of these officers, and who reports directly to such officer, must request payment under the contract on a document that certifies (based on best knowledge, information, and belief) the accuracy, completeness, and truthfulness of relevant data that CMS requests. Such data include specified enrollment information, encounter data, and other information that CMS may specify.

(1) The CEO, CFO, or an individual delegated the authority to sign on behalf of one of these officers, and who reports directly to such officer, must certify that each enrollee for whom the organization is requesting payment is validly enrolled in an MA plan offered by the organization and the information relied upon by CMS in determining payment (based on best knowledge, information, and belief) is accurate, complete, and truthful.

(2) The CEO, CFO, or an individual delegated with the authority to sign on behalf of one of these officers, and who reports directly to such officer, must certify (based on best knowledge, information, and belief) that the data it submits under § 422.310 are accurate, complete, and truthful.

(3) If such data are generated by a related entity, contractor, or subcontractor of an MA organization, such entity, contractor, or subcontractor must similarly certify (based on best knowledge, information, and belief) the accuracy, completeness, and truthfulness of the data.

(4) The CEO, CFO, or an individual delegated the authority to sign on behalf of one of these officers, and who reports directly to such officer, must certify (based on best knowledge, information, and belief) that the information in its bid submission is accurate, complete, and truthful and fully conforms to the requirements in § 422.254.

(5) *Certification of accuracy of data for overpayments.* The CEO, CFO, or COO must certify (based on best knowledge, information, and belief) that the information provided for purposes of reporting and returning of overpayments under § 422.326 is accurate, complete, and truthful.

(m) *Issuance of compliance actions for failure to comply with the terms of the contract.* The MA organization acknowledges that CMS may take compliance actions as described in this section or intermediate sanctions as defined in subpart O of this part.

(1) CMS may take compliance actions as described in paragraph (m)(3) of this section if it determines that the MA organization has not complied with the terms of a current or prior Part C contract with CMS.

(i) CMS may determine that an MA organization is out of compliance with a Part C requirement when the organization fails to meet performance standards articulated in the Part C statutes, regulations in this chapter, or guidance.

(ii) If CMS has not already articulated a measure for determining noncompliance, CMS may determine that an MA organization is out of compliance when its performance in fulfilling Part C requirements represents an outlier relative to the performance of other MA organizations.

(2) CMS bases its decision on whether to issue a compliance action and what level of compliance action to take on an assessment of the circumstances surrounding the noncompliance, including all of the following:

(i) The nature of the conduct.

(ii) The degree of culpability of the MA organization.

(iii) The adverse effect to beneficiaries which resulted or could have resulted from the conduct of the MA organization.

(iv) The history of prior offenses by the MA organization or its related entities.

(v) Whether the noncompliance was self-reported.

(vi) Other factors which relate to the impact of the underlying noncompliance or the lack of the MA organization's oversight of its operations that contributed to the noncompliance.

(3) CMS may take one of three types of compliance actions based on the nature of the noncompliance.

(i) *Notice of noncompliance.* A notice of noncompliance may be issued for any failure to comply with the requirements of the MA organization's current or prior Part C contract with CMS, as described in paragraph (m)(1) of this section.

(ii) *Warning letter.* A warning letter may be issued for serious and/or continued noncompliance with the requirements of the MA organization's current or prior Part C contract with CMS, as described in paragraph (m)(1) of this section and as assessed in accordance with paragraph (m)(2) of this section.

(iii) *Corrective action plan.* (A) Corrective action plans are requested for particularly serious or continued noncompliance with the requirements of the MA organization's current or prior Part C contract with CMS, as described in paragraph (m)(1) of this section and as assessed in accordance with paragraph (m)(2) of this section.

(B) CMS issues a corrective action plan if CMS determines that the MA organization has repeated or not corrected noncompliance identified in prior compliance actions, has substantially impacted beneficiaries or the program with its noncompliance, or must implement a detailed plan to correct the underlying causes of the noncompliance.

(n) *Acknowledgements of CMS release of data*—(1) *Summary CMS payment data.* The contract must provide that the MA organization acknowledges that CMS releases to the public summary reconciled CMS payment data after the reconciliation of Part C and Part D payments for the contract year as follows:

(i) For Part C, the following data—

(A) Average per member per month CMS payment amount for A/B (original Medicare) benefits for each MA plan offered, standardized to the 1.0 (average risk score) beneficiary.

(B) Average per member per month CMS rebate payment amount for each MA plan offered (or, in the case of MSA plans, the monthly MSA deposit amount).

(C) Average Part C risk score for each MA plan offered.

(D) County level average per member per month CMS payment amount for each plan type in that county, weighted by enrollment and standardized to the 1.0 (average risk score) beneficiary in that county.

(ii) For Part D plan sponsors, plan payment data in accordance with § 423.505(o) of this subchapter.

(2) *MA bid pricing data and Part C MLR data.* The contract must provide that the MA organization acknowledges that CMS releases to the public data as described at §§ 422.272 and 422.2490.

(o) *Business continuity.* (1) The MA organization agrees to develop, maintain, and implement a business continuity plan containing policies and procedures to ensure the restoration of business operations following disruptions to business operations which would include natural or man-made disasters, system failures, emergencies, and other similar circumstances and the threat of such occurrences. To meet the requirement, the business continuity plan must, at a minimum, include the following:

(i) *Risk assessment.* Identify threats and vulnerabilities that might affect business operations.

(ii) *Mitigation strategy.* Design strategies to mitigate hazards. Identify essential functions in addition to those specified in paragraph (o)(2) of this section and prioritize the order in which to restore all other functions to normal operations. At a minimum, each MA organization must do the following:

(A) Identify specific events that will activate the business continuity plan.

(B) Develop a contingency plan to maintain, during any business disruption, the availability and, as applicable, confidentiality of communication systems and essential records in all forms (including electronic and paper copies). The contingency plan must do the following:

(*1*) Ensure that during any business disruption the following systems will operate continuously or, should they fail, be restored to operational capacity on a timely basis:

(*i*) Information technology (IT) systems including those supporting claims processing at point of service.

(*ii*) Provider and enrollee communication systems including telephone, Web site, and email.

(*2*) With respect to electronic protected health information, comply with the contingency plan requirements of the Health Insurance Portability and Accountability Act of 1996 Security Regulations at 45 CFR parts 160 and 164, subparts A and C.

(C) Establish a chain of command.

(D) Establish a business communication plan that includes emergency capabilities and procedures to contact and communicate with the following:

(*1*) Employees.

(*2*) First tier, downstream, and related entities.

(*3*) Other third parties (including pharmacies, providers, suppliers, and government and emergency management officials).

(E) Establish employee and facility management plans to ensure that essential operations and job responsibilities can be assumed by other employees or moved to alternate sites as necessary.

(F) Establish a restoration plan including procedures to transition to normal operations.

(G) Comply with all applicable Federal, State, and local laws.

(iii) *Testing and revision.* On at least an annual basis, test and update the business operations continuity plan to ensure the following:

(A) That it can be implemented in emergency situations.

(B) That employees understand how it is to be executed.

(iv) *Training.* On at least an annual basis, educate appropriate employees about the business continuity plan and their own respective roles.

(v) *Records.* (A) Develop and maintain records documenting the elements of the business continuity plan described in paragraphs (o)(1)(i) through (iv) of this section.

(B) Make the information specified in paragraph (o)(1)(v)(A) of this section available to CMS upon request.

(2) *Restoration of essential functions.* Every MA organization must plan to restore essential functions within 72 hours after any of the essential functions fail or otherwise stop functioning as usual. In addition to any essential

functions that the MA organization identifies under paragraph (o)(1)(ii) of this section, for purposes of this paragraph (o)(2) of the section essential functions include, at a minimum, the following:

(i) Benefit authorization (if not waived) for services to be immediately furnished at a hospital, clinic, provider office, or other place of service.

(ii) Operation of call center customer services.

[63 FR 35099, June 26, 1998]

EDITORIAL NOTE: For FEDERAL REGISTER citations affecting § 422.504, see the List of CFR Sections Affected, which appears in the Finding Aids section of the printed volume and at *www.govinfo.gov*.

§ 422.505 Effective date and term of contract.

(a) *Effective date.* The contract is effective on the date specified in the contract between the MA organization and CMS and, for a contract that provides for coverage under an MSA plan, not earlier than January 1999.

(b) *Term of contract.* Each contract is for a period of at least 12 months.

(c) *Renewal of contract.* In accordance with 422.506, contracts are renewed annually only if the MA organization has not provided CMS with a notice of intention not to renew and CMS has not provided the MA organization with a notice of intention not to renew.

(d) *Renewal of contract contingent on reaching agreement on the bid.* Although an MA organization may be determined qualified to renew its contract under this section, if the organization and CMS cannot reach agreement on the bid under subpart F of this part, no renewal will take place, and the failure to reach an agreement is not subject to the appeals provisions in subpart N of this part.

[63 FR 35099, June 26, 1998, as amended at 65 FR 40328, June 29, 2000. Redesignated at 70 FR 4736, Jan. 28, 2005, as amended at 70 FR 4737, Jan. 28, 2005; 72 FR 68723, Dec. 5, 2007]

§ 422.506 Nonrenewal of contract.

(a) *Nonrenewal by an MA organization.* (1) An MA organization may elect not to renew its contract with CMS as of the end of the term of the contract for any reason provided it meets the timeframes for doing so set forth in paragraphs (a)(2) and (a)(3) of this section.

(2) If an MA organization does not intend to renew its contract, it must notify—

(i) CMS in writing, by the first Monday in June of the year in which the contract would end;

(ii) Each Medicare enrollee by mail at least 90 calendar days before the date on which the nonrenewal is effective. The MA organization must also provide information about alternative enrollment options by doing one or more of the following:

(A) Provide a CMS approved written description of alternative MA plan, MA–PD plan, and PDP options available for obtaining qualified Medicare services within the beneficiaries' region.

(B) Place outbound calls to all affected enrollees to ensure beneficiaries know who to contact to learn about their enrollment options.

(3) If an MA organization does not renew a contract under paragraph (a) of this section, CMS may deny an application for a new contract or a service area expansion from the MA organization for 2 years unless there are circumstances that warrant special consideration, as determined by CMS. This prohibition may apply regardless of the product type, contract type or service area of the previous contract.

(4) During the same 2-year period as specified in paragraph (a)(3) of this section, CMS will not contract with an organization whose covered persons also served as covered persons for the nonrenewing sponsor. A ''covered person'' as used in this paragraph means one of the following:

(i) All owners of nonrenewed or terminated organizations who are natural persons, other than shareholders who have an ownership interest of less than 5 percent.

(ii) An owner in whole or part interest in any mortgage, deed of trust, note or other obligation secured (in whole or in part) by the organization, or any of the property or assets thereof, which whole or part interest is equal to or exceeds 5 percent of the total property, and assets of the organization.

(iii) A member of the board of directors or board of trustees of the entity,

if the organization is organized as a corporation.

(b) [Reserved]

[63 FR 35099, June 26, 1998, as amended at 65 FR 40328, June 29, 2000; 67 FR 13289, Mar. 22, 2002; 70 FR 4737, Jan. 28, 2005; 72 FR 68723, Dec. 5, 2007; 74 FR 1542, Jan. 12, 2009; 75 FR 19811, Apr. 15, 2010; 76 FR 21568, Apr. 15, 2011; 80 FR 7961, Feb. 12, 2015; 83 FR 16734, Apr. 16, 2018]

§ 422.508 Modification or termination of contract by mutual consent.

(a) A contract may be modified or terminated at any time by written mutual consent.

(1) If the contract is terminated by mutual consent, except as provided in paragraph (b) of this section, the MA organization must provide notice to its Medicare enrollees and the general public as provided in § 422.512(b)(2) and (b)(3).

(2) If the contract is modified by mutual consent, the MA organization must notify its Medicare enrollees of any changes that CMS determines are appropriate for notification within timeframes specified by CMS.

(3) If the organization submits a request to end the term of its contract after the deadline provided in § 422.506(a)(2)(i), the contract may be terminated by mutual consent in accordance with paragraphs (a) through (d) of this section. CMS may mutually consent to the contract termination if the contract termination does not negatively affect the administration of the Medicare program.

(b) If the contract terminated by mutual consent is replaced the day following such termination by a new MA contract, the MA organization is not required to provide the notice specified in paragraph (a)(1) of this section.

(c) *Agreement to limit new MA applications.* As a condition of the consent to a mutual termination CMS will require, as a provision of the termination agreement language prohibiting the MA organization from applying for new contracts or service area expansions for a period of 2 years, absent circumstances warranting special consideration. This prohibition may apply regardless of the product type, contract type or service area of the previous contract.

(d) *Prohibition against Part C program participation by organizations whose owners, directors, or management employees served in a similar capacity with another organization that mutually terminated its Medicare contract within the previous 2 years.* During the same 2-year period, CMS will not contract with an organization whose covered persons also served as covered persons for the mutually terminating sponsor. A ''covered person'' as used in this paragraph means one of the following:

(1) All owners of nonrenewal or terminated organizations who are natural persons, other than shareholders who have an ownership interest of less than 5 percent.

(2) An owner in whole or part interest in any mortgage, deed of trust, note or other obligation secured (in whole or in part) by the organization, or any of the property or assets thereof, which whole or part interest is equal to or exceeds 5 percent of the total property, and assets of the organization.

(3) A member of the board of directors of the entity, if the organization is organized as a corporation.

[63 FR 35099, June 26, 1998, as amended at 75 FR 19811, Apr. 15, 2010; 76 FR 21569, Apr. 15, 2011; 80 FR 7961, Feb. 12, 2015; 83 FR 16734, Apr. 16, 2018]

§ 422.510 Termination of contract by CMS.

(a) *Termination by CMS.* CMS may at any time terminate a contract if CMS determines that the MA organization meets any of the following:

(1) Has failed substantially to carry out the contract.

(2) Is carrying out the contract in a manner that is inconsistent with the efficient and effective administration of this part.

(3) No longer substantially meets the applicable conditions of this part.

(4) CMS may make a determination under paragraph (a)(1), (2), or (3) of this section if the MA organization has had one or more of the following occur:

(i) Based on creditable evidence, has committed or participated in false, fraudulent or abusive activities affecting the Medicare, Medicaid or other State or Federal health care programs, including submission of false or fraudulent data.

(ii) Substantially failed to comply with the requirements in subpart M of this part relating to grievances and appeals.

(iii) Failed to provide CMS with valid data as required under §422.310.

(iv) Failed to implement an acceptable quality assessment and performance improvement program as required under subpart D of this part.

(v) Substantially failed to comply with the prompt payment requirements in §422.520.

(vi) Substantially failed to comply with the service access requirements in §422.112 or §422.114.

(vii) Failed to comply with the requirements of §422.208 regarding physician incentive plans.

(viii) Substantially fails to comply with the requirements in subpart V of this part.

(ix) Failed to comply with the regulatory requirements contained in this part or part 423 of this chapter or both.

(x) Failed to meet CMS performance requirements in carrying out the regulatory requirements contained in this part or part 423 of this chapter or both.

(xi) Achieves a Part C summary plan rating of less than 3 stars for 3 consecutive contract years. Plan ratings issued by CMS before September 1, 2012 are not included in the calculation of the 3-year period.

(xii) Has failed to report MLR data in a timely and accurate manner in accordance with §422.2460 or that any MLR data required by this subpart is found to be materially incorrect or fraudulent.

(xiii) Fails to meet the preclusion list requirements in accordance with §422.222 and 422.224.

(xiv) The MA organization has committed any of the acts in §422.752(a) that support the imposition of intermediate sanctions or civil money penalties under subpart O of this part.

(xv) Following the issuance of a notice to the MA organization no later than August 1, CMS must terminate, effective December 31 of the same year, an individual MA plan if that plan does not have a sufficient number of enrollees to establish that it is a viable independent plan option.

(xvi) Meets the criteria in §422.514(d)(1) or (2).

(b) *Notice.* If CMS decides to terminate a contract it gives notice of the termination as follows:

(1) *Termination of contract by CMS.*

(i) CMS notifies the MA organization in writing at least 45 calendar days before the intended date of the termination.

(ii) The MA organization notifies its Medicare enrollees of the termination by mail at least 30 calendar days before the effective date of the termination.

(iii) The MA organization notifies the general public of the termination at least 30 calendar days before the effective date of the termination by releasing a press statement to news media serving the affected community or county and posting the press statement prominently on the organization's Web site.

(iv) In the event that CMS issues a termination notice to an MA organization on or before August 1 with an effective date of the following December 31, the MA organization must issue notification to its Medicare enrollees at least 90 days prior to the effective date of the termination.

(2) *Immediate termination of contract by CMS.* (i) The procedures specified in paragraph (b)(1) of this section do not apply if—

(A) CMS determines that a delay in termination, resulting from compliance with the procedures provided in this part prior to termination, would pose an imminent and serious risk to the health of the individuals enrolled with the MA organization; or

(B) The MA organization experiences financial difficulties so severe that its ability to make necessary health services available is impaired to the point of posing an imminent and serious risk to the health of its enrollees, or otherwise fails to make services available to the extent that such a risk to health exists; or

(C) The contract is being terminated based on the grounds specified in paragraph (a)(4)(i) of this section.

(ii) CMS notifies the MA organization in writing that its contract will be terminated on a date specified by CMS. If a termination is effective in the middle of a month, CMS has the right to

recover the prorated share of the capitation payments made to the MA organization covering the period of the month following the contract termination.

(iii) CMS notifies the MA organization's Medicare enrollees in writing of CMS's decision to terminate the MA organization's contract. This notice occurs no later than 30 days after CMS notifies the plan of its decision to terminate the MA contract. CMS simultaneously informs the Medicare enrollees of alternative options for obtaining Medicare services, including alternative MA organizations in a similar geographic area and original Medicare.

(iv) CMS notifies the general public of the termination no later than 30 days after notifying the plan of CMS's decision to terminate the MA contract. This notice is published in one or more newspapers of general circulation in each community or county located in the MA organization's service area.

(c) *Opportunity to develop and implement a corrective action plan*—(1) *General.* (i) Before providing a notice of intent to terminate the contract, CMS will provide the MA organization with notice specifying the MA organization's deficiencies and a reasonable opportunity of at least 30 calendar days to develop and implement a corrective action plan to correct the deficiencies.

(ii) The MA organization is solely responsible for the identification, development, and implementation of its corrective action plan and for demonstrating to CMS that the underlying deficiencies have been corrected within the time period specified by CMS in the notice requesting corrective action.

(2) *Exceptions.* The MA organization will not be provided with an opportunity to develop and implement a corrective action plan prior to termination if—

(i) CMS determines that a delay in termination, resulting from compliance with the procedures provided in this part prior to termination, would pose an imminent and serious risk to the health of the individuals enrolled with the MA organization;

(ii) The MA organization experiences financial difficulties so severe that its ability to make necessary health services available is impaired to the point of posing an imminent and serious risk to the health of its enrollees, or otherwise fails to make services available to the extent that such a risk to health exists; or

(iii) The contract is being terminated based on the violation specified in (a)(4)(i) of this section.

(d) *Appeal rights.* If CMS decides to terminate a contract, it sends written notice to the MA organization informing it of its termination appeal rights in accordance with subpart N of this part.

(e) If CMS makes a determination to terminate a MA organization's contract under § 422.510(a), CMS also imposes the intermediate sanctions at § 422.750(a)(1) and (3) in accordance with the following procedures:

(1) The sanction goes into effect 15 days after the termination notice is sent.

(2) The MA organization has a right to appeal the intermediate sanction in the same proceeding as the termination appeal specified in paragraph (d) of this section.

(3) A request for a hearing does not delay the date specified by CMS when the sanction becomes effective.

(4) The sanction remains in effect—

(i) Until the effective date of the termination; or

(ii) If the termination decision is overturned on appeal, when a final decision is made by the hearing officer or Administrator.

[63 FR 35099, June 26, 1998, as amended at 65 FR 40328, June 29, 2000; 70 FR 52027, Sept. 1, 2005; 72 FR 68723, Dec. 5, 2007; 75 FR 19811, Apr. 15, 2010; 77 FR 22168, Apr. 12, 2012; 78 FR 31307, May 23, 2013; 79 FR 29959, May 23, 2014; 81 FR 80557, Nov. 15, 2016; 83 FR 16734, Apr. 16, 2018; 88 FR 22334, Apr. 12, 2023; 89 FR 30824, Apr. 23, 2024]

§ 422.512 Termination of contract by the MA organization.

(a) *Cause for termination.* The MA organization may terminate the MA contract if CMS fails to substantially carry out the terms of the contract.

(b) *Notice.* The MA organization must give advance notice as follows:

(1) To CMS, at least 90 days before the intended date of termination. This notice must specify the reasons why the MA organization is requesting contract termination.

(2) To its Medicare enrollees, at least 60 days before the termination effective date. This notice must include a written description of alternatives available for obtaining Medicare services within the services area, including alternative MA plans, Medigap options, original Medicare and must receive CMS approval.

(3) To the general public at least 60 days before the termination effective date by publishing an CMS-approved notice in one or more newspapers of general circulation in each community or county located in the MA organization's geographic area.

(c) *Effective date of termination*. The effective date of the termination is determined by CMS and is at least 90 days after the date CMS receives the MA organization's notice of intent to terminate.

(d) *CMS's liability*. CMS's liability for payment to the MA organization ends as of the first day of the month after the last month for which the contract is in effect.

(e) *Effect of termination by the organization*. (1) CMS may deny an application for a new contract or a service area expansion from an MA organization that has terminated its contract within the preceding 2 years unless there are circumstances that warrant special consideration, as determined by CMS. This prohibition may apply regardless of the contract type, product type, or service area of the previous contract.

(2) During the same 2-year period specified in paragraph (e)(1) of this section, CMS will not contract with an organization whose covered persons also served as covered persons for the terminating sponsor. A ''covered person'' as used in this paragraph means one of the following:

(i) All owners of nonrenewal or terminated organizations who are natural persons, other than shareholders who have an ownership interest of less than 5 percent.

(ii) An owner in whole or part interest in any mortgage, deed of trust, note or other obligation secured (in whole or in part) by the organization, or any of the property or assets thereof, which whole or part interest is equal to or exceeds 5 percent of the total property and assets of the organization.

(iii) A member of the board of directors of the entity, if the organization is organized as a corporation.

[63 FR 35099, June 26, 1998, as amended at 67 FR 13288, Mar. 22, 2002; 76 FR 21569, Apr. 15, 2011; 80 FR 7961, Feb. 12, 2015]

§ 422.514 Enrollment requirements.

(a) *Minimum enrollment rules.*Except as provided in paragraph (b) of this section, CMS does not enter into a contract under this subpart unless the organization meets the following minimum enrollment requirement—

(1) At least 5,000 individuals (or 1,500 individuals if the organization is a PSO) are enrolled for the purpose of receiving health benefits from the organization; or

(2) At least 1,500 individuals (or 500 individuals if the organization is a PSO) are enrolled for purposes of receiving health benefits from the organization and the organization primarily serves individuals residing outside of urbanized areas as defined in § 412.62(f) (or, in the case of a PSO, the PSO meets the requirements in § 422.352(c)).

(3) Except as provided for in paragraph (b) of this section, an MA organization must maintain a minimum enrollment as defined in paragraphs (a)(1) and (a)(2) of this section for the duration of its contract.

(b) *Minimum enrollment waiver*. For a contract applicant that does not meet the applicable requirement of paragraph (a) of this section at application for an MA contract, CMS may waive the minimum enrollment requirement for the first 3 years of the contract. To receive a waiver, a contract applicant must demonstrate to CMS's satisfaction that it is capable of administering and managing an MA contract and is able to manage the level of risk required under the contract during the first 3 years of the contract. Factors that CMS takes into consideration in making this evaluation include the extent to which—

(1) The contract applicant management and providers have previous experience in managing and providing health care services under a risk-based payment arrangement to at least as

many individuals as the applicable minimum enrollment for the entity as described in paragraph (a) of this section; or

(2) The contract applicant has the financial ability to bear financial risk under an MA contract. In determining whether an organization is capable of bearing risk, CMS considers factors such as the organization's management experience as described in paragraph (b)(1) of this section and stop-loss insurance that is adequate and acceptable to CMS; and

(3) The contract applicant is able to establish a marketing and enrollment process that allows it to meet the applicable enrollment requirement specified in paragraph (a) of this section before completion of the third contract year.

(c) Failure to meet enrollment requirements. CMS may elect not to renew its contract with an MA organization that fails to meet the applicable enrollment requirement in paragraph (a) of this section.

(d) *Rule on dual eligible enrollment.* In any state where there is a dual eligible special needs plan or any other plan authorized by CMS to exclusively enroll individuals entitled to medical assistance under a state plan under title XIX, CMS does not:

(1) Enter into or renew a contract under this subpart for a MA plan that—

(i) Is not a specialized MA plan for special needs individuals as defined in § 422.2; and

(ii) Projects enrollment in its bid submitted under § 422.254 in which enrollees entitled to medical assistance under a State plan under title XIX constitute a percentage of the plan's total enrollment that meets or exceeds one of the following:—

(A) For plan year 2024, 80 percent.

(B) For plan year 2025, 70 percent.

(C) For plan year 2026 and subsequent years, 60 percent.

(2) Renew a contract under this subpart for an MA plan that—

(i) Is not a specialized MA plan for special needs individuals as defined in § 422.2; and

(ii) Unless the MA plan has been active for less than 1 year and has enrollment of 200 or fewer individuals at the time of such determination, has actual enrollment, as determined by CMS using the January enrollment of the current year in which enrollees who are entitled to medical assistance under a state plan under title XIX, constitute a percentage of the plan's total enrollment that meets or exceeds one of the following:

(A) For renewals for plan year 2024, 80 percent.

(B) For renewals for plan year 2025, 70 percent.

(C) For renewals for plan year 2026 and subsequent years, 60 percent.

(e) *Transition process and procedures.* (1) For coverage effective January 1 of the next year, and subject to the disclosure requirements described in paragraph (e)(2) of this section, an MA organization may transition enrollees in a plan specified in paragraph (d)(2) of this section into another MA plan or plans (including into a dual eligible special needs plan for enrollees who are eligible for such a plan) offered by the MA organization, or another MA organization that shares the same parent organization as the MA organization, for which the individual is eligible in accordance with §§ 422.50 through 422.53 if the MA plan or plans receiving such enrollment—

(i) Would not meet the criteria in paragraph (d)(2)(ii) of this section, as determined in the procedures described in paragraph (e)(3) of this section, with the addition of the newly enrolled individuals (unless such plan is a specialized MA plan for special needs individuals as defined in § 422.2);

(ii) Is an MA–PD plan described at § 422.2;

(iii) Has a combined Part C and Part D premium of $0.00 for individuals eligible for the premium subsidy for full subsidy eligible individuals described in § 423.780(a) of this chapter;

(iv) Is of the same plan type (for example, HMO or PPO) as the plan specified in paragraph (d)(2) of this section; and

(v) For transitions for plan year 2027 and subsequent years, is a dual eligible special needs plan as defined in § 422.2.

(2) An MA organization may transition individuals under paragraph (e)(1) of this section without requiring the individual to file the election form under § 422.66(a) if—

(i) The enrolled individual is eligible to enroll in the MA plan; and

(ii) The MA–PD plan into which individuals are transitioned describes changes to MA–PD benefits and provides information about the MA–PD plan in the Annual Notice of Change, which must be sent consistent with § 422.111(a), (d), and (e).

(3) For the purpose of approving a MA organization to transition enrollment under this paragraph (e), CMS determines whether a non-SNP MA plan would meet the criteria in paragraph (d)(2) of this section by adding the cohort of individuals identified by the MA organization for enrollment in a non-SNP MA plan to the April enrollment of such plan and calculating the resulting percentage of dual eligible enrollment.

(4) In cases where an MA organization does not transition current enrollees under paragraph (e)(1) of this section, the MA organization must send a written notice to enrollees who are not transitioned, consistent with § 422.506(a)(2).

(f) *Special considerations.* Actions taken pursuant to paragraph (d) of this section warrant special consideration to exempt affected MA organizations from the denial of an application for a new contract or service area expansion in accordance with §§ 422.502(b)(3) and (4), 422.503(b)(6) and (7), 422.506(a)(3) and (4), 422.508(c) and (d), and 422.512(e)(1) and (2).

(g) *Applicability to segments.* The rules under paragraphs (d) through (f) of this section also apply to segments of the MA plan as provided for local MA plans under § 422.262(c)(2).

(h) *Rule on dual eligible special needs plans in relation to Medicaid managed care.*

(1) Beginning in 2027, where an MA organization offers a dual eligible special needs plan and the MA organization, its parent organization, or any entity that shares a parent organization with the MA organization also contracts with a State as a Medicaid managed care organization (MCO) (as defined in § 438.2) that enrolls full-benefit dual eligible individuals as defined in § 423.772, during the effective dates and in the same service area (even if there is only partial overlap of the service areas) of that Medicaid MCO contract, the MA organization—

(i) May only offer, or have a parent organization or share a parent organization with another MA organization that offers, one D–SNP for full-benefit dual eligible individuals, except as permitted in paragraph (h)(3) of this section; and

(ii) Must limit new enrollment in the D–SNP to individuals enrolled in, or in the process of enrolling in, the Medicaid MCO.

(2) Beginning in 2030, such D–SNPs may only enroll (or continue to cover) individuals enrolled in (or in the process of enrolling in) the Medicaid MCO, except that such D–SNPs may continue to implement deemed continued eligibility requirements as described in § 422.52(d).

(3)(i) If a State Medicaid agency's contract(s) with the MA organization differentiates enrollment into D–SNPs by age group or to align enrollment in each D–SNP with the eligibility or benefit design used in the State's Medicaid managed care program(s) (as defined in § 438.2), the MA organization, its parent organization, or an entity that shares a parent organization with the MA organization may offer one or more additional D–SNPs for full-benefit dual eligible individuals in the same service area in accordance with the group (or groups) eligible for D–SNPs based on provisions of the contract with the State Medicaid agency under § 422.107.

(ii) If the MA organization, its parent organization, or an entity that shares a parent organization with the MA organization offers both HMO D–SNP(s) and PPO D–SNP(s), and one or more of the—

(A) HMO D–SNPs is subject to paragraph (h)(1) of this section, the PPO D–SNP(s) not subject to paragraph (h)(1) of this section may continue if they no longer accept new enrollment of full-benefit dual eligible individuals in the same service area as the plan (or plans) subject to paragraph (h)(1) of this section.

(B) PPO D–SNPs is subject to paragraph (h)(1) of this section, the HMO D–SNP(s) not subject to paragraph (h)(1) of this section may continue if they no longer accept new enrollment of full-benefit dual eligible individuals in the

same service area as the plan (or plans) subject to paragraph (h)(1) of this section.

[63 FR 35099, June 26, 1998, as amended at 65 FR 40328, June 29, 2000; 83 FR 16734, Apr. 16, 2018; 85 FR 33908, June 2, 2020; 88 FR 22334, Apr. 12, 2023; 89 FR 30824, Apr. 23, 2024; 89 FR 79451, Sept. 30, 2024]

§ 422.516 Validation of Part C reporting requirements.

(a) *Required information.* Each MA organization must have an effective procedure to develop, compile, evaluate, and report to CMS, to its enrollees, and to the general public, at the times and in the manner that CMS requires, and while safeguarding the confidentiality of the provider-patient relationship, information with respect to the following:

(1) The cost of its operations.

(2) The procedures related to and utilization of its services and items.

(3) The availability, accessibility, and acceptability of its services.

(4) To the extent practical, developments in the health status of its enrollees.

(5) Information demonstrating that the MA organization has a fiscally sound operation.

(6) Other matters that CMS may require.

(b) *Significant business transactions.* Each MA organization must report to CMS annually, within 120 days of the end of its fiscal year (unless for good cause shown, CMS authorizes an extension of time), the following:

(1) A description of significant business transactions (as defined in § 422.500) between the MA organization and a party in interest.

(2) With respect to those transactions—

(i) A showing that the costs of the transactions listed in paragraph (c) of this section do not exceed the costs that would be incurred if these transactions were with someone who is not a party in interest; or

(ii) If they do exceed, a justification that the higher costs are consistent with prudent management and fiscal soundness requirements.

(3) A combined financial statement for the MA organization and a party in interest if either of the following conditions is met:

(i) Thirty-five percent or more of the costs of operation of the MA organization go to a party in interest.

(ii) Thirty-five percent or more of the revenue of a party in interest is from the MA organization.

(c) *Requirements for combined financial statements.* (1) The combined financial statements required by paragraph (b)(3) of this section must display in separate columns the financial information for the MA organization and each of the parties in interest.

(2) Inter-entity transactions must be eliminated in the consolidated column.

(3) The statements must have been examined by an independent auditor in accordance with generally accepted accounting principles and must include appropriate opinions and notes.

(4) Upon written request from an MA organization showing good cause, CMS may waive the requirement that the organization's combined financial statement include the financial information required in this paragraph (c) with respect to a particular entity.

(d) *Reporting and disclosure under ERISA.* (1) For any employees' health benefits plan that includes an MA organization in its offerings, the MA organization must furnish, upon request, the information the plan needs to fulfill its reporting and disclosure obligations (with respect to the particular MA organization) under the Employee Retirement Income Security Act of 1974 (ERISA).

(2) The MA organization must furnish the information to the employer or the employer's designee, or to the plan administrator, as the term ''administrator'' is defined in ERISA.

(e) *Loan information.* Each organization must notify CMS of any loans or other special financial arrangements it makes with contractors, subcontractors and related entities.

(f) *Enrollee access to Information.* Each MA organization must make the information reported to CMS under § 422.502(f)(1) available to its enrollees upon reasonable request.

(g) *Data validation.* Each Part C sponsor must subject information collected under paragraph (a) of this section to a yearly independent audit to determine

their reliability, validity, completeness, and comparability in accordance with specifications developed by CMS.

[63 FR 35099, June 26, 1998, as amended at 75 FR 19812, Apr. 15, 2010; 89 FR 30825, Apr. 23, 2024]

§ 422.520 Prompt payment by MA organization.

(a) *Contract between CMS and the MA organization.* (1) The contract between CMS and the MA organization must provide that the MA organization will pay 95 percent of the ''clean claims'' within 30 days of receipt if they are submitted by, or on behalf of, an enrollee of an MA private fee-for-service plan or are claims for services that are not furnished under a written agreement between the organization and the provider.

(2) The MA organization must pay interest on clean claims that are not paid within 30 days in accordance with sections 1816(c)(2)(B) and 1842(c)(2)(B).

(3) All other claims from non-contracted providers must be paid or denied within 60 calendar days from the date of the request.

(b)(1) *Contracts between MA organizations and providers and suppliers.* Contracts or other written agreements between MA organizations and providers must contain a prompt payment provision, the terms of which are developed and agreed to by both the MA organization and the relevant provider.

(2) The MA organization is obligated to pay contracted providers under the terms of the contract between the MA organization and the provider.

(c) *Failure to comply.* If CMS determines, after giving notice and opportunity for hearing, that an MA organization has failed to make payments in accordance with paragraph (a) of this section, CMS may provide—

(1) For direct payment of the sums owed to providers, or MA private fee-for-service plan enrollees; and

(2) For appropriate reduction in the amounts that would otherwise be paid to the organization, to reflect the amounts of the direct payments and the cost of making those payments.

(d) A CMS decision to not conduct a hearing under paragraph (c) of this section does not disturb any potential remedy under State law for 1866(a)(1)(O) of the Act.

[63 FR 35099, June 26, 1998, as amended at 65 FR 40328, June 29, 2000; 70 FR 4738, Jan. 28, 2005]

§ 422.521 Effective date of new significant regulatory requirements.

CMS will not implement, other than at the beginning of a calendar year, requirements under this part that impose a new significant cost or burden on MA organizations or plans, unless a different effective date is required by statute.

[68 FR 50858, Aug. 22, 2003]

§ 422.524 Special rules for RFB societies.

In order to participate as an MA organization, an RFB society—

(a) May not impose any limitation on membership based on any factor related to health status; and

(b) Must offer, in addition to the MA RFB plan, health coverage to individuals who are members of the church or convention or group of churches with which the society is affiliated, but who are not entitled to receive benefits from the Medicare program.

§ 422.527 Agreements with Federally qualified health centers.

The contract between the MA organization and CMS must specify that—

(a) The MA organization must pay a Federally qualified health center (FQHC) a similar amount to what it pays other providers for similar services.

(b) Under such a contract, the FQHC must accept this payment as payment in full, except for allowable cost sharing which it may collect.

(c) Financial incentives, such as risk pool payments or bonuses, and financial withholdings are not considered in determining the payments made by CMS under § 422.316(a).

[70 FR 4738, Jan. 28, 2005]

§ 422.528 Final settlement process and payment.

(a) *Notice of final settlement.* After the calculation of the final settlement amount, CMS sends the MA organization a notice of final settlement. The

notice of final settlement contains at least all of the following information:

(1) A final settlement amount, which may be either an amount due to the MA organization, or an amount due from the MA organization, or $0 if nothing is due to or from the MA organization, for the contract that has been consolidated, nonrenewed, or terminated.

(2) Relevant banking and financial mailing instructions for MA organizations that owe CMS a final settlement amount.

(3) Relevant CMS contact information.

(4) A description of the steps for requesting an appeal of the final settlement amount calculation, in accordance with the requirements specified in § 422.529.

(b) *Request for an appeal.* An MA organization that disagrees with the final settlement amount has 15 calendar days from issuance of the notice of final settlement, as described in paragraph (a) of this section, to request an appeal of the final settlement amount under the process described in § 422.529.

(1) If an MA organization agrees with the final settlement amount, no response is required.

(2) If an MA organization disagrees with the final settlement amount but does not request an appeal within 15 calendar days from the date of the issuance of the notice of final settlement, CMS does not consider subsequent requests for appeal.

(c) *Actions if an MA organization does not request an appeal.* (1) For MA organizations that are owed money by CMS, CMS remits payment to the MA organization within 60 calendar days from the date of the issuance of the notice of final settlement.

(2) For MA organizations that owe CMS money, the MA organization is required to remit payment to CMS within 120 calendar days from issuance of the notice of final settlement. If the MA organization fails to remit payment within that 120-calendar-day period, CMS refers the debt owed to CMS to the Department of the Treasury for collection.

(d) *Actions following submission of a request for appeal.* If an MA organization responds to the notice of final settlement disagreeing with the final settlement amount and requesting appeal, CMS conducts a review under the process described at§ 422.529.

(e) *No additional payment adjustments.* After the final settlement amount is calculated and the notice of final settlement, as described under § 422.528(a), is issued to the MA organization, CMS no longer apply retroactive payment adjustments to the terminated, consolidated or nonrenewed contract and there are no adjustments applied to amounts used in the calculation of the final settlement amount.

[89 FR 30825, Apr. 23, 2024]

§ 422.529 Requesting an appeal of the final settlement amount.

(a) *Appeals process.* If an MA organization does not agree with the final settlement amount described in § 422.528(a), it may appeal under the following three-level appeal process:

(1) *Reconsideration.* An MA organization may request reconsideration of the final settlement amount described in § 422.528(a) according to the following process:

(i) *Manner and timing of request.* A written request for reconsideration must be filed within 15 calendar days from the date that CMS issued the notice of final settlement to the MA organization.

(ii) *Content of request.* The written request for reconsideration must do all of the following:

(A) Specify the calculation with which the MA organization disagrees and the reasons for its disagreement.

(B) Include evidence supporting the assertion that CMS' calculation of the final settlement amount is incorrect.

(C) Not include new reconciliation data or data that was submitted to CMS after the final settlement notice was issued. CMS does not consider information submitted for the purposes of retroactively adjusting a prior reconciliation.

(iii) *Conduct of reconsideration.* In conducting the reconsideration, the CMS reconsideration official reviews the calculations that were used to determine the final settlement amount and any additional evidence timely submitted by the MA organization.

(iv) *Reconsideration decision.* The CMS reconsideration official informs the MA organization of its decision on the reconsideration in writing.

(v) *Effect of reconsideration decision.* The decision of the CMS reconsideration official is final and binding unless a timely request for an informal hearing is filed in accordance with paragraph (a)(2) of this section.

(2) *Informal hearing.* An MA organization dissatisfied with CMS' reconsideration decision made under paragraph (a)(1) of this section is entitled to an informal hearing as provided for under paragraphs (a)(2)(i) through (a)(2)(iv) of this section.

(i) *Manner and timing of request.* A request for an informal hearing must be made in writing and filed with CMS within 15 calendar days of the date of CMS' reconsideration decision.

(ii) *Content of request.* The request for an informal hearing must include a copy of the reconsideration decision and must specify the findings or issues in the decision with which the MA organization disagrees and the reasons for its disagreement.

(iii) *Informal hearing procedures.* The informal hearing is conducted in accordance with the following:

(A) The CMS Hearing Officer provides written notice of the time and place of the informal hearing at least 30 days before the scheduled date.

(B) The CMS reconsideration official provides a copy of the record that was before CMS when CMS made its decision to the hearing officer.

(C) The hearing officer review is conducted by a CMS hearing officer who neither receives testimony nor accepts any new evidence. The CMS hearing officer is limited to the review of the record that was before CMS when CMS made its decision.

(iv) *Decision of the CMS hearing officer.* The CMS hearing officer decides the case and sends a written decision to the MA organization explaining the basis for the decision.

(v) *Effect of hearing officer's decision.* The hearing officer's decision is final and binding, unless the decision is reversed or modified by the CMS Administrator in accordance with paragraph (a)(3) of this section.

(3) *Review by the Administrator.* The Administrator's review is conducted in the following manner:

(i) *Manner and timing of request.* An MA organization that has received a hearing officer's decision may request review by the Administrator within 15 calendar days of the date of issuance of the hearing officer's decision under paragraph (a)(2)(iv) of this section. An MA organization may submit written arguments to the Administrator for review.

(ii) *Discretionary review.* After receiving a request for review, the Administrator has the discretion to elect to review the hearing officer's determination in accordance with paragraph (a)(3)(iii) of this section or to decline to review the hearing officer's decision within 30 calendar days of receiving the request for review. If the Administrator declines to review the hearing officer's decision, the hearing officer's decision is final and binding.

(iii) *Administrator's review.* If the Administrator elects to review the hearing officer's decision, the Administrator reviews the hearing officer's decision, as well as any information included in the record of the hearing officer's decision and any written argument submitted by the MA organization, and determine whether to uphold, reverse, or modify the hearing officer's decision.

(iv) *Effect of Administrator's decision.* The Administrator's decision is final and binding.

(b) *Matters subject to appeal and burden of proof.* (1) The MA organization's appeal is limited to CMS' calculation of the final settlement amount. CMS does not consider information submitted for the purposes of retroactively adjusting a prior reconciliation.

(2) The MA organization bears the burden of proof by providing evidence demonstrating that CMS' calculation of the final settlement amount is incorrect.

(c) *Stay of financial transaction until appeals are exhausted.* If an MA organization requests review of the final settlement amount, the financial transaction associated with the issuance or payment of the final settlement amount is stayed until all appeals are

exhausted. Once all levels of appeal are exhausted or the MA organization fails to request further review within the applicable 15-calendar-day timeframe, CMS communicates with the MA organization to complete the financial transaction associated with the issuance or payment of the final settlement amount, as appropriate.

(d) *Continued compliance with other law required.* Nothing in this section limits an MA organization's responsibility to comply with any other applicable statute or regulation.

[89 FR 30825, Apr. 23, 2024]

§ 422.530 Plan crosswalks.

(a) *General rules*—(1) *Definition of crosswalk.* A crosswalk is the movement of enrollees from one plan (or plan benefit package (PBP)) to another plan (or PBP) under a contract between the MA organization and CMS. To crosswalk enrollees from one PBP to another is to change the enrollment from the first PBP to the second.

(2) *Prohibitions.* Except as described in paragraph (c) of this section, crosswalks are prohibited between different contracts or different plan types (for example, HMO to PPO).

(3) *Compliance with renewal/non-renewal rules.* The MA organization must comply with renewal and non-renewal rules in §§ 422.505 and 422.506 in order to complete plan crosswalks.

(4) *Eligibility.* Enrollees must be eligible for enrollment under §§ 422.50 through 422.54 in order to be moved from one PBP to another PBP.

(5) *Types of MA plans.* For purposes of crosswalk policy in this section, CMS considers the following plans as different plan types:

(i) Health maintenance organizations coordinated care plans.

(ii) Provider-sponsored organizations coordinated care plans.

(iii) Regional or local preferred provider organizations coordinated care plans.

(iv) Special needs plans.

(v) Private Fee-for-service plans.

(vi) MSA plans.

(b) *Allowable crosswalk types*—(1) *All MA plans.* An MA organization may perform a crosswalk in the following circumstances:

(i) *Renewal.* A plan in the following contract year that links to a current contract year plan and retains the entire service area from the current contract year. The following contract year plan must retain the same plan ID as the current contract year plan.

(ii) *Consolidated renewal.* A plan in the following contract year that combines 2 or more complete current contract year plans of the same plan type but not including when a current PBP is split among more than one PBP for the following contract year. The plan ID for the following contract year must be the same as one of the current contract year plan IDs.

(iii) *Renewal with a service area expansion (SAE).* A plan in the following contract year that links to a current contract year plan and retains all of its plan service area from the current contract year, but also adds one or more new counties. The following year contract plan must retain the same plan ID as the current contract year plan.

(iv) *Renewal with a service area reduction (SAR).* (A) A plan in the following contract year that links to a current contract year plan and only retains a portion of its plan service area. The following contract year plan must retain the same plan ID as the current contract year plan. The crosswalk is limited to the enrollees in the remaining service area.

(B) While the MA organization may not affirmatively crosswalk enrollees in the locations that will no longer be part of the service area, the MA organization may offer those affected enrollees in the reduced portion of the service area a continuation in accordance with § 422.74(b)(3)(ii), provided that there are no other MA plan options in the reduced service area.

(C) If the MA organization offers another PBP in the locations that will no longer be part of the service area, current enrollees in the locations that will no longer be part of the service area must be disenrolled and the MA organization must send a non-renewal notice that includes notification of a special enrollment period under § 422.62 and, for applicable enrollees, Medigap guaranteed issue rights.

(D) The MA organization may offer current enrollees in the locations that

will no longer be part of the service area the option of enrolling in the other plan(s) the MA organization offers in the location that is no longer part of the service area, however, no specific plan information for the following contract year may be shared with any beneficiaries prior to the plan marketing period for the next contract year, consistent with 42 CFR 422.2263 and 423.2263.

(2) *Special needs plans (SNPs).* In addition to those described in paragraph (b)(1) of this section, SNPs may also perform the following types of crosswalks:

(i) *Chronic SNPs (C–SNPs).* (A) Renewing C–SNP with one chronic condition that transitions eligible enrollees into another C–SNP with a grouping that contains that same chronic condition.

(B) Non-renewing C–SNP with one chronic condition that transitions eligible enrollees into another C–SNP with a grouping that contains that same chronic condition.

(C) Non-renewing C–SNP with a grouping that is transitioning eligible enrollees into a different grouping C–SNP if the new grouping contains at least one condition that the prior C–SNP contained.

(ii) *Institutional SNP.* (A) Renewing Institutional SNP that transitions enrollees to an Institutional/Institutional Equivalent SNP.

(B) Renewing Institutional Equivalent SNP that transitions enrollees to an Institutional/Institutional Equivalent SNP.

(C) Renewing Institutional/Institutional Equivalent SNP that transitions eligible enrollees to an Institutional SNP.

(D) Renewing Institutional/Institutional Equivalent SNP that transitions eligible enrollees to an Institutional Equivalent SNP.

(E) Non-renewing Institutional/Institutional Equivalent SNP that transitions eligible enrollees to another Institutional/Institutional Equivalent SNP.

(c) *Exceptions.* In order to perform a crosswalk that is not specified in paragraph (b) of this section, an MA organization must request an exception. Crosswalk exceptions are prohibited between different plan types. CMS reviews exception requests and may permit a crosswalk exception in the following circumstances:

(1) When a non-network or partial network Private Fee-For-Service (PFFS) plan changes to either a partial network or to a full network PFFS plan, enrollees may be moved to the new plan when CMS determines it is in the interest of beneficiaries, considering whether the risks to enrollees are such that they would be better served by remaining in the plan, whether there are other suitable managed care plans available, and whether the enrollees are particularly medically vulnerable, such as institutionalized enrollees. Crosswalks from a network based PFFS plan to a non-network or partial network PFFS plan will not be permitted.

(2) When MA contracts offered by two different MA organizations that share the same parent organization are consolidated such that the separate contracts are consolidated under one surviving contract, the enrollees from the consolidating contracts may be crosswalked to an MA plan under the surviving contract.

(3) When a renewing D–SNP with a multi-state service area reduces its service area or, in the case of a D–SNP in an MA regional plan contract, nonrenews and creates state-specific local preferred provider organization plans in its place to accommodate state contracting efforts in the service area, enrollees who are no longer in the service area may be moved into one or more new or renewing D–SNPs, offered under the same parent organization (even if the D–SNPs are offered by two different MA organizations), and for which the enrollees are eligible, as CMS determines is necessary to accommodate changes to the contracts between the state and D–SNP under § 422.107. For this crosswalk exception, CMS will permit enrollees to be moved between different contracts.

(4) When—

(i) A renewing D–SNP has another new or renewing D–SNP, and the two D–SNPs are offered to different populations, enrollees who are no longer eligible for their current D–SNP may be moved into the other new or renewing

D–SNP offered by the same MA organization if they meet the eligibility criteria for the new or renewing D–SNP and CMS determines it is in the best interest of the enrollees to move to the new or renewing D–SNP in order to promote access to and continuity of care for enrollees relative to the absence of a crosswalk exception. For the crosswalk exception in this paragraph (c)(4)(i), CMS does not permit enrollees to be moved between different contracts; or

(ii) An MA organization creates a new MA contract when required by a State as described in §422.107(e), eligible enrollees may be moved from the existing D–SNP that is non-renewing, reducing its service area, or has its eligible population newly restricted by a State, to a D–SNP offered under the D–SNP-only contract, which must be of the same plan type operated by the same parent organization. For the crosswalk exception in this paragraph (c)(4)(ii), CMS permits enrollees to be moved between different contracts.

(iii) For contract year 2027 and subsequent years, where one or more MA organizations that share a parent organization seek to consolidate D–SNPs in the same service area down to a single D–SNP under one MA–PD contract to comply with requirements at §§422.514(h) and 422.504(a)(20), CMS permits enrollees to be moved between different contracts.

(5) Renewing C–SNP with a grouping of multiple conditions that is transitioning eligible enrollees into another C–SNP with one of the chronic conditions from that grouping.

(d) *Procedures.* (1) An MA organization must submit all crosswalks in paragraph (b) of this section in writing through the bid submission process in HPMS by the bid submission deadline announced by CMS.

(2) An MA organization must submit all crosswalk exception requests in paragraph (c)(1) of this section in writing through the crosswalk exceptions process in HPMS by the crosswalk exception request deadline announced by CMS annually. CMS verifies the requests and notifies requesting MA organizations of the approval or denial after the crosswalk exception request deadline.

[86 FR 6099, Jan. 19, 2021, as amended at 87 FR 27896, May 9, 2022; 89 FR 30826, Apr. 23, 2024]

Subpart L—Effect of Change of Ownership or Leasing of Facilities During Term of Contract

SOURCE: 63 FR 35067, June 26, 1998, unless otherwise noted.

EDITORIAL NOTE: Nomenclature changes to subpart L of part 422 appear at 63 FR 35106, June 26, 1998.

§ 422.550 General provisions.

(a) *What constitutes change of ownership*—(1) *Partnership.* The removal, addition, or substitution of a partner, unless the partners expressly agree otherwise as permitted by applicable State law, constitutes a change of ownership.

(2) *Asset transfer.* Transfer of title and property to another party constitutes change of ownership.

(3) *Corporation.* (i) The merger of the MA organization's corporation into another corporation or the consolidation of the MA organization with one or more other corporations, resulting in a new corporate body, constitutes a change of ownership.

(ii) Transfer of corporate stock or the merger of another corporation into the MA organization's corporation, with the MA organization surviving, does not ordinarily constitute change of ownership.

(b) *Advance notice requirement.* (1) An MA organization that has a Medicare contract in effect and is considering or negotiating a change in ownership must notify CMS at least 60 days before the anticipated effective date of the change. The MA organization must also provide updated financial information and a discussion of the financial and solvency impact of the change of ownership on the surviving organization.

(2) If the MA organization fails to give CMS the required notice timely, it continues to be liable for capitation payments that CMS makes to it on behalf of Medicare enrollees after the date of change of ownership.

(c) *Novation agreement defined.* A novation agreement is an agreement among the current owner of the MA organization, the prospective new owner, and CMS—

(1) That is embodied in a document executed and signed by all three parties;

(2) That meets the requirements of § 422.552; and

(3) Under which CMS recognizes the new owner as the successor in interest to the current owner's Medicare contract.

(d) *Effect of change of ownership without novation agreement.* Except to the extent provided in paragraph (b)(2) of this section, the effect of a change of ownership without a novation agreement is that—

(1) The current MA organization, with respect to the affected contract, has substantially failed to comply with the regulatory requirements as described in § 422.510(a)(4)(ix) and the contract may be subject to intermediate enrollment and marketing sanctions as outlined in § 422.750(a)(1) and (a)(3). Intermediate sanctions imposed as part of this section remain in place until CMS approves the change of ownership (including execution of an approved novation agreement), or the contract is terminated.

(i)(A) If the new owner does not participate in the Medicare program in the same service area as the affected contract, it must apply for, and enter into, a contract in accordance with subpart K of this part and part 423 if applicable; and

(B) If the application is conditionally approved, must submit, within 30 days of the conditional approval, the documentation required under § 422.550(c) for review and approval by CMS; or

(ii) If the new owner currently participates in the Medicare program and operates in the same service area as the affected contract, it must, within 30 days of imposition of intermediate sanctions as outlined in paragraph (d)(1) of this section, submit the documentation required under § 422.550(c) for review and approval by CMS.

(2) If the new owner fails to begin the processes required under paragraph (d)(1)(i) or (d)(1)(ii) of this section within 30 days of imposition of intermediate sanctions as outlined in paragraph (d)(1) of this section, the existing contract is subject to termination in accordance with § 422.510(a)(4)(ix).

(e) *Effect of change of ownership with novation agreement.* If the MA organization submits a novation agreement that meets the requirements of § 422.552, and CMS signs it, the new owner becomes the successor in interest to the current owner's Medicare contract.

(f) *Sale of beneficiaries not permitted.* (1) CMS only recognizes the sale or transfer of an organization's entire MA line of business, consisting of all MA contracts held by the MA organization with the exception of the sale or transfer of a full contract between wholly owned subsidiaries of the same parent organization, which is permitted.

(2) CMS does not recognize or allow a sale or transfer that consists solely of the sale or transfer of individual beneficiaries or groups of beneficiaries enrolled in a plan benefit package.

[60 FR 45681, Sept. 1, 1995. Redesignated and amended at 63 FR 35067, 35106, June 26, 1998; 63 FR 52614, Oct. 1, 1998; 65 FR 40328, June 29, 2000; 70 FR 4738, Jan. 28, 2005; 86 FR 6101, Jan. 19, 2021; 89 FR 30826, Apr. 23, 2024]

§ 422.552 Novation agreement requirements.

(a) *Conditions for CMS approval of a novation agreement.* CMS approves a novation agreement if the following conditions are met:

(1) *Advance notification.* The MA organization notifies CMS at least 60 days before the date of the proposed change of ownership. The MA organization also provides CMS with updated financial information and a discussion of the financial and solvency impact of the change of ownership on the surviving organization.

(2) *Advance submittal of agreement.* The MA organization submits to CMS, at least 30 days before the proposed change of ownership date, three signed copies of the novation agreement containing the provisions specified in paragraph (b) of this section, and one copy of other relevant documents required by CMS.

(3) *CMS's determination.* CMS determines that—

(i) The proposed new owner is in fact a successor in interest to the contract;

(ii) Recognition of the new owner as a successor in interest to the contract is in the best interest of the Medicare program; and

(iii) The successor organization meets the requirements to qualify as an MA organization under subpart K of this part.

(b) *Provisions of a novation agreement*—(1) *Assumption of contract obligations*. The new owner must assume all obligations under the contract.

(2) *Waiver of right to reimbursement*. The previous owner must waive its rights to reimbursement for covered services furnished during the rest of the current contract period.

(3) *Guarantee of performance*. (i) The previous owner must guarantee performance of the contract by the new owner during the contract period; or

(ii) The new owner must post a performance bond that is satisfactory to CMS.

(4) *Records access*. The previous owner must agree to make its books and records and other necessary information available to the new owner and to CMS to permit an accurate determination of costs for the final settlement of the contract period.

[50 FR 1346, Jan. 10, 1985, as amended at 56 FR 8853, Mar. 1, 1991; 58 FR 38079, July 15, 1993; 60 FR 45681, Sept. 1, 1995. Redesignated and amended at 63 FR 35067, 35106, June 26, 1998; 70 FR 52027, Sept. 1, 2005]

§ 422.553 Effect of leasing of an MA organization's facilities.

(a) *General effect of leasing*. If an MA organization leases all or part of its facilities to another entity, the other entity does not acquire MA organization status under section 1876 of the Act.

(b) *Effect of lease of all facilities*. (1) If an MA organization leases all of its facilities to another entity, the contract terminates.

(2) If the other entity wishes to participate in Medicare as an MA organization, it must apply for and enter into a contract in accordance with subpart K of this part.

(c) *Effect of partial lease of facilities*. If the MA organization leases part of its facilities to another entity, its contract with CMS remains in effect while CMS surveys the MA organization to determine whether it continues to be in compliance with the applicable requirements and qualifying conditions specified in subpart K of this part.

[50 FR 1346, Jan. 10, 1985; 50 FR 20570, May 17, 1985, as amended at 58 FR 38079, July 15, 1993; 60 FR 45681, Sept. 1, 1995. Redesignated and amended at 63 FR 35067, 35106, June 26, 1998; 70 FR 52027, Sept. 1, 2005]

Subpart M—Grievances, Organization Determinations and Appeals

SOURCE: 63 FR 35107, June 26, 1998, unless otherwise noted.

§ 422.560 Basis and scope.

(a) *Statutory basis*. (1) Section 1852(f) of the Act provides that an MA organization must establish meaningful grievance procedures.

(2) Section 1852(g) of the Act establishes requirements that an MA organization must meet concerning organization determinations and appeals.

(3) Section 1869 of the Act specifies the amount in controversy needed to pursue a hearing and judicial review and authorizes representatives to act on behalf of individuals that seek appeals. These provisions are incorporated for MA appeals by section 1852(g)(5) of the Act and part 405 of this chapter.

(4) Section 1859(f)(8) of the Act provides for, to the extent feasible, unifying grievances and appeals procedures under sections 1852(f), 1852(g), 1902(a)(3), 1902(a)(5), and 1932(b)(4) of the Act for Medicare and Medicaid covered items and services provided by specialized MA plans for special needs individuals described in subsection 1859(b)(6)(B)(ii) of the Act for individuals who are eligible under titles XVIII and XIX of the Act. Beginning January 1, 2021, procedures established under section 1859(f)(8) of the Act apply in place of otherwise applicable grievances and appeals procedures with respect to Medicare and Medicaid covered items and services provided by applicable integrated plans.

(b) *Scope*. This subpart sets forth—

(1) Requirements for MA organizations with respect to grievance procedures, organization determinations, and appeal procedures.

(2) The rights of MA enrollees with respect to organization determinations, and grievance and appeal procedures.

(3) The rules concerning notice of noncoverage of inpatient hospital care.

(4) The rules that apply when an MA enrollee requests immediate QIO review of a determination that he or she no longer needs inpatient hospital care.

(5) Requirements for applicable integrated plans with respect to procedures for integrated grievances, integrated organization determinations, and integrated reconsiderations.

(c) *Relation to ERISA requirements.* Consistent with section 1857(i)(2) of the Act, provisions of this subpart may, to the extent applicable under regulations adopted by the Secretary of Labor, apply to claims for benefits under group health plans subject to the Employee Retirement Income Security Act.

[63 FR 35107, June 26, 1998, as amended at 70 FR 4738, Jan. 28, 2005; 84 FR 15833, Apr. 16, 2019]

§ 422.561 Definitions.

As used in this subpart, unless the context indicates otherwise—

Appeal means any of the procedures that deal with the review of adverse organization determinations on the health care services the enrollee believes he or she is entitled to receive, including delay in providing, arranging for, or approving the health care services (such that a delay would adversely affect the health of the enrollee), or on any amounts the enrollee must pay for a service, as defined under § 422.566(b). These procedures include reconsiderations by the MA organization, and if necessary, an independent review entity, hearings before ALJs, review by the Medicare Appeals Council (Council), and judicial review.

Applicable integrated plan means either of the following:

(1) *Before January 1, 2023.* (i) A fully integrated dual eligible special needs plan with exclusively aligned enrollment or a highly integrated dual eligible special needs plan with exclusively aligned enrollment; and

(ii) The Medicaid managed care organization, as defined in section 1903(m) of the Act, through which such dual eligible special needs plan, its parent organization, or another entity that is owned and controlled by its parent organization covers Medicaid services for dually eligible individuals enrolled in such dual eligible special needs plan and such Medicaid managed care organization.

(2) *On or after January 1, 2023.* (i)(A) A fully integrated dual eligible special needs plan or highly integrated dual eligible special needs plan with exclusively aligned enrollment; and

(B) The Medicaid managed care organization, as defined in section 1903(m) of the Act, through which such dual eligible special needs plan, its parent organization, or another entity that is owned and controlled by its parent organization covers Medicaid services for dually eligible individuals enrolled in such dual eligible special needs plan and such Medicaid managed care organization; or

(ii) A dual eligible special needs plan and affiliated Medicaid managed care plan where—

(A) The dual special needs plan, by State policy, has enrollment limited to those beneficiaries enrolled in a Medicaid managed care organization as described in paragraph (2)(ii)(B) of this definition;

(B) There is a capitated contract between the MA organization, the MA organization's parent organization, or another entity that is owned and controlled by its parent organization; and

(*1*) A Medicaid agency; or

(*2*) A Medicaid managed care organization as defined in section 1903(m) of the Act that contracts with the Medicaid agency; and

(C) Through the capitated contract described in paragraph (2)(ii)(B) of this definition, Medicaid benefits including primary care and acute care, including Medicare cost-sharing as defined in section 1905(p)(3)(B), (C), and (D) of the Act, without regard to the limitation of that definition to qualified Medicare beneficiaries, and at a minimum, one of the following: Home health services as defined in § 440.70 of this chapter,

medical supplies, equipment, and appliances as described in § 440.70(b)(3) of this chapter, or nursing facility services are covered for the enrollees.

Enrollee means an MA eligible individual who has elected an MA plan offered by an MA organization.

Grievance means any complaint or dispute, other than one that constitutes an organization determination, expressing dissatisfaction with any aspect of an MA organization's or provider's operations, activities, or behavior, regardless of whether remedial action is requested.

Integrated appeal means any of the procedures that deal with, or result from, adverse integrated organization determinations by an applicable integrated plan on the health care services the enrollee believes he or she is entitled to receive, including delay in providing, arranging for, or approving the health care services (such that a delay would adversely affect the health of the enrollee), or on any amounts the enrollee must pay for a service. Integrated appeals cover procedures that would otherwise be defined and covered, for non-applicable integrated plans, as an appeal defined in § 422.561 or the procedures required for appeals in accordance with §§ 438.400 through 438.424 of this chapter. Such procedures include integrated reconsiderations.

Integrated grievance means a dispute or complaint that would be defined and covered, for grievances filed by an enrollee in non-applicable integrated plans, under § 422.564 or §§ 438.400 through 438.416 of this chapter. Integrated grievances do not include appeals procedures and QIO complaints, as described in § 422.564(b) and (c). An integrated grievance made by an enrollee in an applicable integrated plan is subject to the integrated grievance procedures in §§ 422.629 and 422.630.

Integrated organization determination means an organization determination that would otherwise be defined and covered, for a non-applicable integrated plan, as an organization determination under § 422.566, an adverse benefit determination under § 438.400(b), or an action under § 431.201 of this chapter. An integrated organization determination is made by an applicable integrated plan and is subject to the integrated organization determination procedures in §§ 422.629, 422.631, and 422.634.

Integrated reconsideration means a reconsideration that would otherwise be defined and covered, for a non-applicable integrated plan, as a reconsideration under § 422.580 and appeal under § 438.400(b) of this chapter. An integrated reconsideration is made by an applicable integrated plan and is subject to the integrated reconsideration procedures in §§ 422.629 and 422.632 through 422.634.

Physician has the meaning given the term in section 1861(r) of the Act.

Representative means an individual appointed by an enrollee or other party, or authorized under State or other applicable law, to act on behalf of an enrollee or other party involved in the grievance or appeal. Unless otherwise stated in this subpart, the representative will have all the rights and responsibilities of an enrollee or party in filing a grievance, and in obtaining an organization determination or in dealing with any of the levels of the appeals process, subject to the applicable rules described in part 405 of this chapter.

[63 FR 35067, June 26, 1998, as amended at 65 FR 40328, June 29, 2000; 68 FR 16667, Apr. 4, 2003; 70 FR 4738, Jan. 28, 2005; 75 FR 19812, Apr. 15, 2010; 82 FR 5124, Jan. 17, 2017; 84 FR 15833, Apr. 16, 2019; 84 FR 26579, June 7, 2019; 87 FR 27897, May 9, 2022]

§ 422.562 General provisions.

(a) *Responsibilities of the MA organization.* (1) An MA organization, with respect to each MA plan that it offers, must establish and maintain—

(i) A grievance procedure as described in § 422.564 or, beginning January 1, 2021, § 422.630 as applicable, for addressing issues that do not involve organization determinations;

(ii) A procedure for making timely organization determinations;

(iii) Appeal procedures that meet the requirements of this subpart for issues that involve organization determinations; and

(2) An MA organization must ensure that all enrollees receive written information about the—

(i) Grievance and appeal procedures that are available to them through the MA organization; and

(ii) Complaint process available to the enrollee under the QIO process as set forth under section 1154(a)(14) of the Act.

(3) In accordance with subpart K of this part, if the MA organization delegates any of its responsibilities under this subpart to another entity or individual through which the organization provides health care services, the MA organization is ultimately responsible for ensuring that the entity or individual satisfies the relevant requirements of this subpart.

(4) An MA organization must employ a medical director who is responsible for ensuring the clinical accuracy of all organization determinations and reconsiderations involving medical necessity. The medical director must be a physician with a current and unrestricted license to practice medicine in a State, Territory, Commonwealth of the United States (that is, Puerto Rico), or the District of Columbia.

(5) An MA organization that offers a dual eligible special needs plan has the following additional responsibilities:

(i) The dual eligible special needs plan must offer to assist an enrollee in that dual eligible special needs plan with obtaining Medicaid covered services and resolving grievances, including requesting authorization of Medicaid services, as applicable, and navigating Medicaid appeals and grievances in connection with the enrollee's own Medicaid coverage, regardless of whether such coverage is in Medicaid fee-for-service or a Medicaid managed care plan, such as a Medicaid MCO, PIHP, or PAHP as defined in § 438.2 of this chapter. If the enrollee accepts the offer of assistance, the plan must provide the assistance. Examples of such assistance include the following:

(A) Explaining to an enrollee how to make a request for Medicaid authorization of a service and how to file appeal following an adverse benefit determination, such as—

(*1*) Assisting the enrollee in identifying the enrollee's specific Medicaid managed care plan or fee-for-service point of contact;

(*2*) Providing specific instructions for contacting the appropriate agency in a fee-for-service setting or for contacting the enrollee's Medicaid managed care plan, regardless of whether the Medicaid managed care plan is affiliated with the enrollee's dual eligible special needs plan; and

(*3*) Assisting the enrollee in making contact with the enrollee's fee-for-service contact or Medicaid managed care plan.

(B) Assisting a beneficiary in filing a Medicaid grievance or a Medicaid appeal.

(C) Assisting an enrollee in obtaining documentation to support a request for authorization of Medicaid services or a Medicaid appeal.

(ii) The dual eligible special needs plan must offer to provide the assistance described in paragraph (a)(5)(i) of this section whenever it becomes aware of an enrollee's need for a Medicaid-covered service. Offering such assistance is not dependent on an enrollee's specific request.

(iii) The dual eligible special needs plan must offer to provide and actually provide assistance as required by paragraph (a)(5)(i) of this section using multiple methods.

(A) When an enrollee accepts the offer of assistance described in paragraph (a)(5)(i) of this section, the dual eligible special needs plan may coach the enrollee on how to self-advocate.

(B) The dual eligible special needs plan must also provide an enrollee reasonable assistance in completing forms and taking procedural steps related to Medicaid grievances and appeals.

(iv) The dual eligible special needs plan must, upon request from CMS, provide documentation demonstrating its compliance with this paragraph (a)(5).

(v) The obligation to provide assistance under paragraph (a)(5)(i) of this section does not create an obligation for a dual eligible special needs plan to represent an enrollee in a Medicaid appeal.

(b) *Rights of MA enrollees.* In accordance with the provisions of this subpart, enrollees have the following rights:

(1) The right to have grievances between the enrollee and the MA organization heard and resolved, as described in § 422.564 or, beginning January 1, 2021, § 422.630, as applicable.

(2) The right to a timely organization determination, as provided under § 422.566 or, beginning January 1, 2021, § 422.631(c), as applicable.

(3) The right to request an expedited organization determination, as provided under §§ 422.570 or, beginning January 1, 2021, § 422.631(e), as applicable.

(4) If dissatisfied with any part of an organization determination, the following appeal rights:

(i) The right to a reconsideration of the adverse organization determination by the MA organization, as provided under § 422.578 or, beginning January 1, 2021, § 422.633, as applicable.

(ii) The right to request an expedited reconsideration, as provided under § 422.584 or, beginning January 1, 2021, § 422.633(e), as applicable.

(iii) If, as a result of a reconsideration, an MA organization affirms, in whole or in part, its adverse organization determination, the right to an automatic reconsidered determination made by an independent, outside entity contracted by CMS, as provided in § 422.592.

(iv) The right to an ALJ hearing if the amount in controversy is met, as provided in § 422.600.

(v) The right to request Council review of the ALJ hearing decision, as provided in § 422.608.

(vi) The right to judicial review of the hearing decision if the amount in controversy is met, as provided in § 422.612.

(c) *Limits on when this subpart applies.* (1) If an enrollee receives immediate QIO review (as provided in § 422.622) of a determination of noncoverage of inpatient hospital care the enrollee is not entitled to review of that issue by the MA organization.

(2) If a contract provider's request for payment has been adjudicated and the enrollee is determined to have no further liability to pay for the services furnished by the MA organization, the claim payment determination is not subject to the appeal process in this subpart.

(d) *When other regulations apply.* (1) Unless this subpart provides otherwise and subject to paragraph (d)(2) of this section, the regulations in part 405 of this chapter (concerning the administrative review and hearing processes and representation of parties under titles II and XVIII of the Act) apply under this subpart to the extent they are appropriate.

(2) The following regulations in part 405 of this chapter, and any references thereto, specifically do not apply under this subpart:

(i) Section 405.950 (time frames for making a redetermination).

(ii) Section 405.970 (time frames for making a reconsideration following a contractor redetermination, including the option to escalate an appeal to the OMHA level).

(iii) Section 405.1016 (time frames for deciding an appeal of a QIC reconsideration, or escalated request for a QIC reconsideration, including the option to escalate an appeal to the Council).

(iv) The option to request that an appeal be escalated from the OMHA level to the Council as provided in § 405.1100(b), and time frames for the Council to decide an appeal of an ALJ's or attorney adjudicator's decision or an appeal that is escalated from the OMHA level to the Council as provided in § 405.1100(c) and (d).

(v) Section 405.1132 (request for escalation to Federal court).

(vi) Sections 405.956(b)(8), 405.966(a)(2), 405.976(b)(5)(ii), 405.1018(c), 405.1028(a), and 405.1122(c), and any other reference to requiring a determination of good cause for the introduction of new evidence by a provider, supplier, or a beneficiary represented by a provider or supplier.

(3) For the sole purpose of applying the regulations at § 405.1038(c) of this chapter, an MA organization is included in the definition of ''contractors'' as it relates to stipulated decisions.

[63 FR 35067, June 26, 1998, as amended at 65 FR 40329, June 29, 2000; 70 FR 4738, Jan. 28, 2005; 70 FR 52027, Sept. 1, 2005; 76 FR 21569, Apr. 15, 2011; 82 FR 5110, Jan. 17, 2017; 84 FR 15834, Apr. 16, 2019; 84 FR 26579, June 7, 2019; 86 FR 6101, Jan. 19, 2021; 90 FR 15910, Apr. 15, 2025]

§ 422.564 Grievance procedures.

(a) *General rule.* Each MA organization must provide meaningful procedures for timely hearing and resolving grievances between enrollees and the organization or any other entity or individual through which the organization provides health care services under any MA plan it offers.

(b) *Distinguished from appeals.* Grievance procedures are separate and distinct from appeal procedures, which address organization determinations as defined in § 422.566(b). Upon receiving a complaint, an MA organization must promptly determine and inform the enrollee whether the complaint is subject to its grievance procedures or its appeal procedures.

(c) *Distinguished from the quality improvement organization (QIO) complaint process.* Under section 1154(a)(14) of the Act, the QIO must review beneficiaries' written complaints about the quality of services they have received under the Medicare program. This process is separate and distinct from the grievance procedures of the MA organization. For quality of care issues, an enrollee may file a grievance with the MA organization; file a written complaint with the QIO, or both. For any complaint submitted to a QIO, the MA organization must cooperate with the QIO in resolving the complaint.

(d) *Method for filing a grievance.* (1) An enrollee may file a grievance with the MA organization either orally or in writing.

(2) An enrollee must file a grievance no later than 60 days after the event or incident that precipitates the grievance.

(e) *Grievance disposition and notification.* (1) The MA organization must notify the enrollee of its decision as expeditiously as the case requires, based on the enrollee's health status, but no later than 30 days after the date the organization receives the oral or written grievance.

(2) The MA organization may extend the 30-day timeframe by up to 14 days if the enrollee requests the extension or if the organization justifies a need for additional information and documents how the delay is in the interest of the enrollee. When the MA organization extends the deadline, it must immediately notify the enrollee in writing of the reasons for the delay.

(3) The MA organization must inform the enrollee of the disposition of the grievance in accordance with the following procedures:

(i) All grievances submitted in writing must be responded to in writing.

(ii) Grievances submitted orally may be responded to either orally or in writing, unless the enrollee requests a written response.

(iii) All grievances related to quality of care, regardless of how the grievance is filed, must be responded to in writing. The response must include a description of the enrollee's right to file a written complaint with the QIO. For any complaint submitted to a QIO, the MA organization must cooperate with the QIO in resolving the complaint.

(f) *Expedited grievances.* An MA organization must respond to an enrollee's grievance within 24 hours if:

(1) The complaint involves an MA organization's decision to invoke an extension relating to an organization determination or reconsideration.

(2) The complaint involves an MA organization's refusal to grant an enrollee's request for an expedited organization determination under § 422.570 or reconsideration under § 422.584.

(g) *Recordkeeping.* The MA organization must have an established process to track and maintain records on all grievances received both orally and in writing, including, at a minimum, the date of receipt, final disposition of the grievance, and the date that the MA organization notified the enrollee of the disposition.

[68 FR 16667, Apr. 4, 2003, as amended at 70 FR 4738, Jan. 28, 2005]

§ 422.566 Organization determinations.

(a) *Responsibilities of the MA organization.* Each MA organization must have a procedure for making timely organization determinations (in accordance with the requirements of this subpart) regarding the benefits an enrollee is entitled to receive under an MA plan, including basic benefits as described under § 422.100(c)(1) and mandatory and optional supplemental benefits as described under § 422.102, and the amount, if any, that the enrollee is required to

pay for a health service. The MA organization must have a standard procedure for making determinations, in accordance with § 422.568, and an expedited procedure for situations in which applying the standard procedure could seriously jeopardize the enrollee's life, health, or ability to regain maximum function, in accordance with §§ 422.570 and 422.572. For an applicable integrated plan, beginning January 1, 2021, the MA organization must comply with §§ 422.629 through 422.634 in lieu of §§ 422.566(c) and (d), 422.568, 422.570 and 422.572 with regard to the procedures for making determinations, including integrated organization determinations and integrated reconsiderations, on a standard and expedited basis.

(b) *Actions that are organization determinations.* An organization determination is any determination made by an MA organization with respect to any of the following:

(1) Payment for temporarily out of the area renal dialysis services, emergency services, post-stabilization care, or urgently needed services.

(2) Payment for any other health services furnished by a provider other than the MA organization that the enrollee believes—

(i) Are covered under Medicare; or

(ii) If not covered under Medicare, should have been furnished, arranged for, or reimbursed by the MA organization.

(3) The MA organization's refusal, pre- or post-service or in connection with a decision made concurrently with an enrollee's receipt of services, to provide or pay for services, in whole or in part, including the type or level of services, that the enrollee believes should be furnished or arranged for by the MA organization.

(4) Reduction, or premature discontinuation, of a previously authorized ongoing course of treatment.

(5) Failure of the MA organization to approve, furnish, arrange for, or provide payment for health care services in a timely manner, or to provide the enrollee with timely notice of an adverse determination, such that a delay would adversely affect the health of the enrollee.

(c) *Who can request an organization determination.* (1) Those individuals or entities who can request an organization determination are—

(i) The enrollee (including his or her representative);

(ii) Any provider that furnishes, or intends to furnish, services to the enrollee; or

(iii) The legal representative of a deceased enrollee's estate.

(2) Those who can request an expedited determination are—

(i) The enrollee (including his or her representative); or

(ii) A physician (regardless of whether the physician is affiliated with the MA organization).

(d) *Who must review organization determinations.* If the MA organization expects to issue a partially or fully adverse medical necessity (or any substantively equivalent term used to describe the concept of medical necessity) decision based on the initial review of the request, the organization determination must be reviewed by a physician or other appropriate health care professional with expertise in the field of medicine or health care that is appropriate for the services at issue, including knowledge of Medicare coverage criteria, before the MA organization issues the organization determination decision. The physician or health care professional reviewing the request need not, in all cases, be of the same specialty or subspecialty as the treating physician or other health care provider. The physician or other health care professional must have a current and unrestricted license to practice within the scope of his or her profession in a State, Territory, Commonwealth of the United States (that is, Puerto Rico), or the District of Columbia.

[63 FR 35067, June 26, 1998, as amended at 65 FR 40329, June 29, 2000; 68 FR 50858, Aug. 22, 2003; 70 FR 4739, Jan. 28, 2005; 75 FR 19812, Apr. 15, 2010; 75 FR 32859, June 10, 2010; 76 FR 21569, Apr. 15, 2011; 84 FR 15834, April 16, 2019; 88 FR 22334, Apr. 12, 2023; 90 FR 15910, Apr. 15, 2025]

§ 422.568 Standard timeframes and notice requirements for organization determinations.

(a) *Method and place for filing a request.* An enrollee must ask for a standard organization determination by

making a request with the MA organization or, if applicable, to the entity responsible for making the determination (as directed by the MA organization), in accordance with the following:

(1) The request may be made orally or in writing, except as provided in paragraph (a)(2) of this section.

(2) Requests for payment must be made in writing (unless the MA organization or entity responsible for making the determination has implemented a voluntary policy of accepting verbal payment requests).

(b) *Timeframes*—(1) *Requests for service or item.* Except as provided in paragraph (b)(2) of this section, when a party has made a request for an item or service, the MA organization must notify the enrollee (and the physician or provider involved, as appropriate) of its determination as expeditiously as the enrollee's health condition requires but no later than either of the following:

(i) For a service or item not subject to the prior authorization rules in § 422.122, 14 calendar days after receiving the request for the standard organization determination.

(ii) Beginning on or after January 1, 2026, for a service or item subject to the prior authorization rules in § 422.122, 7 calendar days after receiving the request for the standard organization determination.

(2) *Extensions; requests for service or item*—(i) *Extension of timeframe on a request for service or item.* The MA organization may extend the timeframe by up to 14 calendar days under any of the following circumstances:

(A) The enrollee requests the extension.

(B) The extension is justified and in the enrollee's interest due to the need for additional medical evidence from a noncontract provider that may change an MA organization's decision to deny an item or service.

(C) The extension is justified due to extraordinary, exigent, or other nonroutine circumstances and is in the enrollee's interest.

(ii) *Notice of extension.* (A) When the MA organization extends the timeframe, it must—

(*1*) Notify the enrollee in writing of the reasons for the delay; and

(*2*) Inform the enrollee of the right to file an expedited grievance if the enrollee disagrees with the MA organization's decision to grant an extension.

(B) The MA organization must notify the enrollee of its determination as expeditiously as the enrollee's health condition requires, but no later than upon expiration of the extension.

(3) *Requests for a Part B drug.* An MA organization must notify the enrollee (and the prescribing physician or other prescriber involved, as appropriate) of its determination as expeditiously as the enrollee's health condition requires, but no later than 72 hours after receipt of the request. This 72-hour period may not be extended under the provisions in paragraph (b)(2) of this section.

(c) *Timeframe for requests for payment.* The MA organization must process requests for payment according to the ''prompt payment'' provisions set forth in § 422.520.

(d) *Written notice for MA organization denials.* The MA organization must give the enrollee and the physician or provider involved, as appropriate, a written notice if—

(1) An MA organization decides to deny a service or an item, Part B drug, or payment in whole or in part, or reduce or prematurely discontinue the level of care for a previously authorized ongoing course of treatment.

(2) An enrollee requests an MA organization to provide an explanation of a practitioner's denial of an item, service or Part B drug, in whole or in part.

(e) *Form and content of the MA organization notice.* The notice of any denial under paragraph (d) of this section must—

(1) Use approved notice language in a readable and understandable form;

(2) State the specific reasons for the denial;

(3) Inform the enrollee of his or her right to a reconsideration;

(4)(i) For service, item, and Part B drug denials, describe both the standard and expedited reconsideration processes, including the enrollee's right to, and conditions for, obtaining an expedited reconsideration and the rest of the appeal process; and

(ii) For payment denials, describe the standard reconsideration process and the rest of the appeal process; and

(5) Comply with any other notice requirements specified by CMS.

(f) *Effect of failure to provide timely notice.* If the MA organization fails to provide the enrollee and the physician or provider involved, as appropriate, with timely notice of an organization determination as specified in this section, this failure itself constitutes an adverse organization determination and may be appealed.

(g) *Dismissing a request.* The MA organization dismisses an organization determination request, either entirely or as to any stated issue, under any of the following circumstances:

(1) The individual or entity making the request is not permitted to request an organization determination under § 422.566(c).

(2) The MA organization determines the party failed to make out a valid request for an organization determination that substantially complies with paragraph (a) of this section.

(3) An enrollee or the enrollee's representative files a request for an organization determination, but the enrollee dies while the request is pending, and both of the following apply:

(i) The enrollee's surviving spouse or estate has no remaining financial interest in the case.

(ii) No other individual or entity with a financial interest in the case wishes to pursue the organization determination.

(4) A party filing the organization determination request submits a timely request for withdrawal of their request for an organization determination with the MA organization.

(h) *Notice of dismissal.* The MA organization must mail or otherwise transmit a written notice of the dismissal of the organization determination request to the parties. The notice must state all of the following:

(1) The reason for the dismissal.

(2) The right to request that the MA organization vacate the dismissal action.

(3) The right to request reconsideration of the dismissal.

(i) *Vacating a dismissal.* If good cause is established, the MA organization may vacate its dismissal of a request for an organization determination within 6 months from the date of the notice of dismissal.

(j) *Effect of dismissal.* The dismissal of a request for an organization determination is binding unless it is modified or reversed by the MA organization upon reconsideration or vacated under paragraph (i) of this section.

(k) *Withdrawing a request.* A party that requests an organization determination may withdraw its request at any time before the decision is issued by filing a request with the MA organization.

[65 FR 40329, June 29, 2000, as amended at 70 FR 4739, Jan. 28, 2005; 70 FR 52027, Sept. 1, 2005; 75 FR 19812, Apr. 15, 2010; 75 FR 32859, June 10, 2010; 80 FR 7961, Feb. 12, 2015; 84 FR 23880, May 23, 2019; 86 FR 6101, Jan. 19, 2021; 89 FR 8976, Feb. 8, 2024; 90 FR 15910, Apr. 15, 2025]

§ 422.570 Expediting certain organization determinations.

(a) *Request for expedited determination.* An enrollee or a physician (regardless of whether the physician is affiliated with the MA organization) may request that an MA organization expedite an organization determination involving the issues described in § 422.566(b)(3) and (b)(4). (This does not include requests for payment of services already furnished.)

(b) *How to make a request.* (1) To ask for an expedited determination, an enrollee or a physician must submit an oral or written request directly to the MA organization or, if applicable, to the entity responsible for making the determination, as directed by the MA organization.

(2) A physician may provide oral or written support for a request for an expedited determination.

(c) *How the MA organization must process requests.* The MA organization must establish and maintain the following procedures for processing requests for expedited determinations:

(1) Establish an efficient and convenient means for individuals to submit oral or written requests. The MA organization must document all oral requests in writing and maintain the documentation in the case file.

(2) Promptly decide whether to expedite a determination, based on the following requirements:

(i) For a request made by an enrollee the MA organization must provide an expedited determination if it determines that applying the standard timeframe for making a determination could seriously jeopardize the life or health of the enrollee or the enrollee's ability to regain maximum function.

(ii) For a request made or supported by a physician, the MA organization must provide an expedited determination if the physician indicates that applying the standard timeframe for making a determination could seriously jeopardize the life or health of the enrollee or the enrollee's ability to regain maximum function.

(d) *Actions following denial.* If an MA organization denies a request for expedited determination, it must take the following actions:

(1) Automatically transfer a request to a standard organization determination and make the determination within the applicable timeframe, established in § 422.568 for a standard determination. The timeframe begins when the MA organization receives the request for expedited determination.

(2) Give the enrollee prompt oral notice of the denial and subsequently deliver, within 3 calendar days, a written letter that—

(i) Explains that the MA organization will process the request using the 14-day timeframe for standard determinations;

(ii) Informs the enrollee of the right to file an expedited grievance if he or she disagrees with the MA organization's decision not to expedite; and

(iii) Informs the enrollee of the right to resubmit a request for an expedited determination with any physician's support; and

(iv) Provides instructions about the grievance process and its timeframes.

(e) *Action on accepted request for expedited determination.* If an MA organization grants a request for expedited determination, it must make the determination and give notice in accordance with § 422.572.

(f) *Prohibition of punitive action.* An MA organization may not take or threaten to take any punitive action against a physician acting on behalf or in support of an enrollee in requesting an expedited determination.

(g) *Dismissing a request.* The MA organization dismisses an expedited organization request in accordance with § 422.568.

[63 FR 35107, June 26, 1998, as amended at 65 FR 40329, June 29, 2000; 70 FR 4739, Jan. 28, 2005; 84 FR 23880, May 23, 2019; 86 FR 6101, Jan. 19, 2021; 89 FR 8977, Feb. 8, 2024]

§ 422.572 Timeframes and notice requirements for expedited organization determinations.

(a) *Timeframes*—(1) *Requests for service or item.* Except as provided in paragraph (b) of this section, an MA organization that approves a request for expedited determination must make its determination and notify the enrollee (and the physician involved, as appropriate) of its decision, whether adverse or favorable, as expeditiously as the enrollee's health condition requires, but no later than 72 hours after receiving the request.

(2) *Requests for a Part B drug.* An MA organization that approves a request for expedited determination must make its determination and notify the enrollee (and the physician or prescriber involved, as appropriate) of its decision as expeditiously as the enrollee's health condition requires, but no later than 24 hours after receiving the request. This 24-hour period may not be extended under the provisions in paragraph (b) of this section.

(b) *Extensions; requests for service or item.* (1) When timeframe may be extended. The MA organization may extend the 72-hour deadline for expedited organization determinations for requests for services or items by up to 14 calendar days if—

(i) The enrollee requests the extension;

(ii) The extension is justified and in the enrollee's interest due to the need for additional medical evidence from a noncontract provider that may change an MA organization's decision to deny an item or service; or

(iii) The extension is justified due to extraordinary, exigent, or other nonroutine circumstances and is in the enrollee's interest.

(2) *Notice of extension.* When the MA organization extends the deadline, it must notify the enrollee in writing of the reasons for the delay and inform the enrollee of the right to file an expedited grievance if he or she disagrees with the MA organization's decision to grant an extension. The MA organization must notify the enrollee of its determination as expeditiously as the enrollee's health condition requires, but no later than upon expiration of the extension.

(c) *Confirmation of oral notice.* If the MA organization first notifies an enrollee of an adverse expedited determination orally, it must mail written confirmation to the enrollee within 3 calendar days of the oral notification.

(d) *How the MA organization must request information from noncontract providers.* If the MA organization must receive medical information from noncontract providers, the MA organization must request the necessary information from the noncontract provider within 24 hours of the initial request for an expedited organization determination. Noncontract providers must make reasonable and diligent efforts to expeditiously gather and forward all necessary information to assist the MA organization in meeting the required timeframe. Regardless of whether the MA organization must request information from noncontract providers, the MA organization is responsible for meeting the timeframe and notice requirements of this section.

(e) *Content of the notice of expedited determination.* (1) The notice of any expedited determination must state the specific reasons for the determination in understandable language.

(2) If the determination is not completely favorable to the enrollee, the notice must—

(i) Inform the enrollee of his or her right to a reconsideration;

(ii) Describe both the standard and expedited reconsideration processes, including the enrollee's right to request, and conditions for obtaining, an expedited reconsideration, and the rest of the appeal process; and

(iii) Comply with any other requirements specified by CMS.

(f) *Effect of failure to provide a timely notice.* If the MA organization fails to provide the enrollee and the physician or prescriber involved, as appropriate, with timely notice of an expedited organization determination as specified in this section, this failure itself constitutes an adverse organization determination and may be appealed.

[63 FR 35107, June 26, 1998, as amended at 65 FR 40329, June 29, 2000; 70 FR 4739, Jan. 28, 2005; 80 FR 7961, Feb. 12, 2015; 84 FR 23881, May 23, 2019; 90 FR 15911, Apr. 15, 2025]

§ 422.574 Parties to the organization determination.

The parties to the organization determination are—

(a) The enrollee (including his or her representative);

(b) An assignee of the enrollee (that is, a physician or other provider who has furnished a service to the enrollee and formally agrees to waive any right to payment from the enrollee for that service);

(c) The legal representative of a deceased enrollee's estate; or

(d) Any other provider or entity (other than the MA organization) determined to have an appealable interest in the proceeding.

[63 FR 35107, June 26, 1998, as amended at 75 FR 19812, Apr. 15, 2010]

§ 422.576 Effect of an organization determination.

The organization determination is binding on all parties unless it is reconsidered under §§ 422.578 through 422.596 or is reopened and revised under § 422.616.

§ 422.578 Right to a reconsideration.

Any party to an organization determination (including one that has been reopened and revised as described in § 422.616) may request that the determination be reconsidered under the procedures described in § 422.582, which address requests for a standard reconsideration. A physician who is providing treatment to an enrollee may, upon providing notice to the enrollee, request a standard reconsideration of a pre-service request for reconsideration on the enrollee's behalf as described in

§ 422.582. An enrollee or physician (acting on behalf of an enrollee) may request an expedited reconsideration as described in § 422.584.

[74 FR 1542, Jan. 12, 2009]

§ 422.580 Reconsideration defined.

A reconsideration consists of a review of an adverse organization determination, the evidence and findings upon which it was based, and any other evidence the parties submit or the MA organization or CMS obtains.

§ 422.582 Request for a standard reconsideration.

(a) *Method and place for filing a request.* A party to an organization determination or, upon providing notice to the enrollee, a physician who is treating an enrollee and acting on the enrollee's behalf, must ask for a reconsideration of the determination by making a written request to the MA organization that made the organization determination. The MA organization may adopt a policy for accepting oral requests.

(b) *Timeframe for filing a request.* Except as provided in paragraph (c) of this section, a request for reconsideration must be filed within 60 calendar days after receipt of the written organization determination notice.

(1) The date of receipt of the organization determination is presumed to be 5 calendar days after the date of the written organization determination, unless there is evidence to the contrary.

(2) For purposes of meeting the 60-calendar day filing deadline, the request is considered as filed on the date it is received by the plan or delegated entity specified in the MA organization's written organization determination.

(c) *Extending the time for filing a request.* (1) *General rule.* If a party or physician acting on behalf of an enrollee shows good cause, the MA organization may extend the timeframe for filing a request for reconsideration.

(2) *How to request an extension of timeframe.* If the 60-day period in which to file a request for reconsideration has expired, a party to the organization determination or a physician acting on behalf of an enrollee may file a request for reconsideration with the MA organization. The request for reconsideration and to extend the timeframe must—

(i) Be in writing; and

(ii) State why the request for reconsideration was not filed on time.

(d) *Parties to the reconsideration.* The parties to the reconsideration are the parties to the organization determination, as described in § 422.574, and any other provider or entity (other than the MA organization) whose rights with respect to the organization determination may be affected by the reconsideration, as determined by the entity that conducts the reconsideration.

(e) *Withdrawing a request.* The party or physician acting on behalf of an enrollee who files a request for reconsideration may withdraw it by filing a request for withdrawal at one of the places listed in paragraph (a) of this section.

(f) *Dismissing a request.* The MA organization dismisses a reconsideration request, either entirely or as to any stated issue, under any of the following circumstances:

(1) The person or entity requesting a reconsideration is not a proper party under § 422.578.

(2) The MA organization determines the party failed to make a valid request for a reconsideration that substantially complies with paragraph (a) of this section.

(3) The party fails to file the reconsideration request within the proper filing time frame in accordance with paragraph (b) of this section.

(4) The enrollee or the enrollee's representative files a request for a reconsideration, but the enrollee dies while the request is pending, and both of the following criteria apply:

(i) The enrollee's surviving spouse or estate has no remaining financial interest in the case.

(ii) No other individual or entity with a financial interest in the case wishes to pursue the reconsideration.

(5) A party filing the reconsideration request submits a timely request for withdrawal of the request for a reconsideration with the MA organization.

(g) *Notice of dismissal.* The MA organization must mail or otherwise transmit a written notice of the dismissal of the

reconsideration request to the parties. The notice must state all of the following:

(1) The reason for the dismissal.

(2) The right to request that the MA organization vacate the dismissal action.

(3) The right to request review of the dismissal by the independent entity.

(h) *Vacating a dismissal.* If good cause is established, the MA organization may vacate its dismissal of a request for reconsideration within 6 months from the date of the notice of dismissal.

(i) *Effect of dismissal.* The MA organization's dismissal is binding unless the enrollee or other party requests review by the independent entity in accordance with § 422.590(h) or the decision is vacated under paragraph (h) of this section.

[74 FR 1542, Jan. 12, 2009, as amended at 86 FR 6101, Jan. 19, 2021; 89 FR 30827, Apr. 23, 2024]

§ 422.584 Expediting certain reconsiderations.

(a) *Who may request an expedited reconsideration.* An enrollee or a physician (regardless of whether he or she is affiliated with the MA organization) may request that an MA organization expedite a reconsideration of a determination that involves the issues described in § 422.566(b)(3) and (b)(4). (This does not include requests for payment of services already furnished.)

(b) *Procedure and timeframe for filing a request.* A request for reconsideration must be filed within 60 calendar days after receipt of the written organization determination notice. (1) To ask for an expedited reconsideration, an enrollee or a physician acting on behalf of an enrollee must submit an oral or written request directly to the MA organization or, if applicable, to the entity responsible for making the reconsideration, as directed by the MA organization.

(2) A physician may provide oral or written support for a request for an expedited reconsideration.

(3) The date of receipt of the organization determination is presumed to be 5 calendar days after the date of the written organization determination, unless there is evidence to the contrary.

(4) For purposes of meeting the 60-calendar day filing deadline, the request is considered as filed on the date it is received by the plan or delegated entity specified in the MA organization's written organization determination.

(c) *How the MA organization must process requests.* The MA organization must establish and maintain the following procedures for processing requests for expedited reconsiderations:

(1) *Handling of requests.* The MA organization must establish an efficient and convenient means for individuals to submit oral or written requests, document all oral requests in writing, and maintain the documentation in the case file.

(2) *Prompt decision.* Promptly decide on whether to expedite the reconsideration or follow the timeframe for standard reconsideration based on the following requirements:

(i) For a request made by an enrollee, the MA organization must provide an expedited reconsideration if it determines that applying the standard timeframe for reconsidering a determination could seriously jeopardize the life or health of the enrollee or the enrollee's ability to regain maximum function.

(ii) For a request made or supported by a physician, the MA organization must provide an expedited reconsideration if the physician indicates that applying the standard timeframe for conducting a reconsideration could seriously jeopardize the life or health of the enrollee or the enrollee's ability to regain maximum function.

(d) *Actions following denial.* If an MA organization denies a request for expedited reconsideration, it must take the following actions:

(1) Automatically transfer a request to the standard timeframe and make the determination within the 30 calendar day or 7 calendar day, as applicable, timeframe established in § 422.590(a) and (c). The timeframe begins the day the MA organization receives the request for expedited reconsideration.

(2) Give the enrollee prompt oral notice, and subsequently deliver, within 3 calendar days, a written letter that—

(i) Explains that the MA organization will process the enrollee's request using the 30-day timeframe for standard reconsiderations;

(ii) Informs the enrollee of the right to file a grievance if he or she disagrees with the organization's decision not to expedite;

(iii) Informs the enrollee of the right to resubmit a request for an expedited reconsideration with any physician's support; and

(iv) Provides instructions about the grievance process and its timeframes.

(e) *Action following acceptance of a request.* If an MA organization grants a request for expedited reconsideration, it must conduct the reconsideration and give notice in accordance with § 422.590.

(f) *Prohibition of punitive action.* An MA organization may not take or threaten to take any punitive action against a physician acting on behalf or in support of an enrollee in requesting an expedited reconsideration.

(g) *Dismissing a request.* The MA organization dismisses an expedited reconsideration request in accordance with § 422.582(f) through (i).

[63 FR 35107, June 26, 1998, as amended at 65 FR 40330, June 29, 2000; 70 FR 4739, Jan. 28, 2005; 84 FR 23881, May 23, 2019; 86 FR 6101, Jan. 19, 2021; 89 FR 30827, Apr. 23, 2024]

§ 422.586 Opportunity to submit evidence.

The MA organization must provide the parties to the reconsideration with a reasonable opportunity to present evidence and allegations of fact or law, related to the issue in dispute, in person as well as in writing. In the case of an expedited reconsideration, the opportunity to present evidence is limited by the short timeframe for making a decision. Therefore, the MA organization must inform the parties of the conditions for submitting the evidence.

§ 422.590 Timeframes and responsibility for reconsiderations.

(a) *Standard reconsideration: Requests for service or item.* (1) Except as provided in paragraph (f) of this section, if the MA organization makes a reconsidered determination that is completely favorable to the enrollee, the MA organization must issue the determination (and effectuate it in accordance with § 422.618(a)) as expeditiously as the enrollee's health condition requires, but no later than 30 calendar days from the date it receives the request for a standard reconsideration.

(2) If the MA organization makes a reconsidered determination that affirms, in whole or in part, its adverse organization determination, it must prepare a written explanation and send the case file to the independent entity contracted by CMS as expeditiously as the enrollee's health condition requires, but no later than 30 calendar days from the date it receives the request for a standard reconsideration (or no later than the expiration of an extension described in paragraph (a)(1) of this section). The organization must make reasonable and diligent efforts to assist in gathering and forwarding information to the independent entity.

(b) *Standard reconsideration: Requests for payment.* (1) If the MA organization makes a reconsidered determination that is completely favorable to the enrollee, the MA organization must issue its reconsidered determination to the enrollee (and effectuate it in accordance with § 422.618(a)(2)) no later than 60 calendar days from the date it receives the request for a standard reconsideration.

(2) If the MA organization affirms, in whole or in part, its adverse organization determination, it must prepare a written explanation and send the case file to the independent entity contracted by CMS no later than 60 calendar days from the date it receives the request for a standard reconsideration. The organization must make reasonable and diligent efforts to assist in gathering and forwarding information to the independent entity.

(c) *Standard reconsideration: Requests for a Part B drug.* (1) If the MA organization makes a reconsidered determination that is completely favorable to the enrollee, the MA organization must issue the determination (and effectuate it in accordance with § 422.618(a)(3)) as expeditiously as the enrollee's health condition requires, but no later than 7 calendar days from

the date it receives the request for a standard reconsideration. This 7 calendar-day period may not be extended under the provisions in paragraph (f) of this section.

(2) If the MA organization makes a reconsidered determination that affirms, in whole or in part, its adverse organization determination, it must prepare a written explanation and send the case file to the independent entity contracted with CMS no later than 7 calendar days from the date it receives the request for a standard reconsideration. The organization must make reasonable and diligent efforts to assist in gathering and forwarding the information to the independent entity.

(d) *Effect of failure to meet timeframe for standard reconsideration.* If the MA organization fails to provide the enrollee with a reconsidered determination within the timeframes specified in paragraph (a), (b), or (c) of this section, this failure constitutes an affirmation of its adverse organization determination, and the MA organization must submit the file to the independent entity in the same manner as described under paragraphs (a)(2), (b)(2), and (c)(2) of this section.

(e) *Expedited reconsideration*—(1) *Timeframe for services or items.* Except as provided in paragraph (f) of this section, an MA organization that approves a request for expedited reconsideration must complete its reconsideration and give the enrollee (and the physician involved, as appropriate) notice of its decision as expeditiously as the enrollee's health condition requires but no later than 72 hours after receiving the request.

(2) *Timeframe for Part B drugs.* An MA organization that approves a request for expedited reconsideration must complete its reconsideration and give the enrollee (and the physician or other prescriber involved, as appropriate) notice of its decision as expeditiously as the enrollee's health condition requires but no later than 72 hours after receiving the request. This 72-hour period may not be extended under the provisions in paragraph (f) of this section.

(3) *Confirmation of oral notice.* If the MA organization first notifies an enrollee of a completely favorable expedited reconsideration orally, it must mail written confirmation to the enrollee within 3 calendar days.

(4) *How the MA organization must request information from noncontract providers.* If the MA organization must receive medical information from noncontract providers, the MA organization must request the necessary information from the noncontract provider within 24 hours of the initial request for an expedited reconsideration. Noncontract providers must make reasonable and diligent efforts to expeditiously gather and forward all necessary information to assist the MA organization in meeting the required timeframe. Regardless of whether the MA organization must request information from noncontract providers, the MA organization is responsible for meeting the timeframe and notice requirements.

(5) *Affirmation of an adverse expedited organization determination.* If, as a result of its reconsideration, the MA organization affirms, in whole or in part, its adverse expedited organization determination, the MA organization must submit a written explanation and the case file to the independent entity contracted by CMS as expeditiously as the enrollee's health condition requires, but not later than within 24 hours of its affirmation. The organization must make reasonable and diligent efforts to assist in gathering and forwarding information to the independent entity.

(f) *Extensions; requests for service or item.* (1) As described in paragraphs (f)(1)(i) through (iii) of this section, the MA organization may extend the standard or expedited reconsideration deadline for services by up to 14 calendar days if—

(i) The enrollee requests the extension; or

(ii) The extension is justified and in the enrollee's interest due to the need for additional medical evidence from a noncontract provider that may change an MA organization's decision to deny an item or service; or

(iii) The extension is justified due to extraordinary, exigent or other nonroutine circumstances and is in the enrollee's interest.

(2) When the MA organization extends the deadline, it must notify the enrollee in writing of the reasons for the delay and inform the enrollee of the right to file an expedited grievance if he or she disagrees with the MA organization's decision to grant an extension. The MA organization must notify the enrollee of its determination as expeditiously as the enrollee's health condition requires, but no later than upon expiration of the extension.

(g) *Failure to meet timeframe for expedited reconsideration.* If the MA organization fails to provide the enrollee with the results of its reconsideration within the timeframe described in paragraph (e)(1) or (2) of this section, as applicable, this failure constitutes an adverse reconsidered determination, and the MA organization must submit the file to the independent entity within 24 hours of expiration of the timeframe set forth in paragraph (e)(1) or (2) of this section.

(h) *Who must reconsider an adverse organization determination.* (1) A person or persons who were not involved in making the organization determination must conduct the reconsideration.

(2) When the issue is the MA organization's denial of coverage based on a lack of medical necessity (or any substantively equivalent term used to describe the concept of medical necessity), the reconsidered determination must be made by a physician with expertise in the field of medicine that is appropriate for the services at issue. The physician making the reconsidered determination need not, in all cases, be of the same specialty or subspecialty as the treating physician.

(i) *Requests for review of a dismissal by the independent entity.* If the MA organization dismisses a request for a reconsideration in accordance with §§ 422.582(f) and 422.584(g), the enrollee or other proper party under § 422.578 has the right to request review of the dismissal by the independent entity. A request for review of a dismissal must be filed in writing with the independent entity within 60 calendar days from the date of the MA organization's dismissal notice.

[84 FR 23881, May 23, 2019, as amended at 86 FR 6102, Jan. 19, 2021; 88 FR 22334, Apr. 12, 2023]

§ 422.592 Reconsideration by an independent entity.

(a) When the MA organization affirms, in whole or in part, its adverse organization determination, the issues that remain in dispute must be reviewed and resolved by an independent, outside entity that contracts with CMS. In accordance with § 422.590(i), the independent entity is responsible for reviewing MA organization dismissals of reconsideration requests.

(b) The independent outside entity must conduct the review as expeditiously as the enrollee's health condition requires but must not exceed the deadlines specified in the contract.

(c) When the independent entity conducts a reconsideration, the parties to the reconsideration are the same parties listed in § 422.582(d) who qualified during the MA organization's reconsideration, with the addition of the MA organization.

(d) The independent entity dismisses a reconsideration request, either entirely or as to any stated issue, under any of the following circumstances:

(1) The person or entity requesting a reconsideration is not a proper party under § 422.578.

(2) The independent entity determines the party failed to make out a valid request for a reconsideration that substantially complies with § 422.582(a) or (b).

(3) The enrollee or the enrollee's representative files a request for a reconsideration, but the enrollee dies while the request is pending, and both of the following criteria apply:

(i) The enrollee's surviving spouse or estate has no remaining financial interest in the case.

(ii) No other individual or entity with a financial interest in the case wishes to pursue the reconsideration.

(4) The party filing the reconsideration request submits with the independent review entity a timely request for withdrawal of the request for reconsideration.

(e) The independent entity mails or otherwise transmits a written notice of the dismissal of the reconsideration request to the parties. The notice must state the following:

(1) The reason for the dismissal.

(2) That there is a right to request that the independent entity vacate the dismissal action.

(3) The right to a review of the dismissal under §§ 422.600 and 422.602.

(f) If good cause is established, the independent entity may vacate its dismissal of a request for reconsideration within 6 months from the date of the notice of dismissal.

(g) The independent entity's dismissal is binding and not subject to further review unless a party meets the requirements in § 422.600 and files a proper and timely request under § 422.602 or the dismissal is vacated under paragraph (f) of this section.

(h) The party or physician acting on behalf of an enrollee who files a request for reconsideration may withdraw the request by filing a request for withdrawal with the independent entity.

(i) If the independent entity determines that the MA organization's dismissal was in error, the independent entity vacates the dismissal and remands the case to the plan for reconsideration consistent with § 422.590. The independent entity's decision regarding an MA organization's dismissal, including a decision to deny a request for review of a dismissal, is binding and not subject to further review.

[63 FR 35107, June 26, 1998, as amended at 86 FR 6102, Jan. 19, 2021]

§ 422.594 Notice of reconsidered determination by the independent entity.

(a) *Responsibility for the notice.* When the independent entity makes the reconsidered determination, it is responsible for mailing a notice of its reconsidered determination to the parties and for sending a copy to CMS.

(b) *Content of the notice.* The notice must—

(1) State the specific reasons for the entity's decisions in understandable language;

(2) If the reconsidered determination is adverse (that is, does not completely reverse the MA organization's adverse organization determination), inform the parties of their right to an ALJ hearing if the amount in controversy meets the requirements of § 422.600;

(3) Describe the procedures that a party must follow to obtain an ALJ hearing; and

(4) Comply with any other requirements specified by CMS.

[63 FR 35107, June 26, 1998, as amended at 65 FR 40330, June 29, 2000; 82 FR 5125, Jan. 17, 2017]

§ 422.596 Effect of a reconsidered determination.

A reconsidered determination is final and binding on all parties unless a party other than the MA organization files a request for a hearing under the provisions of § 422.602, or unless the reconsidered determination is revised under § 422.616.

[65 FR 40331, June 29, 2000]

§ 422.600 Right to a hearing.

(a) If the amount remaining in controversy after reconsideration meets the threshold requirement established annually by the Secretary, any party to the reconsideration (except the MA organization) who is dissatisfied with the reconsidered determination has a right to a hearing before an ALJ.

(b) The amount remaining in controversy, which can include any combination of Part A and Part B services, is computed in accordance with part 405 of this chapter. For purposes of calculating the amount remaining in controversy under this section, references to coinsurance in § 405.1006(d) of this chapter should be read to include coinsurance and copayment amounts.

(c) If the basis for the appeal is the MA organization's refusal to provide services, CMS uses the projected value of those services to compute the amount remaining in controversy.

[63 FR 35107, June 26, 1998, as amended at 70 FR 4740, Jan. 28, 2005; 86 FR 6102, Jan. 19, 2021]

§ 422.602 Request for an ALJ hearing.

(a) *How and where to file a request.* A party must file a written request for a hearing with the entity specified in the IRE's reconsideration notice.

(b) *When to file a request.* (1) Except when an ALJ or attorney adjudicator extends the time frame as provided in part 405 of this chapter, a party must file a request for a hearing within 60 calendar days of receipt of the notice of a reconsidered determination. The time and place for a hearing before an

ALJ will be set in accordance with § 405.1020 of this chapter.

(2) For purposes of this section, the date of receipt of the reconsideration is presumed to be 5 calendar days after the date of the notice of the reconsidered determination, unless there is evidence to the contrary.

(c) *Parties to a hearing.* The parties to a hearing are the parties to the reconsideration, the MA organization, and any other person or entity whose rights with respect to the reconsideration may be affected by the hearing, as determined by the ALJ.

(d) *Insufficient amount in controversy.* (1) If a request for a hearing clearly shows that the amount in controversy is less than that required under § 422.600, the ALJ dismisses the request.

(2) If, after a hearing is initiated, the ALJ finds that the amount in controversy is less than the amount required under § 422.600, the ALJ discontinues the hearing and does not rule on the substantive issues raised in the appeal.

[63 FR 35107, June 26, 1998, as amended at 70 FR 4740, Jan. 28, 2005; 82 FR 5125, Jan. 17, 2017]

§ 422.608 Medicare Appeals Council (Council) review.

Any party to the ALJ's or attorney adjudicator's decision or dismissal, including the MA organization, who is dissatisfied with the decision or dismissal, may request that the Council review the decision or dismissal. The regulations under part 405 of this chapter regarding Council review apply to matters addressed by this subpart to the extent that they are appropriate, except as provided in § 422.562(d)(2).

[82 FR 5125, Jan. 17, 2017]

§ 422.612 Judicial review.

(a) *Review of ALJ's or attorney adjudicator's decision.* Any party, including the MA organization, may request judicial review (upon notifying the other parties) of an ALJ's or attorney adjudicator's decision if—

(1) The Council denied the party's request for review; and

(2) The amount in controversy meets the threshold requirement established annually by the Secretary.

(b) *Review of Council decision.* Any party, including the MA organization, may request judicial review (upon notifying the other parties) of the Council decision if it is the final decision of CMS and the amount in controversy meets the threshold established in paragraph (a)(2) of this section.

(c) *How to request judicial review.* In order to request judicial review, a party must file a civil action in a district court of the United States in accordance with section 205(g) of the Act. See part 405 of this chapter for a description of the procedures to follow in requesting judicial review.

[63 FR 35107, June 26, 1998; 63 FR 52614, Oct. 1, 1998, as amended at 65 FR 40331, June 29, 2000; 70 FR 4740, Jan. 28, 2005; 82 FR 5125, Jan. 17, 2017]

§ 422.616 Reopening and revising determinations and decisions.

(a) Subject to paragraph (e) of this section and the rules at § 422.138(c), an organization or reconsidered determination made by an MA organization, a reconsidered determination made by the independent entity described in § 422.592, or the decision of an Administrative Law Judge (ALJ) or attorney adjudicator or the Council that is otherwise final and binding may be reopened and revised by the entity that made the determination or decision, under the rules in part 405 of this chapter.

(b) Reopening may be at the instigation of any party.

(c) The filing of a request for reopening does not relieve the MA organization of its obligation to make payment or provide services as specified in § 422.618.

(d) Once an entity issues a revised determination or decision, any party may file an appeal.

(e) If the MA organization approved an inpatient hospital admission under the rules at § 412.3(d)(1) and (3) of this chapter, any additional clinical information obtained after the initial organization determination cannot be used

as new and material evidence to establish good cause for reopening the determination.

[63 FR 35107, June 26, 1998; 63 FR 52614, Oct. 1, 1998, as amended at 70 FR 4740, Jan. 28, 2005; 82 FR 5125, Jan. 17, 2017; 90 FR 15911, Apr. 15, 2025]

§ 422.618 How an MA organization must effectuate standard reconsidered determinations or decisions.

(a) *Reversals by the MA organization*—(1) *Requests for service.* If, on reconsideration of a request for service, the MA organization completely reverses its organization determination, the organization must authorize or provide the service under dispute as expeditiously as the enrollee's health condition requires, but no later than 30 calendar days after the date the MA organization receives the request for reconsideration (or no later than upon expiration of an extension described in § 422.590(f)).

(2) *Requests for payment.* If, on reconsideration of a request for payment, the MA organization completely reverses its organization determination, the organization must pay for the service no later than 60 calendar days after the date the MA organization receives the request for reconsideration.

(3) *Requests for a Part B drug.* If, on reconsideration of a request for a Part B drug, the MA organization completely reverses its organization determination, the MA organization must authorize or provide the Part B drug under dispute as expeditiously as the enrollee's health condition requires, but no later than 7 calendar days after the date the MA organization receives the request for reconsideration.

(b) *Reversals by the independent outside entity*—(1) *Requests for service.* If, on reconsideration of a request for service, the MA organization's determination is reversed in whole or in part by the independent outside entity, the MA organization must authorize the service under dispute within 72 hours from the date it receives notice reversing the determination, or provide the service under dispute as expeditiously as the enrollee's health condition requires, but no later than 14 calendar days from that date. The MA organization must inform the independent outside entity that the organization has effectuated the decision.

(2) *Requests for payment.* If, on reconsideration of a request for payment, the MA organization's determination is reversed in whole or in part by the independent outside entity, the MA organization must pay for the service no later than 30 calendar days from the date it receives notice reversing the organization determination. The MA organization must inform the independent outside entity that the organization has effectuated the decision.

(3) *Requests for a Part B drug.* If, on reconsideration of a request for a Part B drug, the MA organization's determination is reversed in whole or in part by the independent outside entity, the MA organization must authorize or provide the Part B drug under dispute within 72 hours from the date it receives notice reversing the determination. The MA organization must inform the independent outside entity that the organization has effectuated the decision.

(c) *Reversals other than by the MA organization or the independent outside entity*—(1) *General rule.* If the independent outside entity's determination is reversed in whole or in part by the ALJ or attorney adjudicator, or at a higher level of appeal, the MA organization must pay for, authorize, or provide the service under dispute as expeditiously as the enrollee's health condition requires, but no later than 60 calendar days from the date it receives notice reversing the determination. The MA organization must inform the independent outside entity that the organization has effectuated the decision or that it has appealed the decision.

(2) *Effectuation exception when the MA organization files an appeal with the Council.* If the MA organization requests Council review consistent with § 422.608, the MA organization may await the outcome of the review before it pays for, authorizes, or provides the service under dispute. A MA organization that files an appeal with the Council must concurrently send a copy of its appeal request and any accompanying documents to the enrollee and

must notify the independent outside entity that it has requested an appeal.

[63 FR 35107, June 26, 1998, as amended at 65 FR 40331, June 29, 2000; 68 FR 50858, Aug. 22, 2003; 80 FR 7962, Feb. 12, 2015; 82 FR 5125, Jan. 17, 2017; 84 FR 23882, May 23, 2019]

§ 422.619 How an MA organization must effectuate expedited reconsidered determinations.

(a) *Reversals by the MA organization*—(1) *Requests for service or item.* If, on reconsideration of an expedited request for service, the MA organization completely reverses its organization determination, the MA organization must authorize or provide the service or item under dispute as expeditiously as the enrollee's health condition requires, but no later than 72 hours after the date the MA organization receives the request for reconsideration (or no later than upon expiration of an extension described in § 422.590(f)).

(2) *Requests for a Part B drug.* If, on reconsideration of a request for a Part B drug, the MA organization completely reverses its organization determination, the MA organization must authorize or provide the Part B drug under dispute as expeditiously as the enrollee's health condition requires, but no later than 72 hours after the date the MA organization receives the request for reconsideration.

(b) *Reversals by the independent outside entity*—(1) *Requests for service or item.* If the MA organization's determination is reversed in whole or in part by the independent outside entity, the MA organization must authorize or provide the service under dispute as expeditiously as the enrollee's health condition requires but no later than 72 hours from the date it receives notice reversing the determination. The MA organization must inform the independent outside entity that the organization has effectuated the decision.

(2) *Requests for a Part B drug.* If, on reconsideration of a request for a Part B drug, the MA organization's determination is reversed in whole or in part by the independent outside entity, the MA organization must authorize or provide the Part B drug under dispute as expeditiously as the enrollee's health condition requires but no later than 24 hours from the date it receives notice reversing the determination. The MA organization must inform the outside entity that the organization has effectuated the decision.

(c) *Reversals other than by the MA organization or the independent outside entity*—(1) *General rule.* If the independent outside entity's expedited determination is reversed in whole or in part by the ALJ or attorney adjudicator, or at a higher level of appeal, the MA organization must authorize or provide the service under dispute as expeditiously as the enrollee's health condition requires, but no later than 60 days from the date it receives notice reversing the determination. The MA organization must inform the independent outside entity that the organization has effectuated the decision.

(2) *Reversals of decisions related to Part B drugs.* If the independent outside entity's determination is reversed in whole or in part by an ALJ/attorney adjudicator or at a higher level of appeal, the MA organization must authorize or provide the Part B drug under dispute as expeditiously as the enrollee's health condition requires but no later than 24 hours from the date it receives notice reversing the determination. The MA organization must inform the outside entity that the organization has effectuated the decision.

(3) *Effectuation exception when the MA organization files an appeal with the Council.* If the MA organization requests Council review consistent with § 422.608, the MA organization may await the outcome of the review before it authorizes or provides the service under dispute. A MA organization that files an appeal with the Council must concurrently send a copy of its appeal request and any accompanying documents to the enrollee and must notify the independent outside entity that it has requested an appeal.

[65 FR 40331, June 29, 2000, as amended at 68 FR 50859, Aug. 22, 2003; 80 FR 7962, Feb. 12, 2015; 82 FR 5125, Jan. 17, 2017; 84 FR 23882, May 23, 2019]

§ 422.620 Notifying enrollees of hospital discharge appeal rights.

(a) *Applicability and scope.* (1) For purposes of §§ 422.620 and 422.622, the term

hospital is defined as any facility providing care at the inpatient hospital level, whether that care is short term or long term, acute or non acute, paid through a prospective payment system or other reimbursement basis, limited to specialty care or providing a broader spectrum of services. This definition also includes critical access hospitals.

(2) For purposes of §§ 422.620 and 422.622, a discharge is a formal release of an enrollee from an inpatient hospital.

(b) *Advance written notice of hospital discharge rights.* For all Medicare Advantage enrollees, hospitals must deliver valid, written notice of an enrollee's rights as a hospital inpatient including discharge appeal rights. The hospital must use a standardized notice, as specified by CMS, in accordance with the following procedures:

(1) *Timing of notice.* The hospital must provide the notice at or near admission, but no later than 2 calendar days following the enrollee's admission to the hospital.

(2) *Content of the notice.* The notice of rights must include the following information:

(i) The enrollee's rights as a hospital inpatient, including the right to benefits for inpatient services and for post hospital services in accordance with 1866(a)(1)(M) of the Act.

(ii) The enrollee's right to request an immediate review, including a description of the process under § 422.622 and the availability of other appeals processes if the enrollee fails to meet the deadline for an immediate review.

(iii) The circumstances under which an enrollee will or will not be liable for charges for continued stay in the hospital in accordance with 1866(a)(1)(M) of the Act.

(iv) The enrollee's right to receive additional information in accordance with section § 422.622(e).

(v) Any other information required by CMS.

(3) *When delivery of notice is valid.* Delivery of the written notice of rights described in this section is valid if—

(i) The enrollee (or the enrollee's representative) has signed and dated the notice to indicate that he or she has received the notice and can comprehend its contents, except as provided in paragraph (b)(4) of this section; and

(ii) The notice is delivered in accordance with paragraph (b)(1) of this section and contains all the elements described in paragraph (b)(2) of this section.

(4) *If an enrollee refuses to sign the notice.* The hospital may annotate its notice to indicate the refusal, and the date of refusal is considered the date of receipt of the notice.

(c) *Follow up notification.* (1) The hospital must present a copy of the signed notice described in paragraph (b)(2) of this section to the enrollee (or enrollee's representative) prior to discharge. The notice should be given as far in advance of discharge as possible, but not more than 2 calendar days before discharge.

(2) Follow up notification is not required if the notice required under 422.620(b) is delivered within 2 calendar days of discharge.

(d) *Physician concurrence required.* Before discharging an enrollee from the inpatient hospital level of care, the MA organization must obtain concurrence from the physician who is responsible for the enrollee's inpatient care.

[71 FR 68723, Nov. 27, 2006]

§ 422.622 Requesting immediate QIO review of the decision to discharge from the inpatient hospital.

(a) *Enrollee's right to an immediate QIO review.* An enrollee has a right to request an immediate review by the QIO when an MA organization or hospital (acting directly or through its utilization committee), with physician concurrence determines that inpatient care is no longer necessary.

(b) *Requesting an immediate QIO review.* (1) An enrollee who wishes to exercise the right to an immediate review must submit a request to the QIO that has an agreement with the hospital as specified in § 476.78 of this chapter. The request must be made no later than the day of discharge and may be in writing or by telephone.

(2) The enrollee, or his or her representative, upon request by the QIO, must be available to discuss the case.

(3) The enrollee may, but is not required to, submit written evidence to

be considered by a QIO in making its decision.

(4) An enrollee who makes a timely request for an immediate QIO review in accordance with paragraph (b)(1) of this section is subject to the financial liability protections under paragraph (f) of this section, as applicable.

(5) When an enrollee does not request an immediate QIO review in accordance with paragraph (b) of this section, he or she may request expedited reconsideration by the MA organization as described in §422.584, but the financial liability rules of paragraph (f) of this section do not apply.

(c) *Burden of proof.* When an enrollee (or his or her representative, if applicable) requests an immediate review by a QIO, the burden of proof rests with the MA organization to demonstrate that discharge is the correct decision, either on the basis of medical necessity, or based on other Medicare coverage policies. Consistent with paragraph (e)(2) of this section, the MA organization should supply any and all information that a QIO requires to sustain the organization's discharge determination.

(d) *Procedures the QIO must follow.* (1) When the QIO receives the enrollee's request for an immediate review under paragraph (b), the QIO must notify the MA organization and the hospital that the enrollee has filed a request for an immediate review.

(2) The QIO determines whether the hospital delivered valid notice consistent with §422.620(b)(3).

(3) The QIO examines the medical and other records that pertain to the services in dispute.

(4) The QIO must solicit the views of the enrollee (or his or her representative) who requested the immediate QIO review.

(5) The QIO must provide an opportunity for the MA organization to explain why the discharge is appropriate.

(6) When the enrollee requests an immediate QIO review in accordance with paragraph (b)(1) of this section, the QIO must make a determination and notify the enrollee, the hospital, the MA organization, and the physician of its determination within one calendar day after it receives all requested pertinent information.

(7) If the QIO does not receive the information needed to sustain an MA organization's decision to discharge, it may make its determination based on the evidence at hand, or it may defer a decision until it receives the necessary information. If this delay results in extended Medicare coverage of an individual's hospital services, the MA organization may be held financially liable for these services, as determined by the QIO.

(8) When the QIO issues its determination, the QIO must notify the enrollee, the MA organization, the physician, and hospital of its decision by telephone, followed by a written notice that must include the following information:

(i) The basis for the determination.

(ii) A detailed rationale for the determination.

(iii) An explanation of the Medicare payment consequences of the determination and the date an enrollee becomes fully liable for the services.

(iv) Information about the enrollee's right to a reconsideration of the QIO's determination as set forth in §422.626(f), including how to request a reconsideration and the time period for doing so.

(e) *Responsibilities of the MA organization and hospital.* (1) When the QIO notifies an MA organization that an enrollee has requested an immediate QIO review, the MA organization must, directly or by delegation, deliver a detailed notice to the enrollee as soon as possible, but no later than noon of the day after the QIO's notification. The detailed notice must include the following information:

(i) A detailed explanation of why services are either no longer reasonable and necessary or are no longer covered.

(ii) A description of any applicable Medicare coverage rule, instruction, or other Medicare policy including information about how the enrollee may obtain a copy of the Medicare policy from the MA organization.

(iii) Any applicable MA organization policy, contract provision, or rationale upon which the discharge determination was based.

(iv) Facts specific to the enrollee and relevant to the coverage determination sufficient to advise the enrollee of the

applicability of the coverage rule or policy to the enrollee's case.

(v) Any other information required by CMS.

(2) Upon notification by the QIO of a request for an immediate review, the MA organization must supply any and all information, including a copy of the notices sent to the enrollee, as specified in § 422.620(b) and (c) and paragraph (e)(1) of this section, that the QIO needs to decide on the determination. The MA organization must supply this information as soon as possible, but no later than noon of the day after the QIO notifies the MA organization that a request for an expedited determination has been received from the enrollee. The MA organization must make the information available by phone (with a written record made of any information not transmitted initially in writing) and/or in writing, as determined by the QIO.

(3) In response to a request from the MA organization, the hospital must supply all information that the QIO needs to make its determination, including a copy of the notices required as specified in § 422.620(b) and (c) and paragraph (e)(1) of this section. The hospital must furnish this information as soon as possible, but no later than by close of business of the day the MA organization notifies the hospital of the request for information. At the discretion of the QIO, the hospital must make the information available by phone or in writing (with a written record of any information not transmitted initially in writing).

(4) Upon an enrollee's request, the MA organization must provide the enrollee a copy of, or access to, any documentation sent to the QIO by the MA organization, including written records of any information provided by telephone. The MA organization may charge the enrollee a reasonable amount to cover the costs of duplicating the documentation for the enrollee and/or delivering the documentation to the enrollee. The MA organization must accommodate such a request by no later than close of business of the first day after the day the material is requested.

(f) *Coverage during QIO expedited review.* (1) An MA organization is financially responsible for coverage of services as provided in this paragraph, regardless of whether it has delegated responsibility for authorizing coverage or discharge determinations to its providers.

(2) When the MA organization determines that hospital services are not, or are no longer, covered,

(i) If the MA organization authorized coverage of the inpatient admission directly or by delegation (or the admission constitutes emergency or urgently needed care, as described in §§ 422.2 and 422.112(c)), the MA organization continues to be financially responsible for the costs of the hospital stay when an appeal is filed under paragraph (a)(1) of this section until noon of the day after the QIO notifies the enrollee of its review determination, except as provided in paragraph (b)(5) of this section. If coverage of the hospital admission was never approved by the MA organization or the admission does not constitute emergency or urgently needed care as described in §§ 422.2 and 422.112(c), the MA organization is liable for the hospital costs only if it is determined on appeal that the hospital stay should have been covered under the MA plan.

(ii) The hospital may not charge the MA organization (or the enrollee) if—

(A) It was the hospital (acting on behalf of the enrollee) that filed the request for immediate QIO review; and

(B) The QIO upholds the non-coverage determination made by the MA organization.

(3) If the QIO determines that the enrollee still requires inpatient hospital care, the hospital must provide the enrollee with a notice consistent with § 422.620(c) of this subpart when the hospital or MA organization once again determines that the enrollee no longer requires inpatient hospital care.

(4) If the hospital determines that inpatient hospital services are no longer necessary, the hospital may not charge the enrollee for inpatient services received before noon of the day after the QIO notifies the enrollee of its review determination.

(g) *Effect of an expedited QIO determination.* The QIO determination is binding upon the enrollee, physician, hospital, and MA organization except in the following circumstances:

(1) *Right to request a reconsideration.* If the enrollee is still an inpatient in the hospital and is dissatisfied with the determination, he or she may request a reconsideration according to the procedures described in § 422.626(g).

(2) *Right to pursue the standard appeal process.* If the enrollee is no longer an inpatient in the hospital and is dissatisfied with this determination, the enrollee may appeal to OMHA for an ALJ hearing, the Council, or a Federal court, as provided for under this subpart.

[71 FR 68723, Nov. 27, 2006, as amended at 75 FR 19812, Apr. 15, 2010; 76 FR 21569, Apr. 15, 2011; 82 FR 5125, Jan. 17, 2017]

§ 422.624 Notifying enrollees of termination of provider services.

(a) *Applicability.* (1) For purposes of §§ 422.624 and 422.626, the term provider includes home health agencies (HHAs), skilled nursing facilities (SNFs), and comprehensive outpatient rehabilitation facilities (CORFs).

(2) *Termination of service defined.* For purposes of this section and § 422.626, a termination of service is the discharge of an enrollee from covered provider services, or discontinuation of covered provider services, when the enrollee has been authorized by the MA organization, either directly or by delegation, to receive an ongoing course of treatment from that provider. Termination includes cessation of coverage at the end of a course of treatment preauthorized in a discrete increment, regardless of whether the enrollee agrees that such services should end.

(b) *Advance written notification of termination.* Prior to any termination of service, the provider of the service must deliver valid written notice to the enrollee of the MA organization's decision to terminate services. The provider must use a standardized notice, required by the Secretary, in accordance with the following procedures—

(1) *Timing of notice.* The provider must notify the enrollee of the MA organization's decision to terminate covered services no later than two days before the proposed end of the services. If the enrollee's services are expected to be fewer than two days in duration, the provider should notify the enrollee at the time of admission to the provider. If, in a non-institutional setting, the span of time between services exceeds two days, the notice should be given no later than the next to last time services are furnished.

(2) *Content of the notice.* The standardized termination notice must include the following information:

(i) The date that coverage of services ends.

(ii) The date that the enrollee's financial liability for continued services begins.

(iii) A description of the enrollee's right to a fast-track appeal under § 422.626, including information about how to contact an independent review entity (IRE), an enrollee's right (but not obligation) to submit evidence showing that services should continue, and the availability of other MA appeal procedures if the enrollee fails to meet the deadline for a fast-track IRE appeal.

(iv) The enrollee's right to receive detailed information in accordance with § 422.626 (e)(1) and (2).

(v) Any other information required by the Secretary.

(c) *When delivery of notice is valid.* Delivery of the termination notice is not valid unless—

(1) The enrollee (or the enrollee's representative) has signed and dated the notice to indicate that he or she has received the notice and can comprehend its contents; and

(2) The notice is delivered in accordance with paragraph (b)(1) of this section and contains all the elements described in paragraph (b)(2) of this section.

(d) *Financial liability for failure to deliver valid notice.* An MA organization is financially liable for continued services until 2 days after the enrollee receives valid notice as specified under paragraph (c) of this section. An enrollee may waive continuation of services if he or she agrees with being discharged sooner than 2 days after receiving the notice.

[68 FR 16667, Apr. 4, 2003, as amended at 75 FR 19812, Apr. 15, 2010]

§ 422.626 Fast-track appeals of service terminations to independent review entities (IREs).

(a) *Enrollee's right to a fast-track appeal of an MA organization's termination decision.* An enrollee of an MA organization has a right to a fast-track appeal of an MA organization's decision to terminate provider services.

(1) An enrollee who desires a fast-track appeal must submit a request for an appeal to an IRE under contract with CMS, in writing or by telephone, by noon of the first day after the day of delivery of the termination notice. If, due to an emergency, the IRE is closed and unable to accept the enrollee's request for a fast-track appeal, the enrollee must file a request by noon of the next day that the IRE is open for business.

(2) If an enrollee makes an untimely request to an IRE, the IRE accepts the request and makes a determination as soon as possible, but the timeframe under paragraph (d)(5) of this section and the financial liability protection under paragraph (b) of this section do not apply.

(b) *Coverage of provider services.* Coverage of provider services continues until the date and time designated on the termination notice, unless the enrollee appeals and the IRE reverses the MA organization's decision. If the IRE's decision is delayed because the MA organization did not timely supply necessary information or records, the MA organization is liable for the costs of any additional coverage required by the delayed IRE decision. If the IRE finds that the enrollee did not receive valid notice, coverage of provider services by the MA organization continues until at least two days after valid notice has been received. Continuation of coverage is not required if the IRE determines that coverage could pose a threat to the enrollee's health or safety.

(c) *Burden of proof.* When an enrollee appeals an MA organization's decision to terminate services to an IRE, the burden of proof rests with the MA organization to demonstrate that termination of coverage is the correct decision, either on the basis of medical necessity, or based on other Medicare coverage policies.

(1) To meet this burden, the MA organization must supply any and all information that an IRE requires to sustain the MA organization's termination decision, consistent with paragraph (e) of this section.

(2) The enrollee may submit evidence to be considered by an IRE in making its decision.

(3) The MA organization or an IRE may require an enrollee to authorize release to the IRE of his or her medical records, to the extent that the records are necessary for the MA organization to demonstrate the correctness of its decision or for an IRE to determine the appeal.

(d) *Procedures an IRE must follow.* (1) On the date an IRE receives the enrollee's request for an appeal, the IRE must immediately notify the MA organization and the provider that the enrollee has filed a request for a fast-track appeal, and of the MA organization's responsibility to submit documentation consistent with paragraph (e)(3) of this section.

(2) When an enrollee requests a fast-track appeal, the IRE must determine whether the provider delivered a valid notice of the termination decision, and whether a detailed notice has been provided, consistent with paragraph (e)(1) of this section.

(3) The IRE must notify CMS about each case in which it determines that improper notification occurs.

(4) Before making its decision, the IRE must solicit the enrollee's views regarding the reason(s) for termination of services as specified in the detailed written notice provided by the MA organization, or regarding any other reason that the IRE uses as the basis of its review determination.

(5) An IRE must make a decision on an appeal and notify the enrollee, the MA organization, and the provider of services, by close of business of the day after it receives the information necessary to make the decision. If the IRE does not receive the information needed to sustain an MA organization's decision to terminate services, it may make a decision on the case based on the information at hand, or it may defer its decision until it receives the

necessary information. If the IRE defers its decision, coverage of the services by the MA organization would continue until the decision is made, consistent with paragraph (b) of this section, but no additional termination notice would be required.

(e) *Responsibilities of the MA organization.* (1) When an IRE notifies an MA organization that an enrollee has requested a fast-track appeal, the MA organization must send a detailed notice to the enrollee by close of business of the day of the IRE's notification. The detailed termination notice must include the following information:

(i) A specific and detailed explanation why services are either no longer reasonable and necessary or are no longer covered.

(ii) A description of any applicable Medicare coverage rule, instruction or other Medicare policy including citations, to the applicable Medicare policy rules, or the information about how the enrollee may obtain a copy of the Medicare policy from the MA organization.

(iii) Any applicable MA organization policy, contract provision, or rationale upon which the termination decision was based.

(iv) Facts specific to the enrollee and relevant to the coverage determination that are sufficient to advise the enrollee of the applicability of the coverage rule or policy to the enrollee's case.

(v) Any other information required by CMS.

(2) Upon an enrollee's request, the MA organization must provide the enrollee a copy of, or access to, any documentation sent to the IRE by the MA organization, including records of any information provided by telephone. The MA organization may charge the enrollee a reasonable amount to cover the costs of duplicating the information for the enrollee and/or delivering the documentation to the enrollee. The MA organization must accommodate such a request by no later than close of business of the first day after the day the material is requested.

(3) Upon notification by the IRE of a fast-track appeal, the MA organization must supply any and all information, including a copy of the notice sent to the enrollee, that the IRE needs to decide on the appeal. The MA organization must supply this information as soon as possible, but no later than by close of business of the day that the IRE notifies the MA organization that an appeal has been received from the enrollee. The MA organization must make the information available by phone (with a written record made of what is transmitted in this manner) and/or in writing, as determined by the IRE.

(4) An MA organization is financially responsible for coverage of services as provided in paragraph (b) of this section, regardless of whether it has delegated responsibility for authorizing coverage or termination decisions to its providers.

(f) *Responsibilities of the provider.* If an IRE reverses an MA organization's termination decision, the provider must provide the enrollee with a new notice consistent with §422.624(b) of this subpart.

(g) *Reconsiderations of IRE decisions.* (1) If the IRE upholds an MA organization's termination decision in whole or in part, the enrollee may request, no later than 60 days after notification that the IRE has upheld the decision that the IRE reconsider its original decision.

(2) The IRE must issue its reconsidered determination as expeditiously as the enrollee's health condition requires but no later than within 14 days of receipt of the enrollee's request for a reconsideration.

(3) If the IRE reaffirms its decision, in whole or in part, the enrollee may appeal the IRE's reconsidered determination to OMHA for an ALJ hearing, the Council, or a Federal court, as provided for under this subpart.

(4) If on reconsideration the IRE determines that coverage of provider services should terminate on a given date, the enrollee is liable for the costs of continued services after that date unless the IRE's decision is reversed on appeal. If the IRE's decision is reversed on appeal, the MA organization must reimburse the enrollee, consistent with the appealed decision, for the costs of

any covered services for which the enrollee has already paid the MA organization or provider.

[68 FR 16667, Apr. 4, 2003, as amended at 75 FR 19812, Apr. 15, 2010; 76 FR 21569, Apr. 15, 2011; 82 FR 5125, Jan. 17, 2017; 89 FR 30827, Apr. 23, 2024]

Requirements Applicable to Certain Integrated Dual Eligible Special Needs Plans

Source: 84 FR 15835, Apr. 16, 2019, unless otherwise noted.

§ 422.629 General requirements for applicable integrated plans.

(a) *Scope.* The provisions in this section and in §§ 422.630 through 422.634 set forth requirements for unified appeals and grievance processes with which applicable integrated plans must comply. Beginning January 1, 2021, these provisions apply to an applicable integrated plan in lieu of §§ 422.564, 422.566(c) and (d), and 422.568 through 422.590, and 422.618(a) and §§ 438.404 through 438.424 of this chapter; provisions governing Part B drugs in §§ 422.568(b)(2), 422.570(d)(2), 422.572(a)(2), 422.584(d)(1), 422.590(c), and 422.590(e)(2) apply to an applicable integrated plan.

(b) *General process.* An applicable integrated plan must create integrated processes for enrollees for integrated grievances, integrated organization determinations, and integrated reconsiderations.

(c) *State flexibilities.* A State may, at its discretion, implement standards for timeframes or notice requirements that are more protective for the enrollee than required by this section and §§ 422.630 through 422.634. The contract under § 422.107 must include any standards that differ from the standards set forth in this section.

(d) *Evidence.* The applicable integrated plan must do the following:

(1) Provide the enrollee—

(i) A reasonable opportunity, in person and in writing, to present evidence and testimony and make legal and factual arguments for integrated grievances, and integrated reconsiderations; and

(ii) Information on how evidence and testimony should be presented to the plan.

(2) Inform the enrollee of the limited time available for presenting evidence sufficiently in advance of the resolution timeframe for appeals as specified in this section if the case is being considered under an expedited timeframe for the integrated grievance or integrated reconsideration.

(e) *Assistance.* In addition to the requirements in § 422.562(a)(5), the applicable integrated plan must provide an enrollee reasonable assistance in completing forms and taking other procedural steps related to integrated grievances and integrated appeals.

(f) *Applicable requirements.* The requirements in §§ 422.560, 422.561, 422.562, 422.566, and 422.592 through 422.626 apply to an applicable integrated plan unless otherwise provided in this section or in §§ 422.630 through 422.634.

(g) *Acknowledgement.* The applicable integrated plan must send to the enrollee written acknowledgement of integrated grievances and integrated reconsiderations upon receiving the request.

(h) *Recordkeeping.* (1) The applicable integrated plan must maintain records of integrated grievances and integrated appeals. Each applicable integrated plan that is a Medicaid managed care organization must review the Medicaid-related information as part of its ongoing monitoring procedures, as well as for updates and revisions to the State quality strategy.

(2) The record of each integrated grievance or integrated appeal must contain, at a minimum:

(i) A general description of the reason for the integrated appeal or integrated grievance.

(ii) The date of receipt.

(iii) The date of each review or, if applicable, review meeting.

(iv) Resolution at each level of the integrated appeal or integrated grievance, if applicable.

(v) Date of resolution at each level, if applicable.

(vi) Name of the enrollee for whom the integrated appeal or integrated grievance was filed.

(vii) Date the applicable integrated plan notified the enrollee of the resolution.

(3) The record of each integrated grievance or integrated appeal must be

accurately maintained in a manner accessible to the State and available upon request to CMS.

(i) *Prohibition on punitive action.* Each applicable integrated plan must ensure that no punitive action is taken against a provider that requests an integrated organization determination or integrated reconsideration, or supports an enrollee's request for these actions.

(j) *Information to providers and subcontractors.* The applicable integrated plan must provide information about the integrated grievance and integrated appeal system to all providers and subcontractors at the time they enter into a contract including, at minimum, information on integrated grievance, integrated reconsideration, and fair hearing procedures and timeframes as applicable. Such information must include the following:

(1) The right to file an integrated grievance and integrated reconsideration.

(2) The requirements and timeframes for filing an integrated grievance or integrated reconsideration.

(3) The availability of assistance in the filing process.

(k) *Review decision-making requirements*—(1) *General rules.* Individuals making decisions on integrated appeals and grievances must take into account all comments, documents, records, and other information submitted by the enrollee or their representative without regard to whether such information was submitted or considered in the initial adverse integrated organization determination.

(2) *Integrated grievances.* Individuals making decisions on integrated grievances must be individuals who—

(i) Were neither involved in any previous level of review or decision-making nor a subordinate of any such individual; and

(ii) If deciding any of the following, have the appropriate clinical expertise in treating the enrollee's condition or disease:

(A) A grievance regarding denial of expedited resolution of an appeal.

(B) A grievance that involves clinical issues.

(3) *Integrated organization determinations.* If the applicable integrated plan expects to issue a partially or fully adverse medical necessity (or any substantively equivalent term used to describe the concept of medical necessity) decision based on the initial review of the request, the integrated organization determination must be reviewed by a physician or other appropriate health care professional with expertise in the field of medicine or health care that is appropriate for the services at issue, including knowledge of Medicare and Medicaid coverage criteria, before the applicable integrated plan issues the integrated organization determination decision. The physician or health care professional reviewing the request need not, in all cases, be of the same specialty or subspecialty as the treating physician or other health care provider. The physician or other health care professional must have a current and unrestricted license to practice within the scope of his or her profession in a State, Territory, Commonwealth of the United States (that is, Puerto Rico), or the District of Columbia.

(4) *Integrated reconsideration determinations.* Individuals making an integrated reconsideration determination must be individuals who—

(i) Were neither involved in any previous level of review or decision-making nor a subordinate of any such individual; and

(ii) If deciding an appeal of a denial that is based on lack of medical necessity (or any substantively equivalent term used to describe the concept of medical necessity), are a physician or other appropriate health care professional who have the appropriate clinical expertise in treating the enrollee's condition or disease, and knowledge of Medicare and Medicaid coverage criteria, before the applicable integrated plan issues the integrated reconsideration determination.

(l) *Parties.* (1) The following individuals or entities can request an integrated grievance, integrated organization determination, and integrated reconsideration, and are parties to the case:

(i) The enrollee.

(ii) The enrollee's representative, including any person authorized under State law.

(2) When the term ''enrollee'' is used throughout §§ 422.629 through 422.634, it includes providers that file a request and authorized representatives consistent with this paragraph, unless otherwise specified.

(3) A provider who is providing treatment to the enrollee may, upon providing notice to the enrollee, request a standard or expedited pre-service integrated reconsideration on behalf of an enrollee.

(4) The following individuals or entities may request an integrated reconsideration and are parties to the case:

(i) An assignee of the enrollee (that is, a physician or other provider who has furnished or intends to furnish a service to the enrollee and formally agrees to waive any right to payment from the enrollee for that service).

(ii) Any other provider or entity (other than the applicable integrated plan) who has an appealable interest in the proceeding.

[84 FR 15835, Apr. 16, 2019, as amended at 84 FR 23883, May 23, 2019; 86 FR 6102, Jan. 19, 2021; 87 FR 27897, May 9, 2022; 88 FR 22335, Apr. 12, 2023]

§ 422.630 Integrated grievances.

(a) *General rule.* In lieu of complying with § 422.564, and the grievance requirements of §§ 438.402, 438.406, 438.408, 438.414, and 438.416 of this chapter, each applicable integrated plan must comply with this section. Each applicable integrated plan must provide meaningful procedures for timely hearing and resolving integrated grievances between enrollees and the applicable integrated plan or any other entity or individual through which the applicable integrated plan provides covered items and services.

(b) *Timing.* An enrollee may file an integrated grievance at any time with the applicable integrated plan.

(c) *Filing.* An enrollee may file an integrated grievance orally or in writing with the applicable integrated plan, or with the State for an integrated grievance related to a Medicaid benefit, if the State has a process for accepting Medicaid grievances.

(d) *Expedited grievances.* An applicable integrated plan must respond to an enrollee's grievance within 24 hours if the complaint involves the applicable integrated plan's—

(1) Decision to invoke an extension relating to an integrated organization determination or integrated reconsideration; or

(2) Refusal to grant an enrollee's request for an expedited integrated organization determination under § 422.631 or expedited integrated reconsideration under § 422.633.

(e) *Resolution and notice.* (1) The applicable integrated plan must resolve standard integrated grievances as expeditiously as the case requires, based on the enrollee's health status, but no later than 30 calendar days from the date it receives the integrated grievance.

(i) All integrated grievances submitted in writing must be responded to in writing.

(ii) Integrated grievances submitted orally may be responded to either orally or in writing, unless the enrollee requests a written response.

(iii) All integrated grievances related to quality of care, regardless of how the integrated grievance is filed, must be responded to in writing. The response must include a description of the enrollee's right to file a written complaint with the QIO with regard to Medicare covered services. For any complaint submitted to a QIO, the applicable integrated plan must cooperate with the QIO in resolving the complaint.

(2) The timeframe for resolving the integrated grievance may be extended by 14 calendar days if the enrollee requests an extension or if the applicable integrated plan justifies the need for additional information and documents how the delay is in the interest of the enrollee. When the applicable integrated plan extends the timeframe, it must—

(i) Make reasonable efforts to promptly notify the enrollee orally of the reasons for the delay; and

(ii) Send written notice to the enrollee of the reasons for the delay immediately, but no later than within 2 calendar days of making the decision to extend the timeframe to resolve the integrated grievance. This notice must explain the right to file an integrated

grievance if the enrollee disagrees with the decision to delay.

§ 422.631 Integrated organization determinations.

(a) *General rule.* An applicable integrated plan must adopt and implement a process for enrollees to request that the plan make an integrated organization determination. The process for requesting that the applicable integrated plan make an integrated organization determination must be the same for all covered benefits. Timeframes and notice requirements for integrated organization determinations for Part B drugs are governed by the provisions for Part B drugs in §§ 422.568(b)(3), 422.570(d)(2), and 422.572(a)(2).

(b) *Requests.* The enrollee, or a provider on behalf of an enrollee, may request an integrated organization determination orally or in writing, except for requests for payment, which must be in writing (unless the applicable integrated plan or entity responsible for making the determination has implemented a voluntary policy of accepting verbal payment requests).

(c) *Expedited integrated organization determinations.* (1) An enrollee, or a provider on behalf of an enrollee, may request an expedited integrated organization determination.

(2) The request can be oral or in writing.

(3) The applicable integrated plan must complete an expedited integrated organization determination when the applicable integrated plan determines (based on a request from the enrollee or on its own) or the provider indicates (in making the request on the enrollee's behalf or supporting the enrollee's request) that taking the time for a standard resolution could seriously jeopardize the enrollee's life, physical or mental health, or ability to attain, maintain, or regain maximum function.

(d) *Timeframes and notice*—(1) *Integrated organization determination notice.*(i) The applicable integrated plan must send an enrollee a written notice (and notify the physician or provider involved, as appropriate) of any adverse decision on an integrated organization determination (including a determination to authorize a service or item in an amount, duration, or scope that is less than the amount previously requested or authorized for an ongoing course of treatment) within the timeframes set forth in this section.

(ii) For an integrated organization determination not reached within the timeframes specified in this section (which constitutes a denial and is thus an adverse decision), the applicable integrated plan must send a notice to the enrollee (and notify the physician or provider involved, as appropriate) on the date that the timeframes expire. Such notice must describe all applicable Medicare and Medicaid appeal rights.

(iii) Integrated organization determination notices must be written in plain language, be available in a language and format that is accessible to the enrollee, and explain the following:

(A) The applicable integrated plan's determination.

(B) The date the determination was made.

(C) The date the determination will take effect.

(D) The reasons for the determination.

(E) The enrollee's right to file an integrated reconsideration and the ability for someone else to file an appeal on the enrollee's behalf.

(F) Procedures for exercising enrollee's rights to an integrated reconsideration.

(G) Circumstances under which expedited resolution is available and how to request it.

(H) If applicable, the enrollee's rights to have benefits continue pending the resolution of the integrated appeal process.

(2) *Timing of notice*—(i) *Standard integrated organization determinations.* (A) The applicable integrated plan must send a notice of its integrated organization determination at least 10 days before the date of action (that is, before the date on which a termination, suspension, or reduction becomes effective), in cases where a previously approved service is being reduced, suspended, or terminated, except in circumstances where an exception is permitted under §§ 431.213 and 431.214 of this chapter.

(B) Except as described in paragraph (d)(2)(i)(A) of this section, the applicable integrated plan must send a notice of its integrated organization determination as expeditiously as the enrollee's health condition requires but no later than either of the following:

(*1*) For a service or item not subject to the prior authorization rules in § 422.122, 14 calendar days after receiving the request for the standard integrated organization determination.

(*2*) Beginning on or after January 1, 2026, for a service or item subject to the prior authorization rules in § 422.122, 7 calendar days after receiving the request for the standard integrated organization determination.

(ii) *Extensions.* The applicable integrated plan may extend the timeframe for a standard or expedited integrated organization determination by up to 14 calendar days if—

(A) The enrollee or provider requests the extension; or

(B) The applicable integrated plan can show that—

(*1*) The extension is in the enrollee's interest; and

(*2*) There is need for additional information and there is a reasonable likelihood that receipt of such information would lead to approval of the request, if received.

(iii) *Notices in cases of extension.* (A) When the applicable integrated plan extends the timeframe, it must notify the enrollee in writing of the reasons for the delay as expeditiously as the enrollee's health condition requires but no later than upon expiration of the extension, and inform the enrollee of the right to file an expedited integrated grievance if he or she disagrees with the applicable integrated plan's decision to grant an extension.

(B) If the applicable integrated plan extends the timeframe for making its integrated organization determination, it must send the notice of its determination as expeditiously as the enrollee's health condition requires and no later than the date the extension expires.

(iv) *Expedited integrated organization determinations.* (A) The applicable integrated plan must provide notice of its expedited integrated organization determination as expeditiously as the enrollee's health condition requires, but no later than 72 hours after receiving the request.

(B) If the applicable integrated plan denies the request for an expedited integrated organization determination, it must:

(*1*) Automatically transfer a request to the standard timeframe and make the determination within the applicable timeframe established in paragraph (d)(2)(i)(B) of this section for a standard integrated organization determination. The timeframe begins the day the applicable integrated plan receives the request for expedited integrated organization determination.

(*2*) Give the enrollee prompt oral notice of the denial and transfer and subsequently deliver, within 3 calendar days, a written letter that—

(*i*) Explains that the applicable integrated plan will process the request using the timeframe for standard integrated organization determinations;

(*ii*) Informs the enrollee of the right to file an expedited integrated grievance if he or she disagrees with the applicable integrated plan's decision not to expedite;

(*iii*) Informs the enrollee of the right to resubmit a request for an expedited integrated organization determination with any physician's support; and

(*iv*) Provides instructions about the integrated grievance process and its timeframes.

(C) If the applicable integrated plan must receive medical information from noncontract providers, the applicable integrated plan must request the necessary information from the noncontract provider within 24 hours of the initial request for an expedited integrated organization determination. Noncontract providers must make reasonable and diligent efforts to expeditiously gather and forward all necessary information to assist the applicable integrated plan in meeting the required timeframe. Regardless of whether the applicable integrated plan must request information from noncontract providers, the applicable integrated plan is responsible for meeting the timeframe and notice requirements of this section.

(3) *Timeframe for requests for payment.* The applicable integrated plan must

process requests for payment according to the ''prompt payment'' provisions set forth in § 422.520.

(e) *Dismissing a request.* The applicable integrated plan dismisses a standard or expedited integrated organization determination request, either entirely or as to any stated issue, under any of the following circumstances:

(1) The individual or entity making the request is not permitted to request an integrated organization determination under § 422.629(*l*).

(2) The applicable integrated plan determines the party failed to make out a valid request for an integrated organization determination that substantially complies with paragraph (b) of this section.

(3) An enrollee or the enrollee's representative files a request for an integrated organization determination, but the enrollee dies while the request is pending, and both of the following apply:

(i) The enrollee's surviving spouse or estate has no remaining financial interest in the case.

(ii) No other individual or entity with a financial interest in the case wishes to pursue the integrated organization determination.

(4) A party filing the integrated organization determination request submits a timely request for withdrawal of their request for an integrated organization determination with the applicable integrated plan.

(f) *Notice of dismissal.* The applicable integrated plan must mail or otherwise transmit a written notice of the dismissal of the integrated organization determination request to the parties. The notice must state all of the following:

(1) The reason for the dismissal.

(2) The right to request that the applicable integrated plan vacate the dismissal action.

(3) The right to request reconsideration of the dismissal.

(g) *Vacating a dismissal.* If good cause is established, the applicable integrated plan may vacate its dismissal of a request for an integrated organization determination within 6 months from the date of the notice of dismissal.

(h) *Effect of dismissal.* The dismissal of a request for an integrated organization determination is binding unless it is modified or reversed by the applicable integrated plan or vacated under paragraph (g) of this section.

(i) *Withdrawing a request.* A party that requests an integrated organization determination may withdraw its request at any time before the decision is issued by filing a request with the applicable integrated plan.

[84 FR 15835, Apr. 16, 2019, as amended at 84 FR 23883, May 23, 2019; 86 FR 6102, Jan. 19, 2021; 87 FR 27897, May 9, 2022; 89 FR 8977, Feb. 8, 2024; 90 FR 15911, Apr. 15, 2025]

§ 422.632 Continuation of benefits while the applicable integrated plan reconsideration is pending.

(a) *Definition.* As used in this section, timely files means files for continuation of benefits on or before the later of the following:

(1) Within 10 calendar days of the applicable integrated plan sending the notice of adverse integrated organization determination.

(2) The intended effective date of the applicable integrated plan's proposed adverse integrated organization determination.

(b) *Continuation of benefits.* The applicable integrated plan must continue the enrollee's benefits under Parts A and B of title XVIII and title XIX if all of the following occur:

(1) The enrollee files the request for an integrated appeal timely in accordance with § 422.633(d);

(2) The integrated appeal involves the termination, suspension, or reduction of previously authorized services;

(3) The services were ordered by an authorized provider;

(4) The period covered by the original authorization has not expired; and

(5) The enrollee timely files for continuation of benefits.

(c) *Duration of continued or reinstated benefits.* If, at the enrollee's request, the applicable integrated plan continues or reinstates the enrollee's benefits, as described in paragraph (b) of this section, while the integrated reconsideration is pending, the benefits must be continued until—

(1) The enrollee withdraws the request for an integrated reconsideration;

(2) The applicable integrated plan issues an integrated reconsideration that is unfavorable to the enrollee related to the benefit that has been continued;

(3) For an appeal involving Medicaid benefits—

(i) The enrollee fails to file a request for a State fair hearing and continuation of benefits, within 10 calendar days after the applicable integrated plan sends the notice of the integrated reconsideration;

(ii) The enrollee withdraws the appeal or request for a State fair hearing; or

(iii) A State fair hearing office issues a hearing decision adverse to the enrollee.

(d) *Recovery of costs.* In the event the appeal or State fair hearing is adverse to the enrollee—

(1) The applicable integrated plan or State agency may not pursue recovery for costs of services furnished by the applicable integrated plan pending the integrated reconsideration, to the extent that the services were furnished solely under of the requirements of this section.

(2) If, after the integrated reconsideration decision is final, an enrollee requests that Medicaid services continue through a State fair hearing, state rules on recovery of costs, in accordance with the requirements of § 438.420(d) of this chapter, apply for costs incurred for services furnished pending appeal subsequent to the date of the integrated reconsideration decision.

[84 FR 15835, Apr. 16, 2019, as amended at 86 FR 6103, Jan. 19, 2021]

§ 422.633 Integrated reconsiderations.

(a) *General rule.* An applicable integrated plan may only have one level of integrated reconsideration for an enrollee.

(b) *External medical reviews.* If a State has established an external medical review process, the requirements of § 438.402(c)(1)(i)(B) of this chapter apply to each applicable integrated plan that is a Medicaid managed care organization, as defined in section 1903 of the Act.

(c) *Case file.* Upon request of the enrollee or his or her representative, the applicable integrated plan must provide the enrollee and his or her representative the enrollee's case file, including medical records, other documents and records, and any new or additional evidence considered, relied upon, or generated by the applicable integrated plan (or at the direction of the applicable integrated plan) in connection with the appeal of the integrated organization determination. This information must be provided free of charge and sufficiently in advance of the resolution timeframe for the integrated reconsideration, or subsequent appeal, as specified in this section.

(d) *Timing.* (1) *Timeframe for filing*—An enrollee has 60 calendar days after receipt of the adverse organization determination notice to file a request for an integrated reconsideration with the applicable integrated plan.

(i) The date of receipt of the adverse organization determination is presumed to be 5 calendar days after the date of the integrated organization determination notice, unless there is evidence to the contrary.

(ii) For purposes of meeting the 60-calendar day filing deadline, the request is considered as filed on the date it is received by the applicable integrated plan.

(2) *Oral inquires*—Oral inquires seeking to appeal an adverse integrated organization determination must be treated as a request for an integrated reconsideration (to establish the earliest possible filing date for the appeal).

(3) *Extending the time for filing a request*—(i) *General rule.* If a party or physician acting on behalf of an enrollee shows good cause, the applicable integrated plan may extend the timeframe for filing a request for an integrated reconsideration.

(ii) *How to request an extension of timeframe.* If the 60-day period in which to file a request for an integrated reconsideration has expired, a party to the integrated organization determination or a physician acting on behalf of an

enrollee may file a request for integrated reconsideration with the applicable integrated plan. The request for integrated reconsideration and to extend the timeframe must—

(A) Be in writing; and

(B) State why the request for integrated reconsideration was not filed on time.

(e) *Expedited integrated reconsiderations.* (1) Applicable integrated plans must accept requests to expedite integrated reconsiderations from either of the following:

(i) An enrollee.

(ii) A provider making the request on behalf of an enrollee, when the request is not a request for expedited payment.

(2) The request can be oral or in writing.

(3) The applicable integrated plan must grant the request to expedite the integrated reconsideration when it determines (for a request from the enrollee), or the provider indicates (in making the request on the enrollee's behalf or supporting the enrollee's request), that taking the time for a standard resolution could seriously jeopardize the enrollee's life, physical or mental health, or ability to attain, maintain, or regain maximum function.

(4) If an applicable integrated plan denies an enrollee's request for an expedited integrated reconsideration, it must automatically transfer a request to the standard timeframe and make the determination within the 30-day timeframe established in paragraph (f)(1) of this section for a standard integrated reconsideration. The 30-day period begins with the day the applicable integrated plan receives the request for expedited integrated reconsideration. The applicable integrated plan must give the enrollee prompt oral notice of the decision, and give the enrollee written notice within 2 calendar days. The written notice must do all of the following:

(i) Include the reason for the denial.

(ii) Inform the enrollee of the right to file a grievance if the enrollee disagrees with the decision not to expedite, including timeframes and procedures for filing a grievance.

(iii) Inform the enrollee of the right to resubmit a request for an expedited determination with any physician's support.

(5) If the applicable integrated plan must receive medical information from noncontract providers, the applicable integrated plan must request the necessary information from the noncontract provider within 24 hours of the initial request for an expedited integrated reconsideration. Noncontract providers must make reasonable and diligent efforts to expeditiously gather and forward all necessary information to assist the applicable integrated plan in meeting the required timeframe. Regardless of whether the applicable integrated plan must request information from noncontract providers, the applicable integrated plan is responsible for meeting the timeframe and notice requirements of this section.

(f) *Resolution and notification.* The applicable integrated plan must make integrated reconsidered determinations as expeditiously as the enrollee's health condition requires but no later than the timeframes established in this section. Integrated reconsidered determinations regarding Part B drugs must comply with the timelines governing Part B drugs established in §§ 422.584(d)(1) and 422.590(c) and (e)(2).

(1) *Standard integrated reconsiderations.* The applicable integrated plan must resolve integrated reconsiderations as expeditiously as the enrollee's health condition requires but no later than 30 calendar days from the date of receipt of the request for the integrated reconsideration. This timeframe may be extended as described in paragraph (f)(3) of this section.

(2) *Expedited integrated reconsiderations.* The applicable integrated plan must resolve expedited integrated reconsiderations as expeditiously as the enrollee's health condition requires but no later than within 72 hours of receipt of the integrated reconsideration. This timeframe may be extended as described in paragraph (f)(3) of this section. In addition to the written notice required under paragraph (f)(4) of this section, the applicable integrated plan must make reasonable efforts to provide prompt oral notice of the expedited resolution to the enrollee.

(3) *Extensions.* (i) The applicable integrated plan may extend the timeframe

for resolving any integrated reconsideration other than those concerning Part B drugs by 14 calendar days if—

(A) The enrollee requests the extension; or

(B) The applicable integrated plan can show that—

(*1*) The extension is in the enrollee's interest; and

(*2*) There is need for additional information and there is a reasonable likelihood that receipt of such information would lead to approval of the request, if received.

(ii) If the applicable integrated plan extends the timeframe for resolving the integrated reconsideration, it must make reasonable efforts to give the enrollee prompt oral notice of the delay, and give the enrollee written notice within 2 calendar days of making the decision to extend the timeframe to resolve the integrated reconsideration. The notice must include the reason for the delay and inform the enrollee of the right to file an expedited grievance if he or she disagrees with the decision to grant an extension.

(4) *Notice of resolution.* The applicable integrated plan must send a written notice to enrollees that includes the integrated reconsidered determination, within the resolution timeframes set forth in this section. The notice of determination must be written in plain language and available in a language and format that is accessible to the enrollee and must explain the following:

(i) The resolution of and basis for the integrated reconsideration and the date it was completed.

(ii) For integrated reconsiderations not resolved wholly in favor of the enrollee:

(A) An explanation of the next level of appeal available under the Medicare and Medicaid programs, and what steps the enrollee must take to pursue the next level of appeal under each program, and how the enrollee can obtain assistance in pursuing the next level of appeal under each program; and

(B) The right to request and receive Medicaid-covered benefits while the next level of appeal is pending, if applicable.

(g) *Withdrawing a request.* The party or physician acting on behalf of an enrollee who files a request for integrated reconsideration may withdraw it by filing a request for withdrawal with the applicable integrated plan.

(h) *Dismissing a request.* The applicable integrated plan dismisses an expedited or standard integrated reconsideration request, either entirely or as to any stated issue, under any of the following circumstances:

(1) The person or entity requesting an integrated reconsideration is not a proper party to request an integrated reconsideration under § 422.629(*l*).

(2) The applicable integrated plan determines the party failed to make a valid request for an integrated reconsideration that substantially complies with § 422.629(*l*) of this section.

(3) The party fails to file the integrated reconsideration request within the proper filing timeframe in accordance with paragraph (d) of this section.

(4) The enrollee or the enrollee's representative files a request for an integrated reconsideration, but the enrollee dies while the request is pending, and both of the following criteria apply:

(i) The enrollee's surviving spouse or estate has no remaining financial interest in the case.

(ii) No other individual or entity with a financial interest in the case wishes to pursue the integrated reconsideration.

(5) A party filing the reconsideration request submits a timely request for withdrawal of their request for an integrated reconsideration with the applicable integrated plan.

(i) *Notice of dismissal.* The applicable integrated plan must mail or otherwise transmit a written notice of the dismissal of the integrated reconsideration request to the parties. The notice must state all of the following:

(1) The reason for the dismissal.

(2) The right to request that the applicable integrated plan vacate the dismissal action.

(3) The right to request review of the dismissal by the independent entity.

(j) *Vacating a dismissal.* If good cause is established, the applicable integrated plan may vacate its dismissal of a request for integrated reconsideration within 6 months from the date of the notice of dismissal.

(k) *Effect of dismissal.* The applicable integrated plan's dismissal is binding unless the enrollee or other party requests review by the independent entity in accordance with § 422.590(h) or the dismissal is vacated under paragraph (j) of this section.

[84 FR 15835, Apr. 16, 2019, as amended at 84 FR 23883, May 23, 2019; 84 FR 26579, June 7, 2019; 86 FR 6103, Jan. 19, 2021; 87 FR 27897, May 9, 2022; 89 FR 30827, Apr. 23, 2024]

§ 422.634 Effect.

(a) *Failure of the applicable integrated plan to send timely notice of a determination.* If the applicable integrated plan fails to adhere to the notice and timing for an integrated organization determination or integrated reconsideration, this failure constitutes an adverse determination for the enrollee.

(1) For an integrated organization determination, this means that the enrollee may request an integrated reconsideration.

(2) For integrated reconsiderations of Medicare benefits, this means the applicable integrated plan must forward the case to the independent review entity, in accordance with the timeframes under paragraph (b) of this section and § 422.592. For integrated reconsiderations of Medicaid benefits, this means that an enrollee or other party may file for a State fair hearing in accordance with § 438.408(f) of this chapter, or if applicable, a State external medical review in accordance with § 438.402(c) of this chapter.

(b) *Adverse integrated reconsiderations.* (1) Subject to paragraph (b)(2) of this section, when the applicable integrated plan affirms, in whole or in part, its adverse integrated organization determination involving a Medicare benefit—

(i) The issues that remain in dispute must be reviewed and resolved by an independent, outside entity that contracts with CMS, in accordance with §§ 422.592 and 422.594 through 422.619;

(ii) For standard integrated reconsiderations, the applicable integrated plan must prepare a written explanation and send the case file to the independent review entity contracted by CMS, as expeditiously as the enrollee's health condition requires, but no later than 30 calendar days from the date it receives the request (or no later than the expiration of an extension described in § 422.633(f)(3)). The applicable integrated plan must make reasonable and diligent efforts to assist in gathering and forwarding information to the independent entity; and

(iii) For expedited integrated reconsiderations, the applicable integrated plan must prepare a written explanation and send the case file to the independent review entity contracted by CMS as expeditiously as the enrollee's health condition requires, but no later than within 24 hours of its affirmation (or no later than the expiration of an extension described in § 422.633(f)(3)). The applicable integrated plan must make reasonable and diligent efforts to assist in gathering and forwarding information to the independent entity.

(2) When the applicable integrated plan affirms, in whole or in part, its adverse integrated organization determination involving a Medicaid benefit, the enrollee or other party (that is not the applicable integrated plan) may initiate a State fair hearing in the timeframe specified in § 438.408(f)(2) following the integrated plan's notice of resolution. If a provider is filing for a State fair hearing on behalf of the enrollee as permitted by State law, the provider needs the written consent of the enrollee, if he or she has not already obtained such consent.

(c) *Final determination.* The reconsidered determination of the applicable integrated plan is binding on all parties unless it is appealed to the next applicable level. In the event that the enrollee pursues the appeal in multiple forums and receives conflicting decisions, the applicable integrated plan is bound by, and must act in accordance with, decisions favorable to the enrollee.

(d) *Services not furnished while the appeal is pending.* (1) If an applicable integrated plan reverses its decision to deny, limit, or delay services that were not furnished while the appeal was pending, the applicable integrated plan must authorize or provide the disputed services promptly and as expeditiously as the enrollee's health condition requires but no later than the earlier of—

(i) 72 hours from the date it reverses its decision; or

(ii)(A) With the exception of a Part B drug, 30 calendar days after the date the applicable integrated plan receives the request for the integrated reconsideration (or no later than upon expiration of an extension described in § 422.633(f)); or

(B) For a Part B drug, 7 calendar days after the date the applicable integrated plan receives the request for the integrated reconsideration.

(2) For a Medicaid benefit, if a State fair hearing officer reverses an applicable integrated plan's integrated reconsideration decision to deny, limit, or delay services that were not furnished while the appeal was pending, the applicable integrated plan must authorize or provide the disputed services promptly and as expeditiously as the enrollee's health condition requires but no later than 72 hours from the date it receives notice reversing the determination.

(3) Reversals by the Part C independent review entity, an administrative law judge or attorney adjudicator at the Office of Medicare Hearings and Appeals, or the Medicare Appeals Council must be effectuated under same timelines applicable to other MA plans as specified in §§ 422.618 and 422.619.

(e) *Services furnished while the appeal is pending.* If the applicable integrated plan or the State fair hearing officer reverses a decision to deny, limit, or delay Medicaid-covered benefits, and the enrollee received the disputed services while the integrated reconsideration was pending, the applicable integrated plan or the State must pay for those services, in accordance with State policy and regulations. If the applicable integrated plan reverses a decision to deny, limit, or delay Medicare-covered benefits, and the enrollee received the disputed services while the integrated reconsideration was pending, the applicable integrated plan must pay for those services.

[63 FR 35107, June 26, 1998, as amended at 87 FR 27898, May 9, 2022]

Subpart N—Medicare Contract Determinations and Appeals

SOURCE: 63 FR 35113, June 26, 1998, unless otherwise noted.

§ 422.641 Contract determinations.

This subpart establishes the procedures for making and reviewing the following contract determinations:

(a) A determination that an entity is not qualified to enter into a contract with CMS under Part C of title XVIII of the Act.

(b) A determination not to authorize a renewal of a contract with an MA organization in accordance with § 422.506(b).

(c) A determination to terminate a contract with an MA organization in accordance with § 422.510(a).

(d) A determination that an entity is not qualified to offer a Specialized MA Plan for Special Needs Individuals as defined in §§ 422.2 and 422.4(a)(1)(iv).

[63 FR 35113, June 26, 1998, as amended at 77 FR 22168, Apr. 12, 2012; 80 FR 7962, Feb. 12, 2015]

§ 422.644 Notice of contract determination.

(a) When CMS makes a contract determination under § 422.641, it gives the MA organization written notice.

(b) The notice specifies—

(1) Reasons for the determination; and

(2) The MA organization's right to request a hearing.

(c) *CMS-initiated terminations*—(1) *General rule.* Except as provided in paragraph (c)(2) of this section, CMS mails notice to the MA organization 45 calendar days before the anticipated effective date of the termination.

(2) *Exception.* If a contract is terminated in accordance with § 422.510(b)(2)(i) of this part, CMS notifies the MA organization of the date that it will terminate the MA organization's contract.

(d) When CMS determines that it will not authorize a contract renewal, CMS

mails the notice to the MA organization by August 1 of the current contract year.

[63 FR 35113, June 26, 1998, as amended at 72 FR 68724, Dec. 5, 2007; 75 FR 19813, Apr. 15, 2010; 80 FR 7962, Feb. 12, 2015]

§ 422.646 Effect of contract determination.

The contract determination is final and binding unless a timely request for a hearing is filed under 422.662.

[72 FR 68724, Dec. 5, 2007]

§ 422.660 Right to a hearing, burden of proof, standard of proof, and standards of review.

(a) *Right to a hearing.* The following parties are entitled to a hearing:

(1) A contract applicant that has been determined to be unqualified to enter into a contract with CMS under Part C of Title XVIII of the Act in accordance with §§ 422.501 and 422.502.

(2) An MA organization whose contract has been terminated in accordance with § 422.510.

(3) An MA organization whose contract has not been renewed in accordance with § 422.506.

(4) An MA organization who has had an intermediate sanction imposed in accordance with § 422.752(a) through (b) of this part.

(5) An applicant that has been determined to be unqualified to offer a Specialized MA Plan for Special Needs Individuals.

(b) *Burden of proof, standard of proof, and standards of review at a hearing.* (1) During a hearing to review a contract determination as described at § 422.641(a) of this subpart, the applicant has the burden of proving by a preponderance of the evidence that CMS' determination was inconsistent with the requirements of §§ 422.501 and 422.502 of this part.

(2) During a hearing to review a contract determination as described at § 422.641(b) of this subpart, the MA organization has the burden of proving by a preponderance of the evidence that CMS' determination was inconsistent with the requirements of § 422.506 of this part.

(3) During a hearing to review a contract determination as described at § 422.641(c) of this subpart, the MA organization has the burden of proving by a preponderance of the evidence that CMS' determination was inconsistent with the requirements of § 422.510 of this part.

(4) During a hearing to review the imposition of an intermediate sanction as described at § 422.750, the MA organization has the burden of proving by a preponderance of the evidence that CMS' determination was inconsistent with the requirements of § 422.752(a) and (b).

(5) During a hearing to review a determination as described at § 422.641(d) of this subpart, the applicant has the burden of proving by a preponderance of the evidence that CMS' determination was inconsistent with the requirements of §§ 422.2; 422.4(a)(1)(iv); 422.101(f); 422.107, if applicable; and 422.152(g) of this part.

(c) *Timing of favorable decisions.* Notice of any decision favorable to the MA organization appealing a determination that it is not qualified to enter into a contract with CMS must be issued by September 1 for the contract in question to be effective on January 1 of the following year.

[75 FR 19813, Apr. 15, 2010, as amended at 77 FR 22168, Apr. 12, 2012; 80 FR 7962, Feb. 12, 2015]

§ 422.662 Request for hearing.

(a) *Method and place for filing a request.* (1) A request for a hearing must be made in writing and filed by an authorized official of the contract applicant or MA organization that was the party to the determination under the appeal.

(2) The request for the hearing must be filed in accordance with the requirements specified in the notice.

(b) *Time for filing a request.* A request for a hearing must be filed within 15 calendar days after the receipt of the notice of the contract determination or intermediate sanction.

(c) *Parties to a hearing.* The parties to a hearing must be—

(1) The parties described in § 422.660;

(2) At the discretion of the hearing officer, any interested parties who make a showing that their rights may be prejudiced by the decision to be rendered at the hearing; and

(3) CMS.

[63 FR 35113, June 26, 1998, as amended at 65 FR 40332, June 29, 2000; 72 FR 68724, Dec. 5, 2007; 75 FR 19813, Apr. 15, 2010]

§ 422.664 Postponement of effective date of a contract determination when a request for a hearing is filed timely.

(a) *Hearing.* When a request for a hearing is timely filed, CMS will postpone the proposed effective date of the contract determination listed at 422.641 until a hearing decision is reached and affirmed by the Administrator following review according to 422.692 in instances where an MA organization or CMS requests Administrator review and the Administrator accepts the matter for review.

(b) *Exceptions:* (1) If a final decision is not reached on CMS' determination for an initial contract by September 1, CMS will not enter into a contract with the applicant for the following year.

(2) A contract terminated in accordance with § 422.510(b)(2)(i) of this part will be terminated on the date specified by CMS and will not be postponed if a hearing is requested.

[72 FR 68724, Dec. 5, 2007, as amended at 75 FR 19813, Apr. 15, 2010; 83 FR 16734, Apr. 16, 2018]

§ 422.666 Designation of hearing officer.

CMS designates a hearing officer to conduct the hearing. The hearing officer need not be an ALJ.

§ 422.668 Disqualification of hearing officer.

(a) A hearing officer may not conduct a hearing in a case in which he or she is prejudiced or partial to any party or has any interest in the matter pending for decision.

(b) A party to the hearing who objects to the designated hearing officer must notify that officer in writing at the earliest opportunity.

(c) The hearing officer must consider the objections, and may, at his or her discretion, either proceed with the hearing or withdraw.

(1) If the hearing officer withdraws, CMS designates another hearing officer to conduct the hearing.

(2) If the hearing officer does not withdraw, the objecting party may, after the hearing, present objections and request that the officer's decision be revised or a new hearing be held before another hearing officer. The objections must be submitted in writing to CMS.

§ 422.670 Time and place of hearing.

(a) The hearing officer—

(1) Fixes a time and place for the hearing, which is not to exceed 30 calendar days after the receipt of the request for the hearing; and

(2) Sends written notice to the parties that informs the parties of the general and specific issues to be resolved, the burden of proof, and information about the hearing procedure.

(b)(1) The hearing officer may, on his or her own motion, change the time and place of the hearing.

(2) The hearing officer may adjourn or postpone the hearing.

(c)(1) The MA organization or CMS may request an extension by filing a written request no later than 10 calendar days prior to the scheduled hearing.

(2) When either the MA organization or CMS requests an extension, the hearing officer will provide a one-time 15 calendar day extension.

(3) Additional extensions may be granted at the discretion of the hearing officer.

[75 FR 19813, Apr. 15, 2010]

§ 422.672 Appointment of representatives.

A party may appoint as its representative at the hearing anyone not disqualified or suspended from acting as a representative before the Secretary or otherwise prohibited by law.

§ 422.674 Authority of representatives.

(a) A representative appointed and qualified in accordance with § 422.672 may, on behalf of the represented party—

(1) Gives or accepts any notice or request pertinent to the proceedings set forth in this subpart;

(2) Presents evidence and allegations as to facts and law in any proceedings affecting that party; and

(3) Obtains information to the same extent as the party.

(b) A notice or request sent to the representative has the same force and effect as if it had been sent to the party.

§ 422.676 Conduct of hearing.

(a) The hearing is open to the parties and to the public.

(b) The hearing officer inquires fully into all the matters at issue and receives in evidence the testimony of witnesses and any documents that are relevant and material.

(c) The hearing officer provides the parties an opportunity to enter any objection to the inclusion of any document.

(d) The MA organization bears the burden of going forward and must first present evidence and argument before CMS presents its evidence and argument.

[63 FR 35113, June 26, 1998, as amended at 75 FR 19813, Apr. 15, 2010]

§ 422.678 Evidence.

The hearing officer rules on the admissibility of evidence and may admit evidence that would be inadmissible under rules applicable to court procedures.

§ 422.680 Witnesses.

(a) The hearing officer may examine the witnesses.

(b) The parties or their representatives are permitted to examine their witnesses and cross-examine witnesses of other parties.

§ 422.682 Witness lists and documents.

Witness lists and documents must be identified and exchanged at least 5 calendar days before the scheduled hearing.

[75 FR 19813, Apr. 15, 2010]

§ 422.684 Prehearing and summary judgment.

(a) *Prehearing.* The hearing officer may schedule a prehearing conference if he or she believes that a conference would more clearly define the issues.

(b) *Summary judgment.* Either party to the hearing may ask the hearing officer to rule on a motion for summary judgment.

[72 FR 68725, Dec. 5, 2007]

§ 422.686 Record of hearing.

(a) A complete record of the proceedings at the hearing is made and transcribed and made available to all parties upon request.

(b) The record may not be closed until a hearing decision has been issued.

§ 422.688 Authority of hearing officer.

In exercising his or her authority, the hearing officer must comply with the provisions of title XVIII and related provisions of the Act, the regulations issued by the Secretary, and general instructions issued by CMS in implementing the Act.

§ 422.690 Notice and effect of hearing decision.

(a) As soon as practical after the close of the hearing, the hearing officer issues a written decision that—

(1) Is based upon the evidence of record; and

(2) Contains separately numbered findings of fact and conclusions of law.

(b) The hearing officer provides a copy of the hearing decision to each party.

(c) The hearing decision is final and binding unless it is reversed or modified by the Administrator following review under § 422.692, or reopened and revised in accordance with § 422.696.

§ 422.692 Review by the Administrator.

(a) *Request for review by Administrator.* CMS or an MA organization that has received a hearing decision may request a review by the Administrator within 15 calendar days after receipt of the hearing decision as provided under § 422.690(b). Both the MA organization and CMS may provide written arguments to the Administrator for review.

(b) *Decision to review the hearing decision.* After receiving a request for review, the Administrator has the discretion to elect to review the hearing decision in accordance with paragraph (d) of this section or to decline to review the hearing decision.

(c) *Notification of Administrator determination.* The Administrator notifies

both parties of his or her determination regarding review of the hearing decision within 30 calendar days after receipt of request for review. If the Administrator declines to review the hearing decision or the Administrator does not make a determination regarding review within 30 calendar days, the decision of the hearing officer is final.

(d) *Review by the Administrator.* If the Administrator elects to review the hearing decision regarding a contract determination, the Administrator shall review the hearing officer's decision and determine, based upon this decision, the hearing record, and any written arguments submitted by the MA organization or CMS, whether the determination should be upheld, reversed, or modified.

(e) *Decision by the Administrator.* The Administrator issues a written decision, and furnishes the decision to the MA organization requesting review.

[63 FR 35113, June 26, 1998, as amended at 72 FR 68725, Dec. 5, 2007; 75 FR 19813, Apr. 15, 2010]

§ 422.694 Effect of Administrator's decision.

A decision by the Administrator under section 422.692 is final and binding unless it is reopened and revised in accordance with § 422.696.

§ 422.696 Reopening of a contract determination or decision of a hearing officer or the Administrator.

(a) *Contract determination.* CMS may reopen and revise an initial determination upon its own motion.

(b) *Decision of hearing officer.* A decision of a hearing officer that is unfavorable to any party and is otherwise final may be reopened and revised by the hearing officer upon the officer's own motion within one year of the notice of the hearing decision. Another hearing officer designated by CMS may reopen and revise the decision if the hearing officer who issued the decision is unavailable.

(c) *Decision of Administrator.* A decision by the Administrator that is otherwise final may be reopened and revised by the Administrator upon the Administrator's own motion within one year of the notice of the Administrator's decision.

(d) *Notices.* (1) The notice of reopening and of any revisions following the reopening is mailed to the parties.

(2) The notice of revision specifies the reasons for revisions.

[63 FR 35113, June 26, 1998, as amended at 72 FR 68725, Dec. 5, 2007; 75 FR 19814, Apr. 15, 2010]

Subpart O—Intermediate Sanctions

SOURCE: 63 FR 35115, June 26, 1998, unless otherwise noted.

§ 422.750 Types of intermediate sanctions and civil money penalties.

(a) The following intermediate sanctions may be imposed and will continue in effect until CMS is satisfied that the deficiencies that are the basis for the sanction determination have been corrected and are not likely to recur:

(1) Suspension of the MA organization's enrollment of Medicare beneficiaries.

(2) Suspension of payment to the MA organization for Medicare beneficiaries enrolled after the date CMS notifies the organization of the intermediate sanction.

(3) Suspension of communication activities to Medicare beneficiaries by an MA organization, as defined by CMS.

(b) CMS may impose civil money penalties as specified in 422.760.

[72 FR 68725, Dec. 5, 2007, as amended at 75 FR 19814, Apr. 15, 2010; 83 FR 16734, Apr. 16, 2018]

§ 422.752 Basis for imposing intermediate sanctions and civil money penalties.

(a) *All intermediate sanctions.* For the violations listed in this paragraph, CMS may impose one or more of the sanctions specified in § 422.750(a) of this subpart on any MA organization with a contract. The MA organization may also be subject to other remedies authorized under law.

(1) Fails substantially to provide medically necessary items and services that are required (under law or under the contract) to be provided to an individual covered under the contract, if the failure has adversely affected (or

has the substantial likelihood of adversely affecting) the individual.

(2) Imposes on MA enrollees premiums in excess of the monthly basic and supplemental beneficiary premiums permitted under section 1854 of the Act and subpart F of this part.

(3) Acts to expel or refuses to re-enroll a beneficiary in violation of the provisions of this part.

(4) Engages in any practice that would reasonably be expected to have the effect of denying or discouraging enrollment (except as permitted by this part) by eligible individuals with the organization whose medical condition or history indicates a need for substantial future medical services.

(5) Misrepresents or falsifies information that it furnishes—

(i) To CMS; or

(ii) To an individual or to any other entity.

(6) Fails to comply with the requirements of § 422.206, which prohibits interference with practitioners' advice to enrollees.

(7) Fails to comply with § 422.216, which requires the organization to enforce the limit on balance billing under a private fee-for service plan.

(8) Employs or contracts with an individual or entity who is excluded from participation in Medicare under section 1128 or 1128A of the Act (or with an entity that employs or contracts with such an excluded individual or entity) for the provision of any of the following:

(i) Health care.

(ii) Utilization review.

(iii) Medical social work.

(iv) Administrative services.

(9) Except as provided under § 423.34 of this chapter, enrolls an individual in any plan under this part without the prior consent of the individual or the designee of the individual.

(10) Transfers an individual enrolled under this part from one plan to another without the prior consent of the individual or the designee of the individual or solely for the purpose of earning a commission.

(11) Fails to comply with communication restrictions described in subpart V of this part or applicable implementing guidance.

(12) Employs or contracts with any individual, agent, provider, supplier or entity who engages in the conduct described in paragraphs (a)(1) through (11) of this section.

(13) Fails to comply with §§ 422.222 and 422.224, that requires the MA organization not to make payment to excluded individuals and entities, nor to individuals and entities on the preclusion list, defined in § 422.2.

(b) *Suspension of enrollment and communications.* If CMS makes a determination that could lead to a contract termination under § 422.510(a), CMS may impose the intermediate sanctions at § 422.750(a)(1) and (3).

(c) *Civil Money Penalties.* (1) *CMS.* In addition to, or in place of, any intermediate sanctions, CMS may impose civil money penalties in the amounts specified in the following:

(i) Section 422.760(b) for any of the determinations at § 422.510(a), except § 422.510(a)(4)(i).

(ii) Section 422.760(c) for any of the determinations at § 422.752(a) except § 422.752(a)(5).

(2) *OIG.* In addition to, or in place of any intermediate sanctions imposed by CMS, the OIG, in accordance with part 1003 of Chapter V of this title, may impose civil money penalties for the following:

(i) Violations listed at 422.752(a).

(ii) Determinations made under § 422.510(a)(4)(i).

(d) *Special rule for non-compliant dual eligible special needs plans.* Notwithstanding any other provision of this section, CMS must impose during plan years 2021 through 2025 intermediate sanctions specified at § 422.750(a) on an MA organization with a contract to operate a dual eligible special needs plan if CMS determines that the dual eligible special needs plan fails to comply with at least one of the criteria for the integration of Medicare and Medicaid benefits provided in the definition of a dual eligible special needs plan at § 422.2. If CMS imposes such an intermediate sanction, the MA organization must submit to CMS a corrective action plan in a form, manner, and timeframe established by CMS. The procedures outlined in § 422.756 apply to the

imposition of the intermediate sanction under this provision.

[63 FR 35115, June 26, 1998; 63 FR 52614, Oct. 1, 1998, as amended at 69 FR 78338, Dec. 30, 2004; 70 FR 4741, Jan. 28, 2005; 70 FR 52027, Sept. 1, 2005; 72 FR 68725, Dec. 5, 2007; 75 FR 19814, Apr. 15, 2010; 79 FR 29959, May 23, 2014; 81 FR 80557, Nov. 15, 2016; 83 FR 16734, Apr. 16, 2018; 84 FR 15839, April 16, 2019]

§ 422.756 Procedures for imposing intermediate sanctions and civil money penalties.

(a) *Notice of intermediate sanction and opportunity to respond*—(1) *Notice of intent.* Before imposing the intermediate sanction, CMS—

(i) Sends a written notice to the MA organization stating the nature and basis of the proposed intermediate sanction and the MA organization's right to a hearing as specified in paragraph (b) of this section; and

(ii) Sends the OIG a copy of the notice.

(2) *Opportunity to respond.* CMS allows the MA organization 10 calendar days after receipt of the notice to provide a written rebuttal. CMS considers receipt of the notice as the day after notice is sent by fax, e-mail, or submitted for overnight mail.

(b) *Hearing.* (1) The MA organization may request a hearing before a CMS hearing officer.

(2) A written request must be received by the designated CMS office within 15 calendar days after the receipt of the notice.

(3) A request for a hearing under § 422.660 does not delay the date specified by CMS when the sanction becomes effective.

(4) The MA organization must follow the right to a hearing procedure as specified at subpart N of this part..

(c) *Effective date and duration of sanctions*—(1) *Effective date.* The effective date of the sanction is the date specified by CMS in the notice.

(2) *Exception.* If CMS determines that the MA organization's conduct poses a serious threat to an enrollee's health and safety, CMS may make the sanction effective on an earlier date that CMS specifies.

(3) *Duration of sanction.* The sanction remains in effect until CMS is satisfied that the deficiencies that are the basis for the sanction determination have been corrected and are not likely to recur.

(i) CMS may require that the MA organization hire an independent auditor to provide CMS with additional information to determine if the deficiencies that are the basis for the sanction determination have been corrected and are not likely to recur. The independent auditor must work in accordance with CMS specifications and must be willing to attest that a complete and full independent review has been performed.

(ii) In instances where intermediate sanctions have been imposed, CMS may require an MA organization to market or to accept enrollments or both for a limited period of time in order to assist CMS in making a determination as to whether the deficiencies that are the bases for the intermediate sanctions have been corrected and are not likely to recur.

(A) If, following this time period, CMS determines the deficiencies have not been corrected or are likely to recur, the intermediate sanctions will remain in effect until such time that CMS is assured the deficiencies have been corrected and are not likely to recur.

(B) The MA organization does not have a right to a hearing under § 422.660(a)(4) of this part to challenge CMS' determination to keep the intermediate sanctions in effect.

(C) During the limited time period, sanctioned sponsoring organizations offering Part D plans under the benchmark that would normally participate in the annual and monthly auto enrollment process for enrollees receiving the low income subsidy will not be allowed to receive or process these types of enrollments.

(d) *Non-renewal or termination by CMS.* In addition to or as an alternative to the sanctions described in § 422.750, CMS may—

(1) Decline to authorize the renewal of an organization's contract in accordance with § 422.506(b); or

(2) Terminate the contract in accordance with § 422.510.

(e) Notice to impose *civil money penalties*—(1) *CMS notice to OIG.* If CMS determines that an MA organization has failed to comply with a requirement as

described in 422.752, CMS notifies the OIG of this determination. OIG may impose a civil money penalty upon an MA organization as specified at 422.752(c)(2).

(2) *CMS notice of civil money penalties to MA organizations.* If CMS makes a determination to impose a CMP as described in 422.752(c)(1), CMS will send a written notice of the Agency's decision to impose a civil money penalty to include—

(i) A description of the basis for the determination.

(ii) The basis for the penalty.

(iii) The amount of the penalty.

(iv) The date the penalty is due.

(v) The MA organization's right to a hearing under subpart T of this part.

(vi) Information about where to file the request for hearing.

[63 FR 35113, June 26, 1998, as amended at 68 FR 50859, Aug. 22, 2003; 70 FR 4741, Jan. 28, 2005; 72 FR 68725, Dec. 5, 2007; 73 FR 55764, Sept. 26, 2008; 75 FR 19814, Apr. 15, 2010; 79 FR 29959, May 23, 2014]

§ 422.758 Collection of civil money penalties imposed by CMS.

(a) When an MA organization does not request a hearing, CMS initiates collection of the civil money penalty following the expiration of the timeframe for requesting an ALJ hearing as specified in subpart T of this part.

(b) If an MA organization requests a hearing and CMS' decision to impose a civil money penalty is upheld, CMS may initiate collection of the civil money penalty once the administrative decision is final.

[72 FR 68726, Dec. 5, 2007]

§ 422.760 Determinations regarding the amount of civil money penalties and assessment imposed by CMS.

(a) *Determining the appropriate amount of any penalty.* In determining the amount of penalty imposed under 422.752(c)(1), CMS will consider as appropriate:

(1) The nature of the conduct;

(2) The degree of culpability of the MA organization;

(3) The adverse effect to enrollees which resulted or could have resulted from the conduct of MA organization;

(4) The financial condition of the MA organization;

(5) The history of prior offenses by the MA organization or principals of the MA organization; and,

(6) Such other matters as justice may require.

(b) *Amount of penalty imposed by CMS.* CMS may impose civil money penalties in the following amounts:

(1) If the deficiency on which the determination is based has directly adversely affected (or has the substantial likelihood of adversely affecting) one or more MA enrollees—up to $25,000 as adjusted annually under 45 CFR part 102 for each determination.

(2) If the deficiency on which the determination is based has directly adversely affected (or has the substantial likelihood of adversely affecting) one or more MA enrollees, CMS may calculate a CMP of up to $25,000 as adjusted annually under 45 CFR part 102 for each MA enrollee directly adversely affected (or with the substantial likelihood of being adversely affected) by a deficiency.

(3)(i) *Definitions for calculating penalty amounts*—(A) *Per determination.* The penalty amounts calculated under paragraph (b)(1) of this section.

(B) *Per enrollee.* The penalty amounts calculated under paragraph (b)(2) of this section.

(C) *Standard minimum penalty.* The per enrollee or per determination penalty amount that is dependent on the type of adverse impact that occurred.

(D) *Aggravating factor(s).* Specific penalty amounts that may increase the per enrollee or per determination standard minimum penalty and are determined based on criteria under paragraph (a) of this section.

(ii) CMS sets minimum penalty amounts in accordance with paragraphs (b)(1) and (2) of this section.

(iii) CMS announces the standard minimum penalty amounts and aggravating factor amounts for per determination and per enrollee penalties on an annual basis.

(iv) CMS has the discretion to issue penalties up to the maximum amount under paragraphs (b)(1) and (2) of this section when CMS determines that an organization's non-compliance warrants a penalty that is higher than would be applied under the minimum penalty amounts set by CMS.

(4) For each week that a deficiency remains uncorrected after the week in which the MA organization receives CMS' notice of the determination—up to $10,000 as adjusted annually under 45 CFR part 102.

(5) If CMS makes a determination that a MA organization has terminated its contract other than in a manner described under 422.512 and that the MA organization has therefore failed to substantially carry out the terms of the contract—$250 as adjusted annually under 45 CFR part 102 per Medicare enrollee from the terminated MA plan or plans at the time the MA organization terminated its contract, or $100,000 as adjusted annually under 45 CFR part 102, whichever is greater.

(c) *Amount of penalty imposed by CMS or OIG.* CMS or the OIG may impose civil money penalties in the following amounts for a determination made under § 422.752(a):

(1) Civil money penalties of not more than $25,000 as adjusted annually under 45 CFR part 102 for each determination made.

(2) With respect to a determination made under § 422.752(a)(4) or (a)(5)(i), not more than $100,000 as adjusted annually under 45 CFR part 102 foreach such determination, except with respect to a determination made under § 422.752(a)(5), an assessment of not more than the amount claimed by such plan or MA organization based upon the misrepresentation or falsified information involved.

(3) Plus with respect to a determination made under § 422.752(a)(2), double the excess amount charged in violation of such paragraph (and the excess amount charged must be deducted from the penalty and returned to the individual concerned).

(4) Plus with respect to a determination made under § 422.752(a)(4), $15,000 as adjusted annually under 45 CFR part 102 for each individual not enrolled as a result of the practice involved.

[72 FR 68726, Dec. 5, 2007, as amended at 74 FR 1542, Jan. 12, 2009; 79 FR 29960, May 23, 2014; 81 FR 61562, Sept. 8, 2016; 86 FR 6103, Jan. 19, 2021; 86 FR 29528, June 2, 2021; 89 FR 30827, Apr. 23, 2024]

§ 422.762 Settlement of penalties.

For civil money penalties imposed by CMS, CMS may settle civil money penalty cases at any time before a final decision is rendered.

[72 FR 68726, Dec. 5, 2007]

§ 422.764 Other applicable provisions.

The provisions of section 1128A of the Act (except subsections (a) and (b)) apply to civil money penalties under this subpart to the same extent that they apply to a civil money penalty or procedure under section 1128A of the Act.

[63 FR 35115, June 26, 1998. Redesignated at 72 FR 68726, Dec. 5, 2007]

Subparts P–S [Reserved]

Subpart T—Appeal procedures for Civil Money Penalties

SOURCE: 72 FR 68726, Dec. 5, 2007, unless otherwise noted.

§ 422.1000 Basis and scope.

(a) *Statutory basis.* (1) Section 1128A(c)(2) of the Act provides that the Secretary may not collect a civil money penalty until the affected party has had notice and opportunity for a hearing.

(2) Section 1857(g) of the Act provides that, for MA organizations out of compliance with the requirements in part 422 specified remedies may be imposed instead of, or in addition to, termination of the MA organization's contract. Section 1857(g)(4) of the Act makes certain provisions of section 1128A of the Act applicable to civil money penalties imposed on MA organizations.

(b) [Reserved]

§ 422.1002 Definitions.

As used in this subpart—

Affected party means an MA organization impacted by an initial determination or if applicable, by any subsequent determination or decision issued under this part. For this definition, ''*party*'' means the affected party or CMS, as appropriate.

ALJ stands for Administrative Law Judge.

Departmental Appeals Board or Board means a Board established in the Office of the Secretary to provide impartial review of disputed decisions made by the operating components of the Department.

MA organization has the meaning given the term in 422.2.

§ 422.1004 Scope and applicability.

(a) *Scope.* This subpart sets forth procedures for reviewing initial determinations that CMS makes with respect to the matters specified in paragraph (b) of this section.

(b) *Initial determinations by CMS.* CMS makes initial determinations with respect to the imposition of civil money penalties in accordance with part 422, subpart O.

§ 422.1006 Appeal rights.

(a) *Appeal rights of MA organizations.* (1) Any MA organization dissatisfied with an initial determination as specified in 422.1004, has a right to a hearing before an ALJ in accordance with this subpart and may request Departmental Appeals Board review of the ALJ decision.

(2) MA organizations may request judicial review of the Departmental Appeals Board's decision that imposes a CMP.

(b) [Reserved]

§ 422.1008 Appointment of representatives.

(a) An affected party may appoint as its representative anyone not disqualified or suspended from acting as a representative in proceedings before the Secretary or otherwise prohibited by law.

(b) If the representative appointed is not an attorney, the party must file written notice of the appointment with the ALJ or the Departmental Appeals Board.

(c) If the representative appointed is an attorney, the attorney's statement that he or she has the authority to represent the party is sufficient.

§ 422.1010 Authority of representatives.

(a) A representative appointed and qualified in accordance with 422.1008 may, on behalf of the represented party—

(1) Give and accept any notice or request pertinent to the proceedings set forth in this part;

(2) Present evidence and allegations as to facts and law in any proceedings affecting that party to the same extent as the party; and

(3) Obtain information to the same extent as the party.

(b) A notice or request may be sent to the affected party, to the party's representative, or to both. A notice or request sent to the representative has the same force and effect as if it had been sent to the party.

§ 422.1012 Fees for services of representatives.

Fees for any services performed on behalf of an affected party by an attorney appointed and qualified in accordance with 422.1008 are not subject to the provisions of section 206 of Title II of the Act, which authorizes the Secretary to specify or limit those fees.

§ 422.1014 Charge for transcripts.

A party that requests a transcript of prehearing or hearing proceedings or Board review must pay the actual or estimated cost of preparing the transcript unless, for good cause shown by that party, the payment is waived by the ALJ or the Departmental Appeals Board, as appropriate.

§ 422.1016 Filing of briefs with the Administrative Law Judge or Departmental Appeals Board, and opportunity for rebuttal.

(a) *Filing of briefs and related documents.* If a party files a brief or related document such as a written argument, contention, suggested finding of fact, conclusion of law, or any other written statement, it must submit an original and 1 copy to the ALJ or the Departmental Appeals Board, as appropriate. The material may be filed by mail or in person and must include a statement certifying that a copy has been furnished to the other party.

(b) *Opportunity for rebuttal.* (1) The other party will have 20 calendar days from the date of mailing or in person filing to submit any rebuttal statement or additional evidence. If a party

submits a rebuttal statement or additional evidence, it must file an original and 1 copy with the ALJ or the Board and furnish a copy to the other party.

(2) The ALJ or the Board will grant an opportunity to reply to the rebuttal statement only if the party shows good cause.

[72 FR 68726, Dec. 5, 2007, as amended at 79 FR 29960, May 23, 2014]

§ 422.1018 Notice and effect of initial determinations.

(a) *Notice of initial determination.* CMS, as required under 422.756(f)(2), mails notice of an initial determination to the affected party, setting forth the basis or reasons for the determination, the effect of the determination, and the party's right to a hearing, and information about where to file the request for hearing.

(b) *Effect of initial determination.* An initial determination is binding unless—

(1) The affected party requests a hearing; or

(2) CMS revises its decision.

§ 422.1020 Request for hearing.

(a) *Manner and timing of request.* (1) An MA organization is entitled to a hearing as specified in 422.1006 and may file a request for a hearing with the Departmental Appeals Board office specified in the initial determination.

(2) The MA organization or its legal representative or other authorized official must file the request, in writing, to the appropriate Departmental Appeals Board office, with a copy to CMS, within 60 calendar days after receipt of the notice of initial determination, to request a hearing before an ALJ to appeal any determination by CMS to impose a civil money penalty.

(b) *Content of request for hearing.* The request for hearing must—

(1) Identify the specific issues, and the findings of fact and conclusions of law with which the affected party disagrees; and

(2) Specify the basis for each contention that the finding or conclusion of law is incorrect.

[72 FR 68726, Dec. 5, 2007, as amended at 79 FR 29960, May 23, 2014]

§ 422.1022 Parties to the hearing.

The parties to the hearing are the affected party and CMS, as appropriate.

§ 422.1024 Designation of hearing official.

(a) The Chair of the Departmental Appeals Board, or his or her delegate designates an ALJ or a member or members of the Departmental Appeals Board to conduct the hearing.

(b) If appropriate, the Chair or the delegate may substitute another ALJ or another member or other members of the Departmental Appeals Board to conduct the hearing.

(c) As used in this part, ''ALJ'' includes a member or members of the Departmental Appeals Board who are designated to conduct a hearing.

§ 422.1026 Disqualification of Administrative Law Judge.

(a) An ALJ may not conduct a hearing in a case in which he or she is prejudiced or partial to the affected party or has any interest in the matter pending for decision.

(b) A party that objects to the ALJ designated to conduct the hearing must give notice of its objections at the earliest opportunity.

(c) The ALJ will consider the objections and decide whether to withdraw or proceed with the hearing.

(1) If the ALJ withdraws, another ALJ will be designated to conduct the hearing.

(2) If the ALJ does not withdraw, the objecting party may, after the hearing, present its objections to the Departmental Appeals Board as reasons for changing, modifying, or reversing the ALJ's decision or providing a new hearing before another ALJ.

§ 422.1028 Prehearing conference.

(a) At any time before the hearing, the ALJ may call a prehearing conference for the purpose of delineating the issues in controversy, identifying the evidence and witnesses to be presented at the hearing, and obtaining stipulations accordingly.

(b) On the request of either party or on his or her own motion, the ALJ may adjourn the prehearing conference and reconvene at a later date.

§ 422.1030 Notice of prehearing conference.

(a) *Timing of notice.* The ALJ will fix a time and place for the prehearing conference and mail written notice to the parties at least 10 calendar days before the scheduled date.

(b) *Content of notice.* The notice will inform the parties of the purpose of the conference and specify what issues are sought to be resolved, agreed to, or excluded.

(c) *Additional issues.* Issues other than those set forth in the notice of determination or the request for hearing may be considered at the prehearing conference if—

(1) Either party gives timely notice to that effect to the ALJ and the other party; or

(2) The ALJ raises the issues in the notice of prehearing conference or at the conference.

§ 422.1032 Conduct of prehearing conference.

(a) The prehearing conference is open to the affected party or its representative, to the CMS representatives and their technical advisors, and to any other persons whose presence the ALJ considers necessary or proper.

(b) The ALJ may accept the agreement of the parties as to the following:

(1) Facts that are not in controversy.

(2) Questions that have been resolved favorably to the affected party after the determination in dispute.

(3) Remaining issues to be resolved.

(c) The ALJ may request the parties to indicate the following:

(1) The witnesses that will be present to testify at the hearing.

(2) The qualifications of those witnesses.

(3) The nature of other evidence to be submitted.

§ 422.1034 Record, order, and effect of prehearing conference.

(a) *Record of prehearing conference.* (1) A record is made of all agreements and stipulations entered into at the prehearing conference.

(2) The record may be transcribed at the request of either party or the ALJ.

(b) *Order and opportunity to object.* (1) The ALJ issues an order setting forth the results of the prehearing conference, including the agreements made by the parties as to facts not in controversy, the matters to be considered at the hearing, and the issues to be resolved.

(2) Copies of the order are sent to all parties and the parties have 10 calendar days to file objections to the order.

(3) After the 10 calendar days have elapsed, the ALJ settles the order.

(c) *Effect of prehearing conference.* The agreements and stipulations entered into at the prehearing conference are binding on all parties, unless a party presents facts that, in the opinion of the ALJ, would make an agreement unreasonable or inequitable.

§ 422.1036 Time and place of hearing.

(a) The ALJ fixes a time and place for the hearing and gives the parties written notice at least 10 calendar days before the scheduled date.

(b) The notice informs the parties of the general and specific issues to be resolved at the hearing.

§ 422.1038 Change in time and place of hearing.

(a) The ALJ may change the time and place for the hearing either on his or her own initiative or at the request of a party for good cause shown, or may adjourn or postpone the hearing.

(b) The ALJ may reopen the hearing for receipt of new evidence at any time before mailing the notice of hearing decision.

(c) The ALJ gives the parties reasonable notice of any change in time or place or any adjournment or reopening of the hearing.

§ 422.1040 Joint hearings.

When two or more affected parties have requested hearings and the same or substantially similar matters are at issue, the ALJ may, if all parties agree, fix a single time and place for the prehearing conference or hearing and conduct all proceedings jointly. If joint hearings are held, a single record of the proceedings is made and a separate decision issued with respect to each affected party.

§ 422.1042 Hearing on new issues.

(a) *Basic rules.* (1) Within the time limits specified in paragraph (b) of this

section, the ALJ may, at the request of either party, or on his or her own motion, provide a hearing on new issues that impinge on the rights of the affected party.

(2) The ALJ may consider new issues even if CMS has not made initial determinations on them, and even if they arose after the request for hearing was filed or after a prehearing conference.

(3) The ALJ may give notice of hearing on new issues at any time after the hearing request is filed and before the hearing record is closed.

(b) *Notice and conduct of hearing on new issues.* (1) Unless the affected party waives its right to appear and present evidence, notice of the time and place of hearing on any new issue will be given to the parties in accordance with 422.1036.

(2) After giving notice, the ALJ will, except as provided in paragraph (c) of this section, proceed to hearing on new issues in the same manner as on an issue raised in the request for hearing.

(c) *Remand to CMS.* At the request of either party, or on his or her own motion, in lieu of a hearing under paragraph (b) of this section, the ALJ may remand the case to CMS for consideration of the new issue and, if appropriate, a determination. If necessary, the ALJ may direct CMS to return the case to the ALJ for further proceedings.

§ 422.1044 Subpoenas.

(a) *Basis for issuance.* The ALJ, upon his or her own motion or at the request of a party, may issue subpoenas if they are reasonably necessary for the full presentation of a case.

(b) *Timing of request by a party.* The party must file a written request for a subpoena with the ALJ at least 5 calendar days before the date set for the hearing.

(c) *Content of request.* The request must:

(1) Identify the witnesses or documents to be produced;

(2) Describe their addresses or location with sufficient particularity to permit them to be found; and

(3) Specify the pertinent facts the party expects to establish by the witnesses or documents, and indicate why those facts could not be established without use of a subpoena.

(d) *Method of issuance.* Subpoenas are issued in the name of the Secretary.

§ 422.1046 Conduct of hearing.

(a) *Participants in the hearing.* The hearing is open to the parties and their representatives and technical advisors, and to any other persons whose presence the ALJ considers necessary or proper.

(b) *Hearing procedures.* (1) The ALJ inquires fully into all of the matters at issue, and receives in evidence the testimony of witnesses and any documents that are relevant and material.

(2) If the ALJ believes that there is relevant and material evidence available which has not been presented at the hearing, he may, at any time before mailing of notice of the decision, reopen the hearing to receive that evidence.

(3) The ALJ decides the order in which the evidence and the arguments of the parties are presented and the conduct of the hearing.

(4) CMS has the burden of coming forward with evidence related to disputed findings that is sufficient (together with any undisputed findings and legal authority) to establish a prima facie case that CMS has a legally sufficient basis for its determination.

(5) The affected party has the burden of coming forward with evidence sufficient to establish the elements of any affirmative argument or defense which it offers.

(6) The affected party bears the ultimate burden of persuasion. To prevail, the affected party must prove by a preponderance of the evidence on the record as a whole that there is no basis for the determination.

(c) *Review of the penalty.* When an administrative law judge finds that the basis for imposing a civil money penalty exists, as specified in 422.752, the administrative law judge may not—

(1) Set a penalty of zero or reduce a penalty to zero, or

(2) Review the exercise of discretion by CMS to impose a civil money penalty.

§ 422.1048 Evidence.

Evidence may be received at the hearing even though inadmissible under the rules of evidence applicable to court procedure. The ALJ rules on the admissibility of evidence.

§ 422.1050 Witnesses.

Witnesses at the hearing testify under oath or affirmation. The representative of each party is permitted to examine his or her own witnesses subject to interrogation by the representative of the other party. The ALJ may ask any questions that he or she deems necessary. The ALJ rules upon any objection made by either party as to the propriety of any question.

§ 422.1052 Oral and written summation.

The parties to a hearing are allowed a reasonable time to present oral summation and to file briefs or other written statements of proposed findings of fact and conclusions of law. Copies of any briefs or other written statements must be sent in accordance with 422.1016.

§ 422.1054 Record of hearing.

A complete record of the proceedings at the hearing is made and transcribed in all cases.

§ 422.1056 Waiver of right to appear and present evidence.

(a) *Waiver procedures.* (1) If an affected party wishes to waive its right to appear and present evidence at the hearing, it must file a written waiver with the ALJ.

(2) If the affected party wishes to withdraw a waiver, it may do so, for good cause, at any time before the ALJ mails notice of the hearing decision.

(b) *Effect of waiver.* If the affected party waives the right to appear and present evidence, the ALJ need not conduct an oral hearing except in one of the following circumstances:

(1) The ALJ believes that the testimony of the affected party or its representatives or other witnesses is necessary to clarify the facts at issue.

(2) CMS shows good cause for requiring the presentation of oral evidence.

(c) *Dismissal for failure to appear.* If, despite the waiver, the ALJ sends notice of hearing and the affected party fails to appear, or to show good cause for the failure, the ALJ will dismiss the appeal in accordance with 422.1060.

(d) *Hearing without oral testimony.* When there is no oral testimony, the ALJ will—

(1) Make a record of the relevant written evidence that was considered in making the determination being appealed, and of any additional evidence submitted by the parties;

(2) Furnish to each party copies of the additional evidence submitted by the other party; and

(3) Give both parties a reasonable opportunity for rebuttal.

(e) Handling of briefs and related statements. If the parties submit briefs or other written statements of evidence or proposed findings of facts or conclusions of law, those documents will be handled in accordance with 422.1016.

§ 422.1058 Dismissal of request for hearing.

(a) The ALJ may, at any time before mailing the notice of the decision, dismiss a hearing request if a party withdraws its request for a hearing or the affected party asks that its request be dismissed.

(b) An affected party may request a dismissal by filing a written notice with the ALJ.

§ 422.1060 Dismissal for abandonment.

(a) The ALJ may dismiss a request for hearing if it is abandoned by the party that requested it.

(b) The ALJ may consider a request for hearing to be abandoned if the party or its representative—

(1) Fails to appear at the prehearing conference or hearing without having previously shown good cause for not appearing; and

(2) Fails to respond, within 10 calendar days after the ALJ sends a ''show cause'' notice, with a showing of good cause.

§ 422.1062 Dismissal for cause.

On his or her own motion, or on the motion of a party to the hearing, the

ALJ may dismiss a hearing request either entirely or as to any stated issue, under any of the following circumstances:

(a) *Res judicata.* There has been a previous determination or decision with respect to the rights of the same affected party on the same facts and law pertinent to the same issue or issues which has become final either by judicial affirmance or, without judicial consideration, because the affected party did not timely request reconsideration, hearing, or review, or commence a civil action with respect to that determination or decision.

(b) *No right to hearing.* The party requesting a hearing is not a proper party or does not otherwise have a right to a hearing.

(c) *Hearing request not timely filed.* The affected party did not file a hearing request timely and the time for filing has not been extended.

§ 422.1064 Notice and effect of dismissal and right to request review.

(a) Notice of the ALJ's dismissal action is mailed to the parties. The notice advises the affected party of its right to request that the dismissal be vacated as provided in 422.1066.

(b) The dismissal of a request for hearing is binding unless it is vacated by the ALJ or the Departmental Appeals Board.

§ 422.1066 Vacating a dismissal of request for hearing.

An ALJ may vacate any dismissal of a request for hearing if a party files a request to that effect within 60 calendar days from receipt of the notice of dismissal and shows good cause for vacating the dismissal.

§ 422.1068 Administrative Law Judge's decision.

(a) *Timing, basis and content.* As soon as practical after the close of the hearing, the ALJ issues a written decision in the case. The decision is based on the evidence of record and contains separate numbered findings of fact and conclusions of law.

(b) *Notice and effect.* A copy of the decision is mailed to the parties and is binding on them unless—

(1) A party requests review by the Departmental Appeals Board within the time period specified in 422.846, and the Board reviews the case;

(2) The Departmental Appeals Board denies the request for review and the party seeks judicial review by filing an action in a United States District Court or, in the case of a civil money penalty, in a United States Court of Appeals;

(3) The decision is revised by an ALJ or the Departmental Appeals Board; or

(4) The decision is a recommended decision directed to the Board.

§ 422.1070 Removal of hearing to Departmental Appeals Board.

(a) At any time before the ALJ receives oral testimony, the Board may remove to itself any pending request for a hearing.

(b) Notice of removal is mailed to each party.

(c) The Board conducts the hearing in accordance with the rules that apply to ALJ hearings under this subpart.

§ 422.1072 Remand by the Administrative Law Judge.

(a) If CMS requests remand, and the affected party concurs in writing or on the record, the ALJ may remand any case properly before him or her to CMS for a determination satisfactory to the affected party.

(b) The ALJ may remand at any time before notice of hearing decision is mailed.

§ 422.1074 Right to request Departmental Appeals Board review of Administrative Law Judge's decision or dismissal.

Either of the parties has a right to request Departmental Appeals Board review of the ALJ's decision or dismissal order, and the parties are so informed in the notice of the ALJ's action.

§ 422.1076 Request for Departmental Appeals Board review.

(a) *Manner and time of filing.* (1) Any party that is dissatisfied with an ALJ's decision or dismissal of a hearing request, may file a written request for review by the Departmental Appeals Board.

(2) The requesting party or its representative or other authorized official must file the request with the DAB within 60 calendar days from receipt of the notice of decision or dismissal, unless the Board, for good cause shown by the requesting party, extends the time for filing.

(b) *Content of request for review.* A request for review of an ALJ decision or dismissal must specify the issues, the findings of fact or conclusions of law with which the party disagrees, and the basis for contending that the findings and conclusions are incorrect.

§ 422.1078 Departmental Appeals Board action on request for review.

(a) *Request by CMS.* The Departmental Appeals Board may dismiss, deny, or grant a request made by CMS for review of an ALJ decision or dismissal.

(b) *Request by the affected party.* The Board may deny or grant the affected party's request for review or may dismiss the request for one of the following reasons:

(1) The affected party requests dismissal of its request for review.

(2) The affected party did not file timely or show good cause for late filing.

(3) The affected party does not have a right to review.

(4) A previous determination or decision, based on the same facts and law, and regarding the same issue, has become final through judicial affirmance or because the affected party failed to timely request reconsideration, hearing, Board review, or judicial review, as appropriate.

(c) *Effect of dismissal.* The dismissal of a request for Departmental Appeals Board review is binding and not subject to further review.

(d) *Review panel.* If the Board grants a request for review of the ALJ's decision, the review will be conducted by a panel of three members of the Board, designated by the Chair or Deputy Chair.

§ 422.1080 Procedures before the Departmental Appeals Board on review.

The parties are given, upon request, a reasonable opportunity to file briefs or other written statements as to fact and law, and to appear before the Departmental Appeals Board to present evidence or oral arguments. Copies of any brief or other written statement must be sent in accordance with 422.1016.

§ 422.1082 Evidence admissible on review.

(a) The Departmental Appeals Board may admit evidence into the record in addition to the evidence introduced at the ALJ hearing, (or the documents considered by the ALJ if the hearing was waived), if the Board considers that the additional evidence is relevant and material to an issue before it.

(b) If it appears to the Board that additional relevant evidence is available, the Board will require that it be produced.

(c) Before additional evidence is admitted into the record—

(1) Notice is mailed to the parties (unless they have waived notice) stating that evidence will be received regarding specified issues; and

(2) The parties are given a reasonable time to comment and to present other evidence pertinent to the specified issues.

(d) If additional evidence is presented orally to the Board, a transcript is prepared and made available to any party upon request.

§ 422.1084 Decision or remand by the Departmental Appeals Board.

(a) When the Departmental Appeals Board reviews an ALJ's decision or order of dismissal, or receives a case remanded by a court, the Board may either issue a decision or remand the case to an ALJ for a hearing and decision or a recommended decision for final decision by the Board.

(b) In a remanded case, the ALJ initiates additional proceedings and takes other actions as directed by the Board in its order of remand, and may take other action not inconsistent with that order.

(c) Upon completion of all action called for by the remand order and any other consistent action, the ALJ promptly makes a decision or, as specified by the Board, certifies the case to the Board with a recommended decision.

(d) The parties have 20 calendar days from the date of a notice of a recommended decision to submit to the Board any exception, objection, or comment on the findings of fact, conclusions of law, and recommended decision.

(e) After the 20-calendar day period, the Board issues its decision adopting, modifying or rejecting the ALJ's recommended decision.

(f) If the Board does not remand the case to an ALJ, the following rules apply:

(1) The Board's decision—

(i) Is based upon the evidence in the hearing record and any further evidence that the Board receives during its review;

(ii) Is in writing and contains separate numbered findings of fact and conclusions of law; and

(iii) May modify, affirm, or reverse the ALJ's decision.

(2) A copy of the Board's decision is mailed to each party.

§ 422.1086 Effect of Departmental Appeals Board Decision.

(a) *General rule.* The Board's decision is binding unless—

(1) The affected party has a right to judicial review and timely files a civil action in a United States District Court or, in the case of a civil money penalty, in a United States Court of Appeals; or

(2) The Board reopens and revises its decision in accordance with 422.862.

(b) *Right to judicial review.* Section 422.1006 specifies the circumstances under which an affected party has a right to seek judicial review.

(c) *Special Rules:* Civil Money Penalty—Finality of Board's decision. When CMS imposes a civil money penalty, notice of the Board's decision (or denial of review) is the final administrative action that initiates the 60-day period for seeking judicial review.

§ 422.1088 Extension of time for seeking judicial review.

(a) Any affected party that is dissatisfied with a Departmental Appeals Board decision and is entitled to judicial review must commence civil action within 60 calendar days from receipt of the notice of the Board's decision, unless the Board extends the time in accordance with paragraph (c) of this section.

(b) The request for extension must be filed in writing with the Board before the 60-calendar day period ends.

(c) For good cause shown, the Board may extend the time for commencing civil action.

§ 422.1090 Basis, timing, and authority for reopening an Administrative Law Judge or Board decision.

(a) *Basis and timing for reopening.* An ALJ of Departmental Appeals Board decision may be reopened, within 60 calendar days from the date of the notice of decision, upon the motion of the ALJ or the Board or upon the petition of either party to the hearing.

(b) *Authority to reopen.* (1) A decision of the Departmental Appeals Board may be reopened only by the Departmental Appeals Board.

(2) A decision of an ALJ may be reopened by that ALJ, by another ALJ if that one is not available, or by the Departmental Appeals Board. For purposes of this paragraph, an ALJ is considered to be unavailable if the ALJ has died, terminated employment, or been transferred to another duty station, is on leave of absence, or is unable to conduct a hearing because of illness.

§ 422.1092 Revision of reopened decision.

(a) *Revision based on new evidence.* If a reopened decision is to be revised on the basis of new evidence that was not included in the record of that decision, the ALJ or the Departmental Appeals Board—

(1) Notifies the parties of the proposed revision; and

(2) Unless the parties waive their right to hearing or appearance—

(i) Grants a hearing in the case of an ALJ revision; and

(ii) Grants opportunity to appear in the case of a Board revision.

(b) *Basis for revised decision and right to review.* (1) If a revised decision is necessary, the ALJ or the Departmental Appeals Board, as appropriate, renders it on the basis of the entire record.

(2) If the decision is revised by an ALJ, the Departmental Appeals Board may review that revised decision at the request of either party or on its own motion.

§ 422.1094 Notice and effect of revised decision.

(a) *Notice.* The notice mailed to the parties states the basis or reason for the revised decision and informs them of their right to Departmental Appeals Board review of an ALJ revised decision, or to judicial review of a Board reviewed decision.

(b) *Effect*—(1) *ALJ revised decision.* An ALJ revised decision is binding unless it is reviewed by the Departmental Appeals Board.

(2) *Departmental Appeals Board revised decision.* A Board revised decision is binding unless a party files a civil action in a district court of the United States within the time frames specified in 423.1088.

[72 FR 68726, Dec. 5, 2007, as amended at 85 FR 72909, Nov. 16, 2020]

Subpart U [Reserved]

Subpart V—Medicare Advantage Communication Requirements

SOURCE: 73 FR 54220, Sept. 18, 2008, unless otherwise noted.

§ 422.2260 Definitions.

The definitions in this section apply for this subpart unless the context indicates otherwise.

Advertisement (Ad) means a read, written, visual, oral, watched, or heard bid for, or call to attention. Advertisements can be considered communications or marketing based on the intent and content of the message.

Alternate format means a format used to convey information to individuals with visual, speech, physical, hearing, and intellectual disabilities (for example, braille, large print, audio).

Banner means a type of advertisement feature typically used in television ads that is intended to be brief, and flashes limited information across a screen for the sole purpose of enticing a prospective enrollee to contact the MA plan (for example, obtain more information) or to alert the viewer that information is forthcoming.

Banner-like advertisement is an advertisement that uses a banner-like feature, that is typically found in some media other than television (for example, outdoors and on the internet).

Communications means activities and use of materials created or administered by the MA organization or any downstream entity to provide information to current and prospective enrollees. Marketing is a subset of communications.

Marketing means communications materials and activities that meet both the following standards for intent and content:

(1) Intended, as determined under paragraph (1)(ii) of this definition, to do any of the following:

(i)(A) Draw a beneficiary's attention to a MA plan or plans.

(B) Influence a beneficiary's decision-making process when making a MA plan selection.

(C) Influence a beneficiary's decision to stay enrolled in a plan (that is, retention-based marketing).

(ii) In evaluating the intent of an activity or material, CMS will consider objective information including, but not limited to, the audience of the activity or material, other information communicated by the activity or material, timing, and other context of the activity or material and is not limited to the MA organization's stated intent.

(2) Include or address content regarding any of the following:

(i) The plan's benefits, benefits structure, premiums, or cost sharing.

(ii) Measuring or ranking standards (for example, Star Ratings or plan comparisons).

(iii) Rewards and incentives as defined under § 422.134(a).

Outdoor advertising (ODA) means outdoor material intended to capture the attention of a passing audience (for example, billboards, signs attached to transportation vehicles). ODA may be communications or marketing material.

Third-party marketing organization (TPMO) means organizations and individuals, including independent agents and brokers, who are compensated to perform lead generation, marketing,

sales, and enrollment related functions as a part of the chain of enrollment (the steps taken by a beneficiary from becoming aware of an MA plan or plans to making an enrollment decision). TPMOs may be a first tier, downstream or related entity (FDRs), as defined under § 422.2, but may also be entities that are not FDRs but provide services to an MA plan or an MA plan's FDR.

[86 FR 6103, Jan. 19, 2021, as amended at 87 FR 27898, May 9, 2022]

§ 422.2261 Submission, review, and distribution of materials.

(a) *General requirements.* MA organizations must submit all marketing materials, all election forms, and certain designated communications materials for CMS review.

(1) The Health Plan Management System (HPMS) Marketing Module is the primary system of record for the collection, review, and storage of materials that must be submitted for review.

(2) Materials must be submitted to the HPMS Marketing Module by the MA organization or, where materials have been developed by a Third Party Marketing Organization for multiple MA organizations or plans, by a Third Party Marketing Organization with prior review of each MA organization on whose behalf the materials were created or will be used.

(b) *CMS review of marketing materials and election forms.* MA organizations may not distribute or otherwise make available any marketing materials or election forms unless one of the following occurs:

(1) CMS has reviewed and approved the material.

(2) The material has been deemed approved; that is, CMS has not rendered a disposition for the material within 45 days (or 10 days if using CMS model or standardized marketing materials as outlined in § 422.2267(e) of this chapter) of submission to CMS; or

(3) The material has been accepted under File and Use, as follows:

(i) The MA organization may distribute certain types of marketing materials, designated by CMS based on the material's content, audience, and intended use, as they apply to potential risk to the beneficiary, 5 days following the submission.

(ii) The MA organization must certify that the material meets all applicable CMS communications and marketing requirements in §§ 422.2260 through 422.2267.

(c) *CMS review of non-marketing communications materials.* CMS does not require submission, or submission and approval, of communications materials prior to use, other than the following exceptions.

(1) Certain designated communications materials that are critical to beneficiaries understanding or accessing their benefits (for example, the Evidence of Coverage (EOC).

(2) Communications materials that, based on feedback such as complaints or data gathered through reviews, warrant additional oversight as determined by CMS, to ensure the information being received by beneficiaries is accurate.

(d) *Standards for CMS review.* CMS reviews materials to ensure the following:

(1) Compliance with all applicable requirements under §§ 422.2260 through 422.2267.

(2) Benefit and cost information is an accurate reflection of what is contained in the MA organization's bid.

(3) CMS may determine, upon review of such materials, that the materials must be modified, or may no longer be used.

[86 FR 6104, Jan. 19, 2021, as amended at 88 FR 22335, Apr. 12, 2023]

§ 422.2262 General communications materials and activities requirements.

MA organizations may not mislead, confuse, or provide materially inaccurate information to current or potential enrollees.

(a) *General rules.* MA organizations must ensure their statements and the terminology used in communications activities and materials adhere to the following requirements:

(1) MA organizations may not do any of the following:

(i) Provide information that is inaccurate or misleading.

(ii) Use of superlatives, unless sources of documentation or data supportive of the superlative is also referenced in the material. Such supportive documentation or data must reflect data, reports, studies, or other documentation that applies to the current or prior contract year.

(A) Including data older than the prior contract year is permitted provided the current and prior contract year data are specifically identified.

(B) [Reserved]

(iii) Engage in activities that could mislead or confuse Medicare beneficiaries, or misrepresent the MA organization.

(iv) Engage in any discriminatory activity such as attempting to recruit Medicare beneficiaries from higher income areas without making comparable efforts to enroll Medicare beneficiaries from lower income areas, or vice versa.

(v) Target potential enrollees based on income levels, unless it is a dual eligible special needs plan or comparable plan as determined by the Secretary.

(vi) Target potential enrollees based on health status, unless it is a special needs plan or comparable plan as determined by the Secretary.

(vii) State or imply plans are only available to seniors rather than to all Medicare beneficiaries.

(viii) Employ MA plan names that suggest that a plan is not available to all Medicare beneficiaries, unless it is a special needs plan or comparable plan as determined by the Secretary. This prohibition does not apply to MA plan names in effect prior to July 31, 2000.

(ix) Display the names or logos or both of co-branded network providers on the organization's member identification card, unless the provider names or logos or both are related to the member selection of specific provider organizations (for example, physicians or hospitals).

(x) Use a plan name that does not include the plan type. The plan type should be included at the end of the plan name, for example, ''Super Medicare Advantage (HMO).'' MA organizations are not required to repeat the plan type when the plan name is used multiple times in the same material.

(xi) Claim they are recommended or endorsed by CMS, Medicare, the Secretary, or HHS.

(xii) Convey that a failure to pay premium will not result in disenrollment, except for factually accurate descriptions of the MA organization's policies adopted in accordance with §422.74(b)(1) and (d)(1) of this chapter.

(xiii) Use the term ''free'' to describe a $0 premium, any type of reduction in premium, reduction in deductibles or cost sharing, low-income subsidy, or cost sharing pertaining to dual eligible individuals.

(xiv) Imply that the plan operates as a supplement to Medicare.

(xv) State or imply a plan is available only to or is designed for beneficiaries who are dually eligible for Medicare and Medicaid, unless it is a dual-eligible special needs plan or comparable plan as determined by the Secretary.

(xvi) Market a non-dual eligible special needs plan as if it were a dual-eligible special needs plan.

(xvii) Target marketing efforts primarily to dual eligible individuals, unless the plan is a dual eligible special needs plan or comparable plan as determined by the Secretary.

(xviii) Claim a relationship with the state Medicaid agency, unless a contract to coordinate Medicaid services for enrollees in that plan is in place.

(xix) Use the Medicare name, CMS logo, and products or information issued by the Federal Government, including the Medicare card, in a misleading way. Use of the Medicare card image is permitted only with authorization from CMS.

(2) MA organizations may do the following:

(i) State that the MA organization is approved to participate in Medicare programs or is contracted to administer Medicare benefits or both.

(ii) Use the term ''Medicare-approved'' to describe benefits or services in materials or both.

(iii) Use the term ''free'' in conjunction with mandatory, supplemental, and preventative benefits provided at a zero cost share for all enrollees.

(b) *Product endorsements and testimonials.* (1) Product endorsements

and testimonials may take any of the following forms:

(i) Television or video ads.

(ii) Radio ads.

(iii) Print ads.

(iv) Social media ads. In cases of social media, the use of a previous post, whether or not associated with or originated by the MA organization, is considered a product endorsement or testimonial.

(v) Other types of ads.

(2) MA organizations may use individuals to endorse the MA organization's product provided the endorsement or testimonial adheres to the following requirements:

(i) The speaker must identify the MA organization's product or company by name.

(ii) Medicare beneficiaries endorsing or promoting the MA organization must have been an enrollee at the time the endorsement or testimonial was created.

(iii) The endorsement or testimonial must clearly state that the individual was paid for the endorsement or testimonial, if applicable.

(iv) If an individual is used (for example, an actor) to portray a real or fictitious situation, the endorsement or testimonial must state that it is an actor portrayal.

(c) *Requirements when including certain telephone numbers in materials.* (1) MA organizations must adhere to the following requirements for including certain telephone numbers in materials:

(i) When a MA organization includes its customer service number, the hours of operation must be prominently included at least once.

(ii) When a MA organization includes its customer service number, it must provide a toll-free TTY number in conjunction with the customer service number in the same font size.

(iii) On every material where 1–800–MEDICARE or Medicare TTY appears, the MA organization must prominently include, at least once, the hours and days of operation for 1–800–MEDICARE (that is, 24 hours a day/7 days a week).

(2) The following advertisement types are exempt from these requirements:

(i) Outdoor advertising.

(ii) Banners or banner-like ads.

(iii) Radio advertisements and sponsorships.

(d) *Standardized material identification (SMID).* (1) MA organizations must use a standardized method of identification for oversight and tracking of materials received by beneficiaries.

(2) The SMID consists of the following three parts:

(i) The MA organization contract or Multi-Contract Entity (MCE) number (that is, ''H'' for MA or Section 1876 Cost Plans, ''R'' for Regional PPO plans (RPPOs), or ''Y'' for MCE, a means of identification available for Plans/Part D sponsors that have multiple MA contracts) followed by an underscore, except that the SMID for multi-plan marketing materials must begin with the word ''MULTI–PLAN'' instead of the MA organization's contract number (for example, H1234_abc123_C or MULTI–PLAN_efg456_M).

(ii) A series of alpha numeric characters (chosen at the MA organization's discretion) unique to the material followed by an underscore.

(iii) An uppercase ''C'' for communications materials or an uppercase ''M'' for marketing materials (for example, H1234_abc123_C or H5678_efg456_M).

(3) The SMID is required on all materials except the following:

(i) Membership ID card.

(ii) Envelopes, radio ads, outdoor advertisements, banners, banner-like ads, and social media comments and posts.

(iii) OMB-approved forms/documents, except those materials specified in § 422.2267.

(iv) Corporate notices or forms (that is, not MA/Part D specific) meeting the definition of communications (see § 422.2260) such as privacy notices and authorization to disclose protected health information (PHI).

(v) Agent-developed communications materials that are not marketing.

(4) Non-English and alternate format materials, based on previously created materials, may have the same SMID as the material on which they are based.

[86 FR 6104, Jan. 19, 2021, as amended at 88 FR 22335, Apr. 12, 2023]

§ 422.2263 General marketing requirements.

Marketing is a subset of communications and therefore must follow the requirements outlined in § 422.2262 as well as this section. Marketing (as defined in § 422.2260) must additionally meet the following requirements:

(a) MA organizations may begin marketing prospective plan year offerings on October 1 of each year for the following contract year. MA organizations may market the current and prospective year simultaneously provided materials clearly indicate what year is being discussed.

(b) In marketing, MA organizations may not do any of the following:

(1) Provide cash or other monetary rebates as an inducement for enrollment or otherwise.

(2) Offer gifts to beneficiaries, unless the gifts are of nominal value (as governed by guidance published by the HHS OIG), are offered to similarly situated beneficiaries without regard to whether or not the beneficiary enrolls, and are not in the form of cash or other monetary rebates.

(3) Provide meals to potential enrollees regardless of value.

(4) Market non-health care related products to prospective enrollees during any MA sales activity or presentation. This is considered cross-selling and is prohibited.

(5) Compare their plan to other plans, unless the information is accurate, not misleading, and can be supported by the MA organization making the comparison.

(6) Display the names or logos or both of provider co-branding partners on marketing materials, unless the materials clearly indicate via a disclaimer or in the body that ''Other providers are available in the network.''

(7) Knowingly target or send unsolicited marketing materials to any MA enrollee during the Open Enrollment Period (OEP).

(i) During the OEP, an MA organization may do any of the following:

(A) Conduct marketing activities that focus on other enrollment opportunities, including but not limited to marketing to age-ins (who have not yet made an enrollment decision), marketing by 5-star plans regarding their continuous enrollment special election period (SEP), and marketing to dual-eligible and LIS beneficiaries who, in general, may make changes once per calendar quarter during the first 9 months of the year;

(B) Send marketing materials when a beneficiary makes a proactive request;

(C) At the beneficiary's request, have one-on-one meetings with a sales agent;

(D) At the beneficiary's request, provide information on the OEP through the call center; and

(E) Include educational information, excluding marketing, on the MA organization's website about the existence of OEP.

(ii) During the OEP, an MA organization may not:

(A) Send unsolicited materials advertising the ability or opportunity to make an additional enrollment change or referencing the OEP;

(B) Specifically target beneficiaries who are in the OEP because they made a choice during Annual Enrollment Period (AEP) by purchase of mailing lists or other means of identification;

(C) Engage in or promote agent or broker activities that intend to target the OEP as an opportunity to make further sales; or

(D) Call or otherwise contact former enrollees who have selected a new plan during the AEP.

(8) Advertise benefits that are not available to beneficiaries in the service area(s) where the marketing appears, unless the advertisement is in local media that serves the service area(s) where the benefits are available and reaching beneficiaries who reside in other service areas is unavoidable.

(9) Market any products or plans, benefits, or costs, unless the MA organization or marketing name(s) as listed in HPMS of the entities offering the referenced products or plans, benefits, or costs are identified in the marketing material.

(i) MA organization or marketing names must be in 12-point font in print and may not be in the form of a disclaimer or fine print.

(ii) For television, online, or social media, the MA organization or marketing name(s) must be either read at the same pace as the phone number or

must be displayed throughout the entire advertisement in a font size equivalent to the advertised phone number, contact information, or benefits.

(iii) For radio or other voice-based advertisements, MA organization or marketing names must be read at the same pace as the advertised phone numbers or other contact information.

(10) MA organizations may not include information about savings available to potential enrollees that are based on a comparison of typical expenses borne by uninsured individuals, unpaid costs of dually eligible beneficiaries, or other unrealized costs of a Medicare beneficiary.

(c) The following requirements apply to how MA organizations must display CMS-issued Star Ratings:

(1) References to individual Star Rating measure(s) must also include references to the overall Star Rating for MA–PDs and the summary rating for MA-only plans.

(2) May not use an individual underlying category, domain, or measure rating to imply overall higher Star Ratings.

(3) Must be clear that the rating is out of 5 stars.

(4) Must clearly identify the Star Ratings contract year.

(5) May only market the Star Ratings in the service area(s) for which the Star Rating is applicable, unless using Star Ratings to convey overall MA organization performance (for example, ''Plan X has achieved 4.5 stars in Montgomery, Chester, and Delaware Counties), in which case the MA organization must do so in a way that is not confusing or misleading.

(6) The following requirements apply to all 5 Star MA contracts:

(i) May not market the 5-star special enrollment period, as defined in § 422.62(b)(15), after November 30 of each year if the contract has not received an overall 5 star for the next contract year.

(ii) May use CMS' 5-star icon or may create their own icon.

(7) The following requirements apply to all Low Performing MA contracts:

(i) The Low Performing Icon must be included on all materials about or referencing the specific contract's Star Ratings.

(ii) Must state the Low Performing Icon means that the MA organization's contract received a summary rating of 2.5 stars or below in Part C or Part D or both for the last 3 years.

(iii) May not attempt to refute or minimize Low Performing Status.

[86 FR 6105, Jan. 19, 2021, as amended at 88 FR 22335, Apr. 12, 2023]

§ 422.2264 Beneficiary contact.

For the purpose of this section, beneficiary contact means any outreach activities to a beneficiary or a beneficiary's caregivers by the MA organization or its agents and brokers.

(a) *Unsolicited contact.* Subject to the rules for contact for plan business in paragraph (b) of this section, the following rules apply when materials or activities are given or supplied to a beneficiary or their caregiver without prior request:

(1) MA organizations may make unsolicited direct contact by conventional mail and other print media (for example, advertisements and direct mail) or email (provided every email contains an opt-out option).

(2) MA organizations may not do any of the following if unsolicited:

(i) Use door to door solicitation, including leaving information of any kind, except that information may be left when an appointment is pre-scheduled but the beneficiary is not home.

(A) Contact is unsolicited door-to-door contact unless an appointment, at the beneficiary's home at the applicable date and time, was previously scheduled.

(B) [Reserved]

(ii) Approach enrollees in common areas such as parking lots, hallways, and lobbies.

(iii) Send direct messages from social media platforms.

(iv) Use telephone solicitation (that is, cold calling), robocalls, text messages, or voicemail messages, including, but not limited to, the following:

(A) Calls based on referrals.

(B) Calls to former enrollees who have disenrolled or those in the process of disenrolling, except to conduct disenrollment surveys for quality improvement purposes.

(C) Calls to beneficiaries who attended a sales event, unless the beneficiary gave express permission to be contacted.

(D) Calls to prospective enrollees to confirm receipt of mailed information.

(3) Calls are not considered unsolicited if the beneficiary provides consent or initiates contact with the plan. For example, returning phone calls or calling an individual who has completed a business reply card requesting contact is not considered unsolicited.

(b) *Contact for plan business.* MA organizations may contact current, and to a more limited extent, former members, including those enrolled in other products offered by the parent organization, to discuss plan business, in accordance with the following requirements:

(1) An MA organization may conduct the following activities as plan business:

(i) Call current enrollees, including those in non-Medicare products, to discuss Medicare products. Examples of such calls include, but are not limited to the following:

(A) Enrollees aging into Medicare from commercial products.

(B) Existing enrollees, including Medicaid enrollees, to discuss other Medicare products or plan benefits.

(C) Members in a Part D plan to discuss other Medicare products.

(ii) Call beneficiaries who submit enrollment applications to conduct business related to enrollment.

(iii) With prior CMS approval, call LIS enrollees that a plan is prospectively losing due to reassignment. CMS decisions to approve calls are for limited circumstances based on the following:

(A) The proximity of cost of the losing plan as compared to the national benchmark; and

(B) The selection of plans in the service area that are below the benchmark.

(iv) Agents/brokers calling clients who are enrolled in other products they may sell, such as automotive or home insurance.

(v) MA organizations may not make unsolicited calls about other lines of business as a means of generating leads for Medicare plans.

(2) If the MA organization reaches out to beneficiaries regarding plan business, as outlined in this section, the MA organization must provide notice to all beneficiaries whom the plan contacts as least once annually, in writing, of the individual's ability to opt out of future calls regarding plan business.

(c) *Events with beneficiaries.* MA organizations and their agents or brokers may hold educational events, marketing or sales events, and personal marketing appointments to meet with Medicare beneficiaries, either face-to-face or virtually. The requirements for each type of event are as follows:

(1) Educational events must be advertised as such and be designed to generally inform beneficiaries about Medicare, including Medicare Advantage, Prescription Drug programs, or any other Medicare program.

(i) At educational events, MA organizations and agents/brokers may not market specific MA plans or benefits.

(ii) MA organizations holding or participating in educational events may do any of the following:

(A) Distribute communications materials.

(B) Answer beneficiary-initiated questions pertaining to MA plans.

(C) Distribute business cards.

(D) Make available and receive beneficiary contact information, including Business Reply Cards, but not including Scope of Appointment forms.

(iii) MA organizations holding or participating in educational events may not conduct sales or marketing presentations or distribute or accept plan applications.

(iv) MA organizations may schedule appointments with residents of long-term care facilities (for example, nursing homes, assisted living facilities, board and care homes) upon a resident's request. If a resident did not request an appointment, any visit by an agent or broker is prohibited as unsolicited door-to-door marketing.

(2) Marketing or sales events are group events that fall within the definition of marketing at § 422.2260.

(i) Marketing events are prohibited from taking place within 12 hours of an educational event, in the same location. The same location is defined as

the entire building or adjacent buildings.

(ii) MA organizations holding or participating in marketing events may do any of the following:

(A) Provide marketing materials.

(B) Distribute and accept plan applications.

(C) Collect Scope of Appointment forms for future personal marketing appointments.

(D) Conduct marketing presentations.

(iii) MA organizations holding or participating in marketing events may not do any of the following:

(A) Require sign-in sheets or require attendees to provide contact information as a prerequisite for attending an event.

(B) Conduct activities, including health screenings, health surveys, or other activities that are used for or could be viewed as being used to target a subset of members (that is, ''cherry-picking'').

(C) Use information collected for raffles or drawings for any purpose other than raffles or drawings.

(3) Personal marketing appointments are those appointments that are tailored to an individual or small group (for example, a married couple). Personal marketing appointments are not defined by the location.

(i) At least 48 hours prior to the scheduled personal marketing, the MA plan (or agent or broker, as applicable) must agree upon and record the Scope of Appointment with the beneficiary(ies), except for:

(A) SOAs that are completed during the last four days of a valid election period for the beneficiary.

(B) Unscheduled in person meetings (walk-ins) initiated by the beneficiary.

(ii) MA organizations holding a personal marketing appointment may do any of the following:

(A) Provide marketing materials.

(B) Distribute and accept plan applications.

(C) Conduct marketing presentations.

(D) Review the individual needs of the beneficiary including, but not limited to, health care needs and history, commonly used medications, and financial concerns.

(iii) MA organizations holding a personal marketing appointment may not do any of the following:

(A) Market any health care related product during a marketing appointment beyond the scope agreed upon by the beneficiary, and documented by the plan in a Scope of Appointment, business reply card, or request to receive additional information, which is valid for 12 months following the date of beneficiary's signature date or the date of the beneficiary's initial request for information.

(B) Market additional health related lines of plan business not identified prior to an individual appointment without a separate Scope of Appointment, identifying the additional lines of business to be discussed; such Scope of Appointment is valid for 12 months following the beneficiary's signature date.

(C) Market non-health related products, such as annuities.

[86 FR 6106, Jan. 19, 2021, as amended at 88 FR 22335, Apr. 12, 2023]

§ 422.2265 Websites.

As required under § 422.111(h)(2), MA organizations must have a website.

(a) *General website requirements.* (1) MA organization websites must meet all of the following requirements:

(i) Maintain current year contract content through December 31 of each year.

(ii) Notify users when they will leave the MA organization's Medicare site.

(iii) Include or provide access to (for example, through a hyperlink) applicable notices, statements, disclosures, or disclaimers with corresponding content. Overarching disclaimers, such as the Federal Contracting Statement, are not required on every page.

(iv) Reflect the most current information within 30 days of any material change.

(v) Keep MA content separate and distinct from other lines of business, including Medicare Supplemental Plans.

(2) MA organization websites may not do any of the following:

(i) Require beneficiaries to enter any information other than zip code, county, or state for access to non-beneficiary-specific website content.

(ii) Provide links to foreign drug sales, including advertising links.

(iii) State that the MA organization is not responsible for the content of their social media pages or the website of any first tier, downstream, or related entity that provides information on behalf of the MA organization.

(b) *Required content.* MA organization's websites must include the following content:

(1) A toll-free customer service number, TTY number, and days and hours of operation.

(2) A physical or Post Office Box address.

(3) A PDF or copy of a printable provider directory.

(4) A provider directory searchable by every element required in the model provider directory, such as name, location, specialty.

(5) When applicable, a searchable pharmacy directory combined with a provider directory.

(6) Information on enrollees' and MA organizations' rights and responsibilities upon disenrollment. MA organizations may either post this information or provide specific information on where it is located in the Evidence of Coverage together with a link to that document.

(7) A description of and information on how to file a grievance, request an organization determination, and an appeal.

(8) Prominently displayed link to the Medicare.gov electronic complaint form.

(9) Disaster and emergency policy consistent with § 422.100(m)(5)(iii).

(10) A Notice of Privacy Practices as required under the HIPAA Privacy Rule (45 CFR 164.520).

(11) For PFFS plans, a link to the PFFS Terms and Conditions of Payment.

(12) For MSA plans, the following statements:

(i) ''You must file Form 1040, 'US Individual Income Tax Return,' along with Form 8853, 'Archer MSA and Long-Term Care Insurance Contracts' with the Internal Revenue Service (IRS) for any distributions made from your Medicare MSA account to ensure you aren't taxed on your MSA account withdrawals. You must file these tax forms for any year in which an MSA account withdrawal is made, even if you have no taxable income or other reason for filing a Form 1040. MSA account withdrawals for qualified medical expenses are tax free, while account withdrawals for non-medical expenses are subject to both income tax and a fifty (50) percent tax penalty.''

(ii) ''Tax publications are available on the IRS website at *http://www.irs.gov* or from 1–800–TAX–FORM (1–800–829–3676).''

(13) Instructions on how to appoint a representative including a link to the downloadable version of the CMS Appointment of Representative Form (CMS Form–1696).

(14) Enrollment instructions and forms.

(c) *Required posted materials.* MA organization's website must provide access to the following materials, in a printable format, within the timeframes specified in paragraphs (c)(1) and (2) of this section.

(1) The following materials for each plan year must be posted on the website by October 15 prior to the beginning of the plan year:

(i) Evidence of Coverage.

(ii) Annual Notice of Change (for renewing plans).

(iii) Summary of Benefits.

(iv) Provider Directory.

(v) Provider/Pharmacy Directory.

(2) The following materials must be posted on the website throughout the year and be updated as required:

(i) Prior Authorization Forms for physicians and enrollees.

(ii) When applicable, Part D Model Coverage Determination and Redetermination Request Forms.

(iii) Exception request forms for physicians (which must be posted by January 1 for new plans).

(iv) CMS Star Ratings document, which must be posted within 21 days after its release on the Medicare Plan Finder.

[86 FR 6107, Jan. 19, 2021, as amended at 87 FR 27898, May 9, 2022; 88 FR 22336, Apr. 12, 2023]

§ 422.2266 Activities with healthcare providers or in the healthcare setting.

(a) *Where marketing is prohibited.* The requirements in paragraphs (c) through (e) of this section apply to activities in the health care setting. Marketing activities and materials are not permitted in areas where care is being administered, including but not limited to the following:

(1) Exam rooms.

(2) Hospital patient rooms.

(3) Treatment areas where patients interact with a provider and clinical team (including such areas in dialysis treatment facilities).

(4) Pharmacy counter areas.

(b) *Where marketing is permitted.* Marketing activities and materials are permitted in common areas within the health care setting, including the following:

(1) Common entryways.

(2) Vestibules.

(3) Waiting rooms.

(4) Hospital or nursing home cafeterias.

(5) Community, recreational, or conference rooms.

(c) *Provider-initiated activities.* Provider-initiated activities are activities conducted by a provider at the request of the patient, or as a matter of a course of treatment, and occur when meeting with the patient as part of the professional relationship between the provider and patient. Provider-initiated activities do not include activities conducted at the request of the MA organization or pursuant to the network participation agreement between the MA organization and the provider. Provider-initiated activities that meet the definition in this paragraph (c) fall outside of the definition of marketing in § 422.2260. Permissible provider-initiated activities include:

(1) Distributing unaltered, printed materials created by CMS, such as reports from Medicare Plan Finder, the ''Medicare & You'' handbook, or ''Medicare Options Compare'' (from *https://www.medicare.gov*), including in areas where care is delivered.

(2) Providing the names of MA organizations with which they contract or participate or both.

(3) Answering questions or discussing the merits of a MA plan or plans, including cost sharing and benefit information, including in areas where care is delivered.

(4) Referring patients to other sources of information, such as State Health Insurance Assistance Program (SHIP) representatives, plan marketing representatives, State Medicaid Office, local Social Security Offices, CMS' website at *https://www.medicare.gov*, or 1–800–MEDICARE.

(5) Referring patients to MA plan marketing materials available in common areas;

(6) Providing information and assistance in applying for the LIS.

(7) Announcing new or continuing affiliations with MA organizations, once a contractual agreement is signed. Announcements may be made through any means of distribution.

(d) *Plan-initiated provider activities.* Plan-initiated provider activities are those activities conducted by a provider at the request of an MA organization. During a plan-initiated provider activity, the provider is acting on behalf of the MA organization. For the purpose of plan-initiated activities, the MA organization is responsible for compliance with all applicable regulatory requirements.

(1) During plan-initiated provider activities, MA organizations must ensure that the provider does not:

(i) Accept or collect Scope of Appointment forms.

(ii) Accept Medicare enrollment applications.

(iii) Make phone calls or direct, urge, or attempt to persuade their patients to enroll in a specific plan based on financial or any other interests of the provider.

(iv) Mail marketing materials on behalf of the MA organization.

(v) Offer inducements to persuade patients to enroll in a particular MA plan or organization.

(vi) Conduct health screenings as a marketing activity.

(vii) Distribute marketing materials or enrollment forms in areas where care is being delivered.

(viii) Offer anything of value to induce enrollees to select the provider.

(ix) Accept compensation from the MA organization for any marketing or enrollment activities performed on behalf of the MA organization.

(2) During plan-initiated provider activities, the provider may do any of the following:

(i) Make available, distribute, and display communications materials, including in areas where care is being delivered.

(ii) Provide or make available marketing materials and enrollment forms in common areas.

(e) *MA organization activities in the health care setting.* MA organization activities in the health care setting are those activities, including marketing activities that are conducted by MA organization staff or on behalf of the MA organization, or by any downstream entity, but not by a provider. All marketing must comply with the requirements in paragraphs (a) and (b) of this section. However, during MA organization activities, the following is permitted:

(1) Accepting and collect Scope of Appointment forms.

(2) Accepting enrollment forms.

(3) Making available, distributing, and displaying communications materials, including in areas where care is being delivered.

(f) *Activities of Institutional Special Needs Plans (I–SNPs) Serving Long-Term Care Facility Residents* (1) Depending on the context of a given situation, I–SNP contracted with a long-term care facility can be viewed as both a provider and a plan.

(2) I–SNPs may use staff operating in a social worker capacity to provide information, including marketing materials (excluding enrollment forms), to residents of a long term care facility.

(3) Social workers of the I–SNP (whether employees, agents, or contracted providers) may not accept or collect a scope of appointment or enrollment form on behalf of the I–SNP.

(4) Unless the beneficiary or the beneficiary's authorized representative initiates additional contact with or by the plan, all other marketing and outreach activities in the beneficiary's room must follow the requirements for beneficiary contact under § 422.2264

(5) All other activities with healthcare providers or in the healthcare setting must comply with §§ 422.2266(a), (b), (c), (d), and (e).

[86 FR 6108, Jan. 19, 2021]

§ 422.2267 Required materials and content.

For information CMS deems to be vital to the beneficiary, including information related to enrollment, benefits, health, and rights, the agency may develop materials or content that are either standardized or provided in a model form. Such materials and content are collectively referred to as required.

(a) *Standards for required materials and content.* All required materials and content, regardless of categorization as standardized in paragraph (b) of this section or model in paragraph (c) of this section, must meet the following:

(1) Be in a 12pt font, Times New Roman or equivalent.

(2) For markets with a significant non-English speaking population, be in the language of these individuals. Specifically, MA organizations must translate required materials into any non-English language that is the primary language of at least 5 percent of the individuals in a plan benefit package (PBP) service area.

(3) Be provided to enrollees on a standing basis in any non-English language identified in paragraphs (a)(2) and (4) of this section or accessible format upon receiving a request for the materials in a non-English language or accessible format or when otherwise learning of the enrollee's primary language or need for an accessible format. This requirement also applies to the individualized plans of care described in § 422.101(f)(1)(ii) for special needs plan enrollees.

(4) For any fully integrated dual eligible special needs plan or highly integrated dual eligible special needs plan, as defined at § 422.2, or applicable integrated plan, as defined at § 422.561, be translated into the language(s) required by the Medicaid translation standard as specified through their capitated Medicaid managed care contract in addition to the language(s) required by the Medicare translation

standard in paragraph (a)(2) of this section.

(5) Be provided to the beneficiary within CMS's specified timeframes.

(b) *Standardized materials.* Standardized materials and content are required materials and content that must be used in the form and manner provided by CMS.

(1) When CMS issues standardized material or content, an MA organization must use the document without alteration except for the following:

(i) Populating variable fields.

(ii) Correcting grammatical errors.

(iii) Adding customer service phone numbers.

(iv) Adding plan name, logo, or both.

(v) Deleting content that does not pertain to the plan type (for example, removing Part D language for a MA-only plan).

(vi) Adding the SMID.

(vii) A Notice of Privacy Practices as required under the HIPAA Privacy Rule (45 CFR 164.520).

(2) The MA organization may develop accompanying language for standardized material or content, provided that language does not conflict with the standardized material or content. For example, CMS may issue standardized content associated with an appeal notification and MA organizations may draft a letter that includes the standardized content in the body of the letter; the remaining language in the letter is at the plan's discretion, provided it does not conflict with the standardized content or other regulatory standards.

(c) *Model materials.* Model materials and content are those required materials and content created by CMS as an example of how to convey beneficiary information. When drafting required materials or content based on CMS models, MA organizations:

(1) Must accurately convey the vital information in the required material or content to the beneficiary, although the MA organization is not required to use CMS model materials or content verbatim; and

(2) Must follow CMS's specified order of content, when specified.

(d) *Delivery of required materials.* MA organizations must mail required materials in hard copy or provide them electronically, following the requirements in paragraphs (d)(1) and (2) of this section.

(1) For hard copy mailed materials, each enrollee must receive his or her own copy, except in cases of non-beneficiary-specific material(s) where the MA organization has determined multiple enrollees are living in the same household and it has reason to believe the enrollees are related. In that case, the MA organization may mail one copy to the household. The MA organization must provide all enrollees an opt-out process so the enrollees can each receive his or her own copy, instead of a copy to the household. Materials specific to an individual beneficiary must always be mailed to that individual.

(2) Materials may be delivered electronically following the requirements in paragraphs (d)(2)(i) and (ii) of this section.

(i) Without prior authorization from the enrollee, MA organizations may mail new and current enrollees a notice informing enrollees how to electronically access the following required materials: the Evidence of Coverage, Provider and Pharmacy Directories, and Formulary. The following requirements apply:

(A) The MA organization may mail one notice for all materials or multiple notices.

(B) Notices for prospective year materials may not be mailed prior to September 1 of each year, but must be sent in time for an enrollee to access the specified materials by October 15 of each year.

(C) The MA organization may send the notice throughout the year to new enrollees.

(D) The notice must include the website address to access the materials, the date the materials will be available if not currently available, and a phone number to request that hard-copy materials be mailed.

(E) The notice must provide the enrollee with the option to request hardcopy materials. Requests may be material specific, and must have the option of a one-time request or a permanent request that must stay in place until the enrollee chooses to receive electronic materials again.

(F) Hard copies of requested materials must be sent within three business days of the request.

(ii) With prior authorization from the enrollee, MA organizations may provide any required material or content electronically. To do so, MA organizations must:

(A) Obtain prior consent from the enrollee. The consent must specify both the media type and the specific materials being provided in that media type.

(B) Provide instructions on how and when enrollees can access the materials.

(C) Have a process through which an enrollee can request hard copies be mailed, providing the beneficiary with the option of a one-time request or a permanent request (which must stay in place until the enrollee chooses to receive electronic materials again), and with the option of requesting hard copies for all or a subset of materials. Hard copies must be mailed within three business days of the request.

(D) Have a process for automatic mailing of hard copies when electronic versions or the chosen media type is undeliverable.

(e) *CMS required materials and content.* The following are required materials that must be provided to current and prospective enrollees, as applicable, in the form and manner outlined in this section. Unless otherwise noted or instructed by CMS and subject to §422.2263(a) of this chapter, required materials may be sent once a fully executed contract is in place, but no later than the due dates listed for each material in this section.

(1) *Evidence of Coverage (EOC).* The EOC is a standardized communications material through which certain required information (under §422.111(b)) must be provided annually and must be provided:

(i) To current enrollees of the plan by October 15, prior to the year to which the EOC applies.

(ii) To new enrollees within 10 calendars days from receipt of CMS confirmation of enrollment or by last day of month prior to effective date, whichever is later.

(2) *Part C explanation of benefits (EOB).* The EOB is a model communications material through which plans must provide the information required under §422.111(k). MA organizations may send this monthly or per claim with a quarterly summary.

(3) *Annual notice of change (ANOC).* The ANOC is a standardized marketing material through which plans must provide the information required under §422.111(d)(2) annually.

(i) Must send for enrollee receipt no later than September 30 of each year.

(ii) Enrollees with an October 1, November 1, or December 1 effective date must receive within 10 calendar days from receipt of CMS confirmation of enrollment or by last day of month prior to effective date, whichever is later.

(4) *Pre-Enrollment checklist (PECL).* The PECL is a standardized communications material that plans must provide to prospective enrollees with the enrollment form, so that the enrollees understand important plan benefits and rules. For telephonic enrollments, the contents of the PECL must be reviewed with the prospective enrollee prior to the completion of the enrollment. It references information on the following:

(i) The EOC.

(ii) Provider directory.

(iii) Pharmacy directory.

(iv) Formulary.

(v) Premiums/copayments/coinsurance.

(vi) Emergency/urgent coverage.

(vii) Plan-type rules.

(viii) Effect on current coverage.

(5) *Summary of Benefits (SB).* MA organizations must disseminate a summary of highly utilized coverage that include benefits and cost sharing to prospective enrollees, known as the SB. The SB is a model marketing material. It must be in a clear and accurate form.

(i) The SB must be provided with an enrollment form as follows:

(A) In hard copy with a paper enrollment form.

(B) For online enrollment, the SB must be made available electronically (for example, via a link) prior to the completion and submission of enrollment request.

(C) For telephonic enrollment, the beneficiary must be verbally told where the SB can be accessed.

(ii) The SB must include the following information:

(A) Information on the following medical benefits, starting in the top half of the first page and in the order as identified in paragraphs (A)(1) through (A)(10), including—

(*1*) Monthly Plan Premium.

(*2*) Deductible/Out-of-pocket limits.

(*3*) Inpatient/Outpatient Hospital coverage.

(*4*) Ambulatory Surgical Center (ASC).

(*5*) Doctor Visits (Primary Care Providers and Specialists).

(*6*) Preventive Care.

(*7*) Emergency Care/Urgently Needed Services.

(*8*) Diagnostic Services/Labs/Imaging.

(*9*) Hearing Services/Dental Services/Vision Services.

(*10*) Mental Health Services.

(B) Information on prescription drug expenses, including:

(*1*) Deductible, the initial coverage phase, coverage gap, and catastrophic coverage.

(*2*) A statement that costs may differ based on pharmacy type or status (for example, preferred/non-preferred, mail order, long-term care (LTC) or home infusion, and 30-or 90-day supply), when applicable.

(C) For Medicare Medical Savings Account Plans (MSAs), the SB must include the following:

(*1*) The amount Medicare deposits into the beneficiaries MSA account.

(*2*) A statement that the beneficiary pays nothing once the deductible is met.

(D) For dual eligible special needs plan (D–SNP)s, the SB must identify or describe the Medicaid benefits to prospective enrollees. This may be done by either of the following:

(*1*) Including the Medicaid benefits in the SB.

(*2*) Providing a separate document identifying the Medicaid benefits that accompanies the SB.

(E) For D–SNPs open to dually eligible enrollees with differing levels of cost, the SB must:

(*1*) State how cost sharing and benefits differ depending on the level of Medicaid eligibility.

(*2*) Describe the Medicaid benefits, if any, provided by the plan.

(F) Fully integrated dual eligible SNPs (FIDE SNPs) and highly integrated D–SNPs, as defined in § 422.2, that provide Medicaid benefits have the option to display integrated Medicare and Medicaid benefits in the SB.

(G) MA organizations may describe or identify other health related benefits in the SB.

(6) *Enrollment/Election form.* This is a model communications material through which plans must provide the information required under § 422.60(c).

(7) *Enrollment Notice.* This is a model communications material through which plans must provide the information required under § 422.60(e)(3).

(8) *Disenrollment Notice.* This is a model communications material through which plans must provide the information required under § 422.74(b).

(9) *Mid-Year Change Notification.* This is a model communications material through which plans must provide a notice to enrollees when there is a mid-year change in benefits or plan rules, under the following timelines:

(i) Notices of changes in plan rules, unless otherwise addressed elsewhere in this part, must be provided 30 days in advance.

(ii) For National Coverage Determination (NCD) changes announced or finalized less than 30 days before their effective date, a notification is required as soon as possible.

(iii) Mid-year NCD or legislative changes must be provided no later than 30 days after the NCD is announced or the legislative change is effective.

(A) Plans may include the change in next plan mass mailing (for example, newsletter), provided it is within 30 days.

(B) The notice must also appear on the MA organization's website.

(10) *Non-renewal Notice.* This is a standardized communications material through which plans must provide the information required under § 422.506.

(i) The Non-renewal Notice must be provided at least 90 calendar days before the date on which the nonrenewal is effective. For contracts ending on December 31, the notice must be dated October 2 to ensure national consistency in the application of Medigap Guaranteed Issue (GI) rights to all enrollees, except for those enrollees in

special needs plans (SNPs). Information about non-renewals or service area reductions may not be released to the public, including the Non-renewal Notice, until CMS provides notification to the plan.

(ii) The Non-renewal Notice must do all of the following:

(A) Inform the enrollee that the plan will no longer be offered and the date the plan will end.

(B) Provide information about any applicable open enrollment periods or special election periods or both (for example, Medicare open enrollment, non-renewal special election period), including the last day the enrollee has to make a Medicare health plan selection.

(C) Explain what the enrollee must do to continue receiving Medicare coverage and what will happen if the enrollee chooses to do nothing.

(D) As required under §422.506(a)(2)(ii)(A), provide a CMS-approved written description of alternative MA plan, MA–PD plan, and PDP options available for obtaining qualified Medicare services within the beneficiary's' region in the enrollee's notice.

(E) Specify when coverage will start after a new Medicare plan is chosen.

(F) List 1–800–MEDICARE contact information together with other organizations that may be able to assist with comparing plans (for example, SHIPs).

(G) Explain Medigap to applicable enrollees and the special right to buy a Medigap policy, and include a Medigap fact sheet with the non-renewal notice that explains Medigap coverage, policy, options to compare Medigap policies, and options to buy a Medigap policy.

(H) Include the MA organization's call center telephone number, TTY number, and hours and days of operation.

(11) *Provider Directory*. This is a model communications material through which plans must provide the information under §422.111(b)(3). The Provider Directory must:

(i) Be provided to current enrollees of the plan by October 15 of the year prior to the applicable year.

(ii) Be provided to new enrollees within 10 calendar days from receipt of CMS confirmation of enrollment or by last day of month prior to effective date, whichever is later.

(iii) Be provided to current enrollees upon request, within three business days of the request.

(iv) Be updated any time the MA organization becomes aware of changes.

(A) Updates to the online provider directories must be completed within 30 days of receiving information requiring update.

(B)(*1*) Updates to hardcopy provider directories must be completed within 30 days.

(*2*) Hard copy directories that include separate updates via addenda are considered up-to-date.

(12) *Provider Termination Notice*. This is a model communications material through which plans must provide the information required under §422.111(e).

(i) The written Provider Termination Notice must be provided in hard copy via U.S. mail (first class postage is recommended, but not required).

(ii) The written Provider Termination Notice must do all of the following:

(A) Inform the enrollee that the provider will no longer be in the network and the date the provider will leave the network.

(B) Include names and phone numbers of in-network providers that the enrollee may access for continued care (this information may be supplemented with information for accessing a current provider directory, including both online and direct mail options).

(C) Explain how the enrollee may request a continuation of ongoing medical treatment or therapies with their current provider.

(D) Provide information about the annual coordinated election period and the MA open enrollment period, as well as explain that an enrollee who is impacted by the provider termination may contact 1–800–MEDICARE to request assistance in identifying and switching to other coverage, or to request consideration for a special election period, as specified in §422.62(b)(26), based on the individual's unique circumstances and consistent with existing parameters for this SEP.

(E) Include the MA organization's call center telephone number, TTY

number, and hours and days of operation.

(iii) The telephonic Provider Termination Notice specified in § 422.111(e)(1)(i) must relay the same information as the written Provider Termination Notice as described in paragraph (e)(12)(ii) of this section.

(13) *Star Ratings Document.* This is a standardized marketing material through which Star Ratings information is conveyed to prospective enrollees.

(i) The Star Ratings Document is generated through HPMS.

(ii) The Star Ratings Document must be provided with an enrollment form, as follows:

(A) In hard copy with a paper enrollment form.

(B) For online enrollment, made available electronically (for example, via a link) prior to the completion and submission of enrollment request.

(C) For telephonic enrollment, the beneficiary must be verbally told where they can access the Star Ratings Document.

(iii) New MA organizations that have no Star Ratings are not required to provide the Star Ratings Document until the following contract year.

(iv) Updated Star Ratings must be used within 21 calendar days of release of updated information on Medicare Plan Finder.

(v) Updated Star Ratings must not be used until CMS releases Star Ratings on Medicare Plan Finder.

(14) *Organization Determination Notice.* This is a model communications material through which plans must provide the information under § 422.568.

(15) *Excluded Provider Notice.* This is a model communications material through which plans must notify enrollees when a provider they visit or consult has been excluded from participating in the Medicare program based on an OIG exclusion or the CMS preclusion list.

(16) *Notice of Denial of Medical Coverage or Payment (NDMCP) (also known as the Integrated Denial Notice (IDN)).* This is a standardized communications material used to convey beneficiary appeal rights when a plan has denied a service as non-covered or excluded from benefits.

(17) *Notice of Medicare Non-Coverage (NOMNC).* This is a standardized communications material used to convey beneficiary appeal rights when a plan is terminating previously-approved coverage in a Skilled Nursing Facility (SNF), Comprehensive Outpatient Rehabilitation Facility (CORF), or Home Health setting (HHA).

(18) *Detailed Explanation of Non-Coverage (DENC).* This is a standardized communications material used to convey to a beneficiary why their current Medicare covered SNF, CORF or HHA services should end.

(19) *Appointment of Representative (AOR).* This is a standardized communications material used to authorize or appoint an individual to act on behalf of a beneficiary for the purpose of a specific appeal, grievance, or organization determination.

(20) *An Important Message From Medicare About Your Rights (IM).* This is a standardized communications material used to convey a beneficiary's rights as a hospital inpatient and appeal rights when their covered inpatient hospital stay is ending.

(21) *Detailed Notice of Discharge Form (DND).* This is a standardized communications material, as required under § 422.622(e), used to convey to a beneficiary why their current Medicare covered inpatient hospital stay should end.

(22) *Medicare Outpatient Observation Notice (MOON).* This is a standardized communications material used to inform a beneficiary that he or she is an outpatient receiving observation services.

(23) *Appeal and Grievance Data Form.* This is a standardized communications material used to convey organization-specific grievance and appeals data.

(24) *Request for Administrative Law Judge (ALJ) Hearing.* This is a standardized communications material used to formally request a reconsideration of the independent review entity's determination.

(25) *Attorney Adjudicator Review in Lieu of ALJ Hearing.* This is a standardized communications material used to request that an attorney adjudicator review a previously determined decision rather than having an ALJ do so.

(26) *Notice of Right to an Expedited Grievance*. This is a model communications material used to convey a Medicare enrollee's rights to request that a decision be made on a grievance or appeal within a shorter timeframe.

(27) *Waiver of Liability Statement*. This is a model communications material used by non-contracted providers to waive beneficiary liability for payment for denied services while utilizing the enrollee appeals process under subpart M of part 422.

(28) *Notice of Appeal Status*. This is a model communications material used to inform a beneficiary of the denial of an appeal and additional appeal rights.

(29) *Notice of Dismissal of Appeal*. This is a model communications material used to convey the rationale by an MA organization to dismiss beneficiary's appeal.

(30) *Member ID card*. The member ID card is a model communications material that plans must provide to enrollees as required under §422.111(i). The member ID card—

(i) Must be provided to new enrollees within ten calendars days from receipt of CMS confirmation of enrollment or by the last day of the month prior to the plan effective date, whichever is later;

(ii) Must include the plan's—

(A) Website address;

(B) Customer service number (the member ID card is excluded from the hours of operations requirement under §422.2262(c)(1)(i)); and

(C) Contract/PBP number;

(iii) Must include, if issued for a PPO and PFFS plan, the phrase ''Medicare limiting charges apply.'';

(iv) May not use a member's Social Security number (SSN), in whole or in part;

(v) Must be updated whenever information on a member's existing card changes; in such cases an updated card must be provided to the member;

(vi) Is excluded from the translation requirement under paragraphs (a)(2) through (4) of this section;

(vii) Is excluded from the 12-point font size requirement under paragraph (a)(1) of this section; and

(viii) For dual eligible special needs plans that are applicable integrated plans, as defined in §422.561, must be an integrated member ID card that serves as the ID card for both the Medicare and Medicaid plans in which the enrollee is enrolled, beginning no later than contract year 2027.

(31) *Notice of availability of language assistance services and auxiliary aids and services (Notice of Availability)*.

(i) Prior to contract year 2026 marketing on September 30, 2025, the notice is referred to as the *Multi-language insert (MLI)*. This is a standardized communications material which states, ''We have free interpreter services to answer any questions you may have about our health or drug plan. To get an interpreter, just call us at [1–xxx–xxx–xxxx]. Someone who speaks [language] can help you. This is a free service.'' in the following languages: Spanish, Chinese, Tagalog, French, Vietnamese, German, Korean, Russian, Arabic, Italian, Portuguese, French Creole, Polish, Hindi, and Japanese.

(A) Additional languages that meet the 5 percent service area threshold, as required under paragraph (a)(2) of this section, must be added to the MLI used in that service area. A plan may also opt to include in the MLI any additional language that do not meet the 5 percent service area threshold, where it determines that this inclusion would be appropriate.

(B) Except where otherwise provided in paragraph (e)(31)(i)(G) of this section, the MLI must be provided with all required materials under paragraph (e) of this section.

(C) The MLI may be included as a part of the required material or as a standalone material in conjunction with the required material.

(D) When used as a standalone material, the MLI may include organization name and logo.

(E) When mailing multiple required materials together, only one MLI is required.

(F) The MLI may be provided electronically when a required material is provided electronically as permitted under paragraph (d)(2) of this section.

(G) At plan option for CY 2025 marketing and communications beginning September 30, 2024, the plan may use the model notice described in

§ 422.2267(e)(31)(ii) to satisfy the MLI requirements set forth in paragraph (e)(31)(i) of this section.

(ii) For CY 2026 marketing and communications beginning September 30, 2025, the required notice is referred to as the Notice of availability of language assistance services and auxiliary aids and services (Notice of Availability). This is a model communications material through which MA organizations must provide a notice of availability of language assistance services and auxiliary aids and services that, at a minimum, states that the MA organization provides language assistance services and appropriate auxiliary aids and services free of charge.

(A) This notice of availability of language assistance services and auxiliary aids and services must be provided in English and at least the 15 languages most commonly spoken by individuals with limited English proficiency of the relevant State or States associated with the plan's service area and must be provided in alternate formats for individuals with disabilities who require auxiliary aids and services to ensure effective communication.

(B) If there are additional languages in a particular service area that meet the 5 percent service area threshold, described in paragraph (a)(2) of this section, beyond the languages described in paragraph (e)(31)(i) of this section, the notice of availability of language assistance services and auxiliary aids and services must also be translated into those languages. MA organizations may also opt to translate the notice in any additional languages that do not meet the 5 percent service area threshold, where the MA organization determines that this inclusion would be appropriate.

(C) The notice must be provided with all required materials under paragraph (e) of this section.

(D) The notice may be included as a part of the required material or as a standalone material in conjunction with the required material.

(E) When used as a standalone material, the notice may include organization name and logo.

(F) When mailing multiple required materials together, only one notice is required.

(G) The notice may be provided electronically when a required material is provided electronically as permitted under paragraph (d)(2) of this section.

(32) *Federal Contracting Statement*. This is model content through which plans must convey that they have a contract with Medicare and that enrollment in the plan depends on contract renewal.

(i) The Federal Contracting Statement must include all of the following:

(A) Legal or marketing name of the organization.

(B) Type of plan (for example, HMO, HMO SNP, PPO, PFFS, PDP).

(C) A statement that the organization has a contract with Medicare (when applicable, MA organizations may incorporate a statement that the organization has a contract with the state/Medicaid program).

(D) A statement that enrollment depends on contract renewal.

(ii) MA organizations must include the Federal Contracting Statement on all marketing materials with the exception of the following:

(A) Banners and banner-like advertisements.

(B) Outdoor advertisements.

(C) Text messages.

(D) Social media.

(E) Envelopes.

(33) *Star Ratings Disclaimer*. This is model content through which plans must:

(i) Convey that MA organizations are evaluated yearly by Medicare.

(ii) Convey that the ratings are based on a 5-star rating system.

(iii) Include the model content in disclaimer form or within the material whenever Star Ratings are mentioned in marketing materials, with the exception of when Star Ratings are published on small objects (that is, a giveaway items such as a pens or rulers).

(34) *SSBCI disclaimer*. This is model content and must be used by MA organizations that offer CMS-approved SSBCI as specified in § 422.102(f). In the SSBCI disclaimer, MA organizations must include the information required in paragraphs (i) through (iii) of this section. MA organizations must do all of the following:

(i) Convey the benefits mentioned are a part of special supplemental benefits.

(ii) List the chronic condition(s) the enrollee must have to be eligible for the SSBCI offered by the applicable MA plan(s), in accordance with the following requirements.

(A) The following applies when only one type of SSBCI is mentioned:

(*1*) If the number of condition(s) is five or fewer, then list all condition(s).

(*2*) If the number of conditions is more than five, then list the top five conditions, as determined by the MA organization, and convey that there are other eligible conditions not listed.

(B) The following applies when multiple types of SSBCI are mentioned:

(*1*) If the number of condition(s) is five or fewer, then list all condition(s), and if relevant, state that these conditions may not apply to all types of SSBCI mentioned.

(*2*) If the number of conditions is more than five, then list the top five conditions, as determined by the MA organization, for which one or more listed SSBCI is available, and convey that there are other eligible conditions not listed.

(iii) Convey that even if the enrollee has a listed chronic condition, the enrollee will not necessarily receive the benefit because coverage of the item or service depends on the enrollee being a ''chronically ill enrollee'' as defined in §422.102(f)(1)(i)(A) and on the applicable MA plan's coverage criteria for a specific SSBCI required by §422.102(f)(4).

(iv) Meet the following requirements for the SSBCI disclaimer in ads:

(A) For television, online, social media, radio, or other voice-based ads, either read the disclaimer at the same pace as, or display the disclaimer in the same font size as, the advertised phone number or other contact information.

(B) For outdoor advertising (as defined in §422.2260), display the disclaimer in the same font size as the advertised phone number or other contact information.

(v) Include the SSBCI disclaimer in all marketing and communications materials that mention SSBCI.

(35) *Accommodations Disclaimer*. This is model content through which MA organizations must:

(i) Convey that accommodations for persons with special needs are available.

(ii) Provide a telephone number and TTY number.

(iii) Include the model content in disclaimer form or within the body of the material on any advertisement of invitation to all events described under §422.2264(c).

(36) *Mailing Statements*. This is standardized content. It consists of statements on envelopes that MA organizations must include when mailing information to current members, as follows:

(i) MA organizations must include the following statement when mailing information about the enrollee's current plan: ''Important [Insert Plan Name] information.''

(ii) MA organizations must include the following statement when mailing health and wellness information: ''Health and wellness or prevention information.''

(iii) The MA organization must include the plan name; however, if the plan name is elsewhere on the envelope, the plan name does not need to be repeated in the disclaimer.

(iv) Delegated or sub-contracted entities and downstream entities that conduct mailings on behalf of a multiple MA organizations must also comply with this requirement; however, they do not have to include a plan name.

(37) *Promotional Give-Away Disclaimer*. This is model content. The disclaimer consists of a statement that must make clear that there is no obligation to enroll in a plan, and must be included when offering a promotional give-away such as a drawing, prizes, or a free gift.

(38) *Provider Co-branded Material Disclaimer*. This is model content through which MA organizations must:

(i) Convey, as applicable, that other pharmacies, physicians or providers are available in the plan's network.

(ii) Include the model content in disclaimer form or within the material whenever co-branding relationships with network provider are mentioned, unless the co-branding is with a provider network or health system that represents 90 percent or more of the network as a whole.

(39) *Out of Network Non-Contracted Provider Disclaimer*. This is standardized content. The disclaimer consists of the statement: ''Out-of-network/non-contracted providers are under no obligation to treat Plan members, except in emergency situations. Please call our customer service number or see your Evidence of Coverage for more information, including the cost-sharing that applies to out-of-network services,'' and must be included whenever materials reference out-of-network/non-contracted providers.

(40) *NCQA SNP Approval Statement*. This is model content and must be used by SNPs who have received NCQA approval. MA organizations must:

(i) Convey that MA organization has been approved by the National Committee for Quality Assurance (NCQA) to operate as a Special Needs Plan (SNP).

(ii) Include the last contract year of NCQA approval.

(iii) Convey that the approval is based on a review of [insert Plan Name's] Model of Care.

(iv) Not include numeric SNP approval scores.

(41) *Third-party marketing organization disclaimer*. This is standardized content. If a TPMO does not sell for all MA organizations in the service area the disclaimer consists of the statement: ''We do not offer every plan available in your area. Currently we represent [insert number of organizations] organizations which offer [insert number of plans] products in your area. Please contact *Medicare.gov*, 1–800–MEDICARE, or your local State Health Insurance Program to get information on all of your options.'' If the TPMO sells for all MA organizations in the service area the disclaimer consists of the statement: ''Currently we represent [insert number of organizations] organizations which offer [insert number of plans] products in your area. You can always contact *Medicare.gov*, 1–800–MEDICARE, or your local State Health Insurance Program for help with plan choices.'' The MA organization must ensure that the disclaimer is as follows:

(i) Used by any TPMO, as defined under § 422.2260, that sells plans on behalf of more than one MA organization.

(ii) Verbally conveyed within the first minute of a sales call.

(iii) Electronically conveyed when communicating with a beneficiary through email, online chat, or other electronic means of communication.

(iv) Prominently displayed on TPMO websites.

(v) Included in any marketing materials, including print materials and television advertisements, developed, used or distributed by the TPMO.

(42) *Mid-year supplemental benefits notice*. This is a model communications material through which plans must inform each enrollee of the availability of any item or service covered as a supplemental benefit that the enrollee has not begun to use by June 30 of the plan year.

(i) The notice must be sent on an annual basis, no earlier than June 30 of the plan year, and no later than July 31 of the plan year.

(ii) The notice must include the following content:

(A) *Mandatory supplemental benefits*. For each mandatory supplemental benefit an enrollee has not used, the MA organization must include the same information about the benefit that is provided in the Evidence of Coverage.

(B) *Optional supplemental benefits*. For each optional supplemental benefit an enrollee has not used, the MA organization must include the same information about the benefit that is provided in the Evidence of Coverage.

(C) *SSBCI*. For plans that include SSBCI—

(*1*) The MA organization must include an explanation of SSBCI available under the plan (including eligibility criteria and limitations and scope of the covered items and services) and must include point-of-contact information for eligibility assessments, including providing point-of-contact information (which can be the customer service line or a separate dedicated line), with trained staff that enrollees can contact to inquire about or begin the SSBCI eligibility determination process and to address any other questions the enrollee may have about the availability of SSBCI under their plan;

(*2*) When an enrollee has been determined eligible for SSBCI but has not

used SSBCI, the MA organization must include a description of the unused SSBCI for which the enrollee is eligible, and must include a description of any limitations on the benefit; and

(*3*) The disclaimer specified at paragraph (e)(34) of this section.

(D) The information about all supplemental benefits listed in the notice must include all of the following:

(*1*) Scope of benefit.

(*2*) Applicable cost-sharing.

(*3*) Instructions on how to access the benefit.

(*4*) Any applicable network information.

(E) Supplemental benefits listed consistent with the format of the EOC.

(F) A customer service number, and required TTY number, to call for additional help.

[86 FR 6108, Jan. 19, 2021, as amended at 87 FR 27898, May 9, 2022; 88 FR 22336, Apr. 12, 2023; 88 FR 34780, May 31, 2023; 89 FR 30827, Apr. 23, 2024; 89 FR 63827, Aug. 6, 2024; 90 FR 15911, Apr. 15, 2025]

§ 422.2272 Licensing of marketing representatives and confirmation of marketing resources.

In its marketing, the MA organization must:

(a) Demonstrate to CMS' satisfaction that marketing resources are allocated to marketing to the disabled Medicare population as well as beneficiaries age 65 and over.

(b) Establish and maintain a system for confirming that enrolled beneficiaries have, in fact, enrolled in the MA plan, and understand the rules applicable under the plan.

(c) Employ as marketing representatives only individuals who are licensed by the State to conduct marketing activities (as defined in the Medicare Marketing Guidelines) in that State, and whom the organization has informed that State it has appointed, consistent with the appointment process provided for under State law.

(d) Report to the State in which the MAO appoints an agent or broker, the termination of any such agent or broker, including the reasons for such termination if State law requires that the reasons for the termination be reported.

(e) Establish and implement an oversight plan that monitors agent and broker activities, identifies non-compliance with CMS requirements, and reports non-compliance to CMS.

[73 FR 54220, Sept. 18, 2008, as amended at 73 FR 54250, Sept. 18, 2008; 76 FR 21569, Apr. 15, 2011; 83 FR 16735, Apr. 16, 2018; 88 FR 22337, Apr. 12, 2023]

§ 422.2274 Agent, broker, and other third-party requirements.

If an MA organization uses agents and brokers to sell its Medicare plans, the requirements in paragraphs (a) through (e) of this section are applicable. If an MA organization makes payments to third parties, the requirements in paragraph (f) of this section are applicable.

(a) *Definitions.* For purposes of this section, the following definitions are applicable:

Compensation. (i) Includes monetary or non-monetary remuneration of any kind relating to the sale, renewal, or services related to a plan or product offered by an MA organization including, but not limited to the following:

(A) Commissions.

(B) Bonuses.

(C) Gifts.

(D) Prizes or awards.

(E) Beginning with contract year 2025, payment of fees to comply with state appointment laws, training, certification, and testing costs.

(F) Beginning with contract year 2025, reimbursement for mileage to, and from, appointments with beneficiaries.

(G) Beginning with contract year 2025, reimbursement for actual costs associated with beneficiary sales appointments such as venue rent, snacks, and materials.

(H) Beginning with contract year 2025, any other payments made to an agent or broker that are tied to enrollment, related to an enrollment in an MA plan or product, or for services conducted as a part of the relationship associated with the enrollment into an MA plan or product.

Fair market value (FMV) means, for purposes of evaluating agent or broker compensation under the requirements of this section only, the amount that CMS determines could reasonably be

expected to be paid for an enrollment or continued enrollment into an MA plan. Beginning January 1, 2021, the national FMV is $539, the FMV for Connecticut, Pennsylvania, and the District of Columbia is $607, the FMV for California and New Jersey is $672, and the FMV for Puerto Rico and the U.S. Virgin Islands is $370. For contract year 2025, there will be a one-time increase of $100 to the FMV to account for administrative payments included under the compensation rate. For subsequent years, FMV is calculated by adding the current year FMV and the product of the current year FMV and MA growth percentage for aged and disabled beneficiaries, which is published for each year in the rate announcement issued under § 422.312.

Initial enrollment year means the first year that a beneficiary is enrolled in a plan versus subsequent years (c.f., *renewal year*) that a beneficiary remains enrolled in a plan.

Like plan type means one of the following:

(i) PDP replaced with another PDP.

(ii) MA or MA–PD replaced with another MA or MA–PD.

(iii) Cost plan replaced with another cost plan.

Plan year and *enrollment year* mean the year beginning January 1 and ending December 31.

Renewal year means all years following the initial enrollment year in the same plan or in different plan that is a like plan type.

Unlike plan type means one of the following:

(i) An MA or, MA–PD plan to a PDP or Section 1876 Cost Plan.

(ii) A PDP to a Section 1876 Cost Plan or an MA or MA–PD plan.

(iii) A Section 1876 Cost Plan to an MA or MA–PD plan or PDP.

(b) *Agent/broker requirements.* Agents and brokers who represent MA organizations must follow the requirements in paragraphs (b)(1) through (3) of this section. Representation includes selling products (including Medicare Advantage plans, Medicare Advantage-Prescription Drug plans, Medicare Prescription Drug plans, and section 1876 Cost plans) as well as outreach to existing or potential beneficiaries and answering or potentially answering questions from existing or potential beneficiaries.

(1) Be licensed and appointed under State law (if required under applicable State law).

(2) Be trained and tested annually as required under paragraph (c)(4) of this section, and achieve an 85 percent or higher on all forms of testing.

(3) Secure and document a Scope of Appointment prior to meeting with potential enrollees.

(c) *MA organization oversight.* MA organizations must oversee first tier, downstream, and related entities that represent the MA organization to ensure agents and brokers abide by all applicable State and Federal laws, regulations, and requirements. MA organizations must do all of the following:

(1) As required under applicable State law, employ as marketing representatives only individuals who are licensed by the State to conduct marketing (as defined in this subpart) of health insurance in that State, and whom the MA organization has informed that State it has appointed, consistent with the appointment process for agents and brokers provided for under State law.

(2) As required under applicable State law, report the termination of an agent or broker to the State and the reason for termination.

(3) Report to CMS all enrollments made by unlicensed agents or brokers and for-cause terminations of agents or brokers.

(4) On an annual basis, provide training and testing to agents and brokers on Medicare rules and regulations, the plan products that agents and brokers will sell, including any details specific to each plan product, and relevant State and Federal requirements.

(5) On an annual basis for plan years through 2024, by the last Friday in July, report to CMS whether the MA organization intends to use employed, captive, or independent agents or brokers in the upcoming plan year and the specific rates or range of rates the plan will pay independent agents and brokers. Following the reporting deadline, MA organizations may not change their decisions related to agent or broker type, or their compensation rates and ranges, until the next plan year.

(6) On an annual basis by October 1, have in place full compensation structures for the following plan year. The structure must include details on compensation dissemination, including specifying payment amounts for initial enrollment year and renewal year compensation.

(7) Submit agent or broker marketing materials to CMS through HPMS prior to use, following the requirements for marketing materials in this subpart.

(8) Ensure beneficiaries are not charged marketing consulting fees when considering enrollment in MA plans.

(9) Establish and maintain a system for confirming that:

(i) Beneficiaries enrolled by agents or brokers understand the product, including the rules applicable under the plan.

(ii) Agents and brokers appropriately complete Scope of Appointment records for all marketing appointments (including telephonic and walk-in).

(10) Demonstrate that marketing resources are allocated to marketing to the disabled Medicare population as well as to Medicare beneficiaries age 65 and over.

(11) Must comply with State requests for information about the performance of a licensed agent or broker as part of a state investigation into the individual's conduct. CMS will establish and maintain a memorandum of understanding (MOU) to share compliance and oversight information with States that agree to the MOU.

(12) Ensure that, prior to an enrollment, CMS' required questions and topics regarding beneficiary needs in a health plan choice are fully discussed. Topics include information regarding primary care providers and specialists (that is, whether or not the beneficiary's current providers are in the plan's network), regarding pharmacies (that is, whether or not the beneficiary's current pharmacy is in the plan's network), prescription drug coverage and costs (including whether or not the beneficiary's current prescriptions are covered), costs of health care services, premiums, benefits, and specific health care needs.

(13) Beginning with contract year 2025, ensure that no provision of a contract with an agent, broker, or other TPMO has a direct or indirect effect of creating an incentive that would reasonably be expected to inhibit an agent or broker's ability to objectively assess and recommend which plan best fits the health care needs of a beneficiary.

(d) *Compensation requirements.* MA organizations must ensure they meet the requirements in paragraphs (d)(1) through (5) of this section in order to pay compensation. These compensation requirements only apply to independent agents and brokers.

(1) *General rules.* (i) MA organizations may only pay agents or brokers who meet the requirements in paragraph (b) of this section.

(ii) For contract years through contract year 2024, MA organizations may determine, through their contracts, the amount of compensation to be paid, provided it does not exceed limitations outlined in this section. Beginning with contract year 2025, MA organizations are limited to the compensation amounts outlined in this section.

(iii) MA organizations may determine their payment schedule (for example, monthly or quarterly). Payments (including payments for AEP enrollments) must be made during the year of the beneficiary's enrollment.

(iv) MA organizations may only pay compensation for the number of months a member is enrolled.

(2) Initial enrollment year compensation. For each enrollment in an initial enrollment year for contract years through contract year 2024, MA organizations may pay compensation at or below FMV.

(i) MA organizations may pay either a full or pro-rated initial enrollment year compensation for:

(A) A beneficiary's first year of enrollment in any plan; or

(B) A beneficiary's move from an employer group plan to a non-employer group plan (either within the same parent organization or between parent organizations).

(ii) MA organizations must pay prorated initial enrollment year compensation for:

(A) A beneficiary's plan change(s) during their initial enrollment year.

(B) A beneficiary's selection of an ''unlike plan type'' change. In that case, the new plan would only pay the months that the beneficiary is enrolled, and the previous plan would recoup the months that the beneficiary was not in the plan.

(3) *Renewal compensation.* For each enrollment in a renewal year for contract years through contract year 2024, MA plans may pay compensation at a rate of up to 50 percent of FMV. For contract years beginning with contract year 2025, for each enrollment in a renewal year, MA organizations may pay compensation at 50 percent of FMV.

(i) MA plans may pay compensation for a renewal year:

(A) In any year following the initial enrollment year the beneficiary remains in the same plan; or

(B) When a beneficiary enrolls in a new ''like plan type''.

(ii) [Reserved]

(4) *Other compensation scenarios.* (i) When a beneficiary enrolls in an MA–PD, MA organizations may pay only the MA compensation (and not compensation for Part D enrollment under § 423.2274 of this chapter).

(ii) When a beneficiary enrolls in both a section 1876 Cost Plan and a stand-alone PDP, the 1876 Cost Plan sponsor may pay compensation for the cost plan enrollment and the Part D sponsor must pay compensation for the Part D enrollment.

(iii) When a beneficiary enrolls in a MA-only plan and a PDP plan, the MA plan sponsor may pay for the MA plan enrollment and the Part D plan may pay for the PDP plan enrollment.

(iv) When a beneficiary changes from two plans (for example, a MA plan and a stand-alone PDP) (dual enrollments) to one plan (MA–PD), the MA organization may only pay compensation at the renewal rate for the MA–PD product.

(5) *Additional compensation, payment, and compensation recovery requirements (Charge-backs).* (i) MA organizations must retroactively pay or recoup funds for retroactive beneficiary changes for the current and previous calendar years. MA organizations may choose to recoup or pay compensation for years prior to the previous calendar year, but they must do both (recoup amounts owed and pay amounts due) during the same year.

(ii) Compensation recovery is required when:

(A) A beneficiary makes any plan change (regardless of the parent organization) within the first three months of enrollment (known as rapid disenrollment), except as provided in paragraph (d)(5)(iii) of this section.

(B) Any other time period a beneficiary is not enrolled in a plan, but the plan paid compensation based on that time period.

(iii) Rapid disenrollment compensation recovery does not apply when:

(A) A beneficiary enrolls effective October 1, November 1, or December 1 and subsequently uses the Annual Election Period to change plans for an effective date of January 1.

(B) A beneficiary's enrollment change is not in the best interests of the Medicare program, including for the following reasons:

(*1*) Other creditable coverage (for example, an employer plan).

(*2*) Moving into or out of an institution.

(*3*) Gain or loss of employer/union sponsored coverage.

(*4*) Plan termination, non-renewal, or CMS imposed sanction.

(*5*) To coordinate with Part D enrollment periods or the State Pharmaceutical Assistance Program.

(*6*) Becoming LIS or dually eligible for Medicare and Medicaid.

(*7*) Qualifying for another plan based on special needs.

(*8*) Due to an auto, facilitated, or passive enrollment.

(*9*) Death.

(*10*) Moving out of the service area.

(*11*) Non-payment of premium.

(*12*) Loss of entitlement or retroactive notice of entitlement.

(*13*) Moving into a 5-star plan.

(*14*) Moving from an LPI plan into a plan with three or more stars.

(iv)(A) When rapid disenrollment compensation recovery applies, the entire compensation must be recovered.

(B) For other compensation recovery, plans must recover a pro-rated amount of compensation (whether paid for an initial enrollment year or renewal year) from an agent or broker equal to the number of months not enrolled.

(*1*) If a plan has paid full initial compensation, and the enrollee disenrolls prior to the end of the enrollment year, the total number of months not enrolled (including months prior to the effective date of enrollment) must be recovered from the agent or broker.

(*2*) Example: A beneficiary enrolls upon turning 65 effective April 1 and disenrolls September 30 of the same year. The plan paid full initial enrollment year compensation. Recovery is equal to 6/12ths of the initial enrollment year compensation (for January through March and October through December).

(e) *Payments other than compensation (administrative payments).* (1) For contract years through contract year 2024, payments made for services other than enrollment of beneficiaries (for example, training, customer service, agent recruitment, operational overhead, or assistance with completion of health risk assessments) must not exceed the value of those services in the marketplace.

(2) Beginning with contract year 2025, administrative payments are included in the calculation of enrollment-based compensation.

(f) *Payments for referrals.* Payments may be made to individuals for the referral (including a recommendation, provision, or other means of referring beneficiaries) to an agent, broker or other entity for potential enrollment into a plan. The payment may not exceed $100 for a referral into an MA or MA–PD plan and $25 for a referral into a PDP plan.

(g) *TPMO oversight.* In addition to any applicable FDR requirements under § 422.504(i), when doing business with a TPMO, either directly or indirectly through a downstream entity, MA plans must implement the following as a part of their oversight of TPMOs:

(1) When a TPMO is not otherwise an FDR, the MA organization is responsible for ensuring that the TPMO adheres to any requirements that apply to the MA plan.

(2) Contracts, written arrangements, and agreements between the TPMO and an MA plan, or between the TPMO and an MA plan's FDR, must ensure the TPMO:

(i) Discloses to the MA organization any subcontracted relationships used for marketing, lead generation, and enrollment.

(ii) Record all marketing, sales, and enrollment calls, including the audio portion of calls via web-based technology, in their entirety.

(iii) Reports to plans monthly any staff disciplinary actions or violations of any requirements that apply to the MA plan associated with beneficiary interaction to the plan.

(iv) Uses the TPMO disclaimer as required under § 422.2267(e)(41).

(3) Ensure that the TPMO, when conducting lead generating activities, either directly or indirectly for an MA organization, must, when applicable:

(i) Disclose to the beneficiary that his or her information will be provided to a licensed agent for future contact. This disclosure must be provided as follows:

(A) Verbally when communicating with a beneficiary through telephone.

(B) In writing when communicating with a beneficiary through mail or other paper.

(C) Electronically when communicating with a beneficiary through email, online chat, or other electronic messaging platform.

(ii) Disclose to the beneficiary that he or she is being transferred to a licensed agent who can enroll him or her into a new plan.

(4) Beginning October 1, 2024, personal beneficiary data collected by a TPMO for marketing or enrolling them into an MA plan may only be shared with another TPMO when prior express written consent is given by the beneficiary. Prior express written consent from the beneficiary to share the data and be contacted for marketing or enrollment purposes must be obtained through a clear and conspicuous disclosure that lists each entity receiving the data and allows the beneficiary to consent or reject to the sharing of their data with each individual TPMO.

[86 FR 6112, Jan. 19, 2021, as amended at 87 FR 27899, May 9, 2022; 88 FR 22337, Apr. 12, 2023; 89 FR 30829, Apr. 23, 2024; 89 FR 63827, Aug. 6, 2024]

§ 422.2276 Employer group retiree marketing.

MA organizations may develop marketing materials designed for members of an employer group who are eligible for employer-sponsored benefits through the MA organization, and furnish these materials only to the group members. These materials are not subject to CMS prior review and approval.

Subpart W [Reserved]

Subpart X—Requirements for a Minimum Medical Loss Ratio

SOURCE: 78 FR 31307, May 23, 2013, unless otherwise noted.

§ 422.2400 Basis and scope.

This subpart is based on sections 1857(e)(4), 1860D–12(b)(3)(D), and 1106 of the Act, and sets forth medical loss ratio requirements for Medicare Advantage organizations, financial penalties and sanctions against MA organizations when minimum medical loss ratios are not achieved by MA organizations, and release of medical loss ratio data to entities outside of CMS.

[81 FR 80557, Nov. 15, 2016]

§ 422.2401 Definitions.

Non-claims costs means those expenses for administrative services that are not—

(1) Incurred claims (as provided in § 422.2420(b)(2) through (4));

(2) Expenditures on quality improving activities (as provided in § 422.2430);

(3) Licensing and regulatory fees (as provided in § 422.2420(c)(2)(i));

(4) State and Federal taxes and assessments (as provided in § 422.2420(c)(2)(ii) and (iii)).

[78 FR 31307, May 23, 2013; 78 FR 43821, July 22, 2013]

§ 422.2410 General requirements.

(a) For contracts beginning in 2014 or later, an MA organization (defined at § 422.2) is required to report the information required under § 422.2460 for each contract under this part for each contract year.

(b) *MLR requirement.* If CMS determines for a contract year that an MA organization has an MLR for a contract that is less than 0.85, the MA organization has not met the MLR requirement and must remit to CMS an amount equal to the product of the following:

(1) The total revenue of the MA contract for the contract year.

(2) The difference between 0.85 and the MLR for the contract year.

(c) If CMS determines that an MA organization has an MLR for a contract that is less than 0.85 for 3 or more consecutive contract years, CMS does not permit the enrollment of new enrollees under the contract for coverage during the second succeeding contract year.

(d) If CMS determines that an MA organization has an MLR for a contract that is less than 0.85 for 5 consecutive contract years, CMS terminates the contract per § 422.510(b)(1) and (d) effective as of the second succeeding contract year.

[78 FR 31307, May 23, 2013, as amended at 83 FR 16736, Apr. 16, 2018]

§ 422.2420 Calculation of the medical loss ratio.

(a) *Determination of MLR.* (1) The MLR for each contract under this part is the ratio of the numerator (as defined in paragraph (b) of this section) to the denominator (as defined in paragraph (c) of this section). An MLR may be increased by a credibility adjustment according to the rules at § 422.2440, or subject to an adjustment determined by CMS to be warranted based on exceptional circumstances for areas outside the 50 states and the District of Columbia.

(2) The MLR for an MA contract—

(i) Not offering Medicare prescription drug benefits must only reflect costs and revenues related to the benefits defined at § 422.100(c); and

(ii) That includes MA–PD plans (defined at § 422.2) must also reflect costs and revenues for benefits described at § 423.104(d) through (f) of this chapter.

(b) Determining the *MLR numerator.* (1) For a contract year, the numerator of the MLR for an MA contract (other than an MSA contract) must equal the sum of paragraphs (b)(1)(i) through (iii) of this section, and the numerator of the MLR for an MSA contract must equal the sum of paragraphs (b)(1)(i),

(iii), and (iv) of this section. The numerator must be determined in accordance with paragraphs (b)(5) and (6) of this section.

(i) Incurred claims for all enrollees, as defined in paragraphs (b)(2) through (4) of this section.

(ii) The amount of the reduction, if any, in the Part B premium for all MA plan enrollees under the contract for the contract year.

(iii) The expenditures under the contract for activities that improve health care quality, as defined in § 422.2430.

(iv) The amount of the annual deposit into the medical savings account described at § 422.4(a)(2).

(2) *Incurred claims for clinical services and prescription drug costs.* Incurred claims must include the following:

(i) Amounts that the MA organization pays (including under capitation contracts) for covered services, described at paragraph (a)(2) of this section, provided to all enrollees under the contract.

(ii) For an MA contract that includes MA–PD plans (described in paragraph (a)(2) of this section), drug costs provided to all enrollees under the contract, as defined at § 423.2420(b)(2)(i) of this chapter.

(iii) Unpaid claims reserves for the current contract year, including claims reported in the process of adjustment.

(iv) Percentage withholds from payments made to contracted providers.

(v) Incurred but not reported claims based on past experience, and modified to reflect current conditions such as changes in exposure, claim frequency or severity.

(vi) Changes in other claims-related reserves.

(vii) Claims that are recoverable for anticipated coordination of benefits.

(viii) Claims payments recoveries received as a result of subrogation.

(ix) [Reserved]

(x) Reserves for contingent benefits and the medical claim portion of lawsuits.

(xi) The amount of incentive and bonus payments made to providers.

(3) Adjustments that must be deducted from incurred claims include the following:

(i) Overpayment recoveries received from providers.

(4) *Exclusions from incurred claims.* The following amounts must not be included in incurred claims:

(i) Non-claims costs, as defined in § 422.2401, which include the following:

(A) Amounts paid to third party vendors for secondary network savings.

(B) Amounts paid to third party vendors for any of the following:

(*1*) Network development.

(*2*) Administrative fees.

(*3*) Claims processing.

(*4*) Utilization management.

(C) Amounts paid, including amounts paid to a provider, for professional or administrative services that do not represent compensation or reimbursement for covered services provided to an enrollee, such as the following:

(*1*) Medical record copying costs.

(*2*) Attorneys' fees.

(*3*) Subrogation vendor fees.

(*4*) Bona fide service fees.

(*5*) Compensation to any of the following:

(*i*) Paraprofessionals.

(*ii*) Janitors.

(*iii*) Quality assurance analysts.

(*iv*) Administrative supervisors.

(*v*) Secretaries to medical personnel.

(*vi*) Medical record clerks.

(D) Unsettled balances from the Medicare Prescription Payment Plan.

(ii) Amounts paid to CMS as a remittance under § 422.2410(b).

(5) Incurred claims under this part for policies issued by one MA organization and later assumed by another entity must be reported by the assuming organizations for the entire MLR reporting year during which the policies were assumed and no incurred claims under this part for that contract year must be reported by the ceding MA organization.

(6) Reinsured incurred claims for a block of business that was subject to indemnity reinsurance and administrative agreements effective before March 23, 2010, for which the assuming entity is responsible for 100 percent of the ceding entity's financial risk and takes on all of the administration of the block, must be reported by the assuming issuer and must not be reported by the ceding issuer.

(c) *Determining the MLR denominator.* For a contract year, the denominator of the MLR for an MA contract must

equal the total revenue under the contract. Total revenue under the contract is as described in paragraph (c)(1) of this section, net of deductions described in paragraph (c)(2) of this section, taking into account the exclusions described in paragraph (c)(3) of this section, and n accordance with paragraphs (c)(4) and (c)(5) of this section.

(1) CMS' payments to the MA organization for all enrollees under a contract, reported on a direct basis, including the following:

(i) Payments under §422.304(a)(1) through (3) and (c).

(ii) The amount applied to reduce the Part B premium, as provided under §422.266(b)(3).

(iii) Payments under §422.304(b)(1), as reconciled per §423.329(c)(2)(ii) of this chapter.

(iv) All premiums paid by or on behalf of enrollees to the MA organization as a condition of receiving coverage under an MA plan, including CMS' payments for low income premium subsidies under §422.304(b)(2).

(v) All unpaid premium amounts that an MA organization could have collected from enrollees in the MA plan(s) under the contract.

(vi) All changes in unearned premium reserves.

(vii) Payments under §423.315(e) of this chapter.

(2) The following amounts must be deducted from total revenue in calculating the MLR:

(i) *Licensing and regulatory fees.* (A) Statutory assessments to defray the operating expenses of any State or Federal department, such as the ''user fee'' described in section 1857(e)(2) of the Act.

(B) Examination fees in lieu of premium taxes as specified by State law.

(ii) *Federal taxes and assessments.* All Federal taxes and assessments allocated to health insurance coverage.

(iii) *State taxes and assessments.* State taxes and assessments such as the following:

(A) Any industry-wide (or subset) assessments (other than surcharges on specific claims) paid to the State directly.

(B) Guaranty fund assessments.

(C) Assessments of State industrial boards or other boards for operating expenses or for benefits to sick employed persons in connection with disability benefit laws or similar taxes levied by States.

(D) State income, excise, and business taxes other than premium taxes.

(iv) *Community benefit expenditures.* Community benefit expenditures are payments made by a Federal income tax-exempt MA organization for community benefit expenditures as defined in paragraph (c)(2)(iv)(A) of this section, limited to the amount defined in paragraph (c)(2)(iv)(B) of this section, and allocated to a contract as required under paragraph (d)(1) of this section.

(A) Community benefit expenditures means expenditures for activities or programs that seek to achieve the objectives of improving access to health services, enhancing public health and relief of government burden.

(B) Such payment may be deducted up to the limit of either 3 percent of total revenue under this part or the highest premium tax rate in the State for which the Part D sponsor is licensed, multiplied by the Part D sponsor's earned premium for the contract.

(3) The following amounts must not be included in total revenue:

(i) The amount of unpaid premiums for which the MA organization can demonstrate to CMS that it made a reasonable effort to collect.

(ii) The following EHR payments and adjustments:

(A) EHR incentive payments for meaningful use of certified electronic health records by qualifying MAOs, MA EPs and MA-affiliated eligible hospitals that are administered under 42 CFR part 495 subpart C.

(B) EHR payment adjustments for a failure to meet meaningful use requirements that are administered under 42 CFR part 495 subpart C.

(iii) Coverage Gap Discount Program payments under §423.2320 of this chapter.

(4) Total revenue (as defined at §422.2420(c)) for policies issued by one MA organization and later assumed by another entity must be reported by the assuming entity for the entire MLR reporting year during which the policies were assumed and no revenue under

this part for that contract year must be reported by the ceding MA organization.

(5) Total revenue (as defined at § 422.2420(c)) that is reinsured for a block of business that was subject to indemnity reinsurance and administrative agreements effective prior to March 23, 2010, for which the assuming entity is responsible for 100 percent of the ceding entity's financial risk and takes on all of the administration of the block, must be reported by the assuming issuer and must not be reported by the ceding issuer.

(d) *Allocation of expense*—(1) *General requirements.* (i) Each expense must be included under only one type of expense, unless a portion of the expense fits under the definition of or criteria for one type of expense and the remainder fits into a different type of expense, in which case the expense must be prorated between types of expenses.

(ii) Expenditures that benefit multiple contracts, or contracts other than those being reported, including but not limited to those that are for or benefit self-funded plans, must be reported on a pro rata share.

(2) *Description of the methods used to allocate expenses.* (i) Allocation to each category must be based on a generally accepted accounting method that is expected to yield the most accurate results. Specific identification of an expense with an activity that is represented by one of the categories in paragraph (b) or (c) of this section will generally be the most accurate method.

(ii) Shared expenses, including expenses under the terms of a management contract, must be apportioned pro rata to the contracts incurring the expense.

(iii)(A) Any basis adopted to apportion expenses must be that which is expected to yield the most accurate results and may result from special studies of employee activities, salary ratios, premium ratios or similar analyses.

(B) Expenses that relate solely to the operations of a reporting entity, such as personnel costs associated with the adjusting and paying of claims, must be borne solely by the reporting entity and are not to be apportioned to other entities within a group.

[78 FR 31307, May 23, 2013; 78 FR 43821, July 22, 2013; 83 FR 16736, Apr. 16, 2018; 85 FR 33908, June 2, 2020; 90 FR 15911, Apr. 15, 2025]

§ 422.2430 Activities that improve health care quality.

(a) *Activity requirements.* (1) Activities conducted by an MA organization to improve quality must either—

(i) Fall into one of the categories in paragraph (a)(2) of this section and meet all of the requirements in paragraph (a)(3) of this section; or

(ii) Be listed in paragraph (a)(4) of this section.

(2) *Categories of quality improving activities.* The activity must be designed to achieve one or more of the following:

(i) To improve health outcomes through the implementation of activities such as quality reporting, effective case management, care coordination, chronic disease management, and medication and care compliance initiatives, including through the use of the medical homes model as defined for purposes of section 3602 of the Patient Protection and Affordable Care Act, for treatment or services under the plan or coverage.

(ii) To prevent hospital readmissions through a comprehensive program for hospital discharge that includes patient-centered education and counseling, comprehensive discharge planning, and post-discharge reinforcement by an appropriate health care professional.

(iii) To improve patient safety and reduce medical errors through the appropriate use of best clinical practices, evidence-based medicine, and health information technology under the plan or coverage.

(iv) To promote health and wellness.

(v) To enhance the use of health care data to improve quality, transparency, and outcomes and support meaningful use of health information technology. Such activities, such as Health Information Technology (HIT) expenses, are required to accomplish the activities that improve health care quality and that are designed for use by health

plans, health care providers, or enrollees for the electronic creation, maintenance, access, or exchange of health information, and are consistent with meaningful use requirements, and which may in whole or in part improve quality of care, or provide the technological infrastructure to enhance current quality improving activities or make new quality improvement initiatives possible.

(3) The activity must be designed for all of the following:

(i) To improve health quality.

(ii) To increase the likelihood of desired health outcomes in ways that are capable of being objectively measured and of producing verifiable results and achievements.

(iii) To be directed toward individual enrollees or incurred for the benefit of specified segments of enrollees or provide health improvements to the population beyond those enrolled in coverage as long as no additional costs are incurred due to the non-enrollees.

(iv) To be grounded in evidence-based medicine, widely accepted best clinical practice, or criteria issued by recognized professional medical associations, accreditation bodies, government agencies or other nationally recognized health care quality organizations.

(4)(i) For an MA contract that includes MA–PD plans (described in § 422.2420(a)(2)), Medication Therapy Management Programs meeting the requirements of § 423.153(d) of this chapter.

(ii) Fraud reduction activities, including fraud prevention, fraud detection, and fraud recovery.

(b) *Exclusions.* Expenditures and activities that must not be included in quality improving activities include, but are not limited to, the following:

(1) Those that are designed primarily to control or contain costs other than those that are related to fraud reduction.

(2) The pro rata share of expenses that are for lines of business or products other than those being reported, including but not limited to, those that are for or benefit self-funded plans.

(3) Those which otherwise meet the definitions for quality improving activities but which were paid for with grant money or other funding separate from premium revenue.

(4) Those activities that can be billed or allocated by a provider for care delivery and that are reimbursed as clinical services.

(5) Establishing or maintaining a claims adjudication system, including costs directly related to upgrades in health information technology that are designed primarily or solely to improve claims payment capabilities (and that are not related to fraud reduction activities under paragraph (a)(4)(ii) of this section) or to meet regulatory requirements for processing claims, including ICD–10 implementation costs in excess of 0.3 percent of total revenue under this part, and maintenance of ICD–10 code sets adopted in accordance with to the Health Insurance Portability and Accountability Act (HIPAA), 42 U.S.C. 1320d–2, as amended.

(6) That portion of the activities of health care professional hotlines that does not meet the definition of activities that improve health quality.

(7) All retrospective and concurrent utilization review.

(8) [Reserved]

(9) The cost of developing and executing provider contracts and fees associated with establishing or managing a provider network, including fees paid to a vendor for the same reason.

(10) Provider credentialing.

(11) Marketing expenses.

(12) Costs associated with calculating and administering individual enrollee or employee incentives.

(13) That portion of prospective utilization review that does not meet the definition of activities that improve health quality.

(14) Any function or activity not expressly permitted by CMS under this part.

[78 FR 31307, May 23, 2013, as amended at 83 FR 16736, Apr. 16, 2018]

§ 422.2440 Credibility adjustment.

(a) An MA organization may add the credibility adjustment specified under paragraph (e) of this section to a contract's MLR if the contract's experience is partially credible, as defined in paragraph (d)(1) of this section.

(b) An MA organization may not add a credibility adjustment to a contract's

MLR if the contract's experience is fully credible, as defined in paragraph (d)(2) of this section.

(c) For those contract years for which a contract has non-credible experience, as defined in paragraph (d)(3) of this section, sanctions under § 422.2410(b) through (d) will not apply.

(d)(1) A contract's experience is partially credible if it is based on the experience of at least 2,400 member months and fewer than or equal to 180,000 member months.

(2) A contract's experience is fully credible if it is based on the experience of more than 180,000 member months.

(3) A contract's experience is non-credible if it is based on the experience of fewer than 2,400 member months.

(e)(1) The credibility adjustment for a partially credible MA contract, other than an MSA contract, is equal to the base credibility factor determined under paragraph (f) of this section.

(2) The credibility adjustment for a partially credible MA MSA contract is the product of the base credibility factor, as determined under paragraph (f) of this section, multiplied by the deductible factor, as determined under paragraph (g) of this section.

(f) The base credibility factor for partially credible experience is determined based on the number of member months for all enrollees under the contract and the factors shown in Table 1 of this section. When the number of member months used to determine credibility exactly matches a member month category listed in Table 1 of this section, the value associated with that number of member months is the base credibility factor. The base credibility factor for a number of member months between the values shown in Table 1 of this section is determined by linear interpolation.

(g) The deductible factor is based on the enrollment-weighted average deductible for all MSA plans under the MA MSA contract, where the deductible for each plan under the contract is weighted by the plan's portion of the total number of member months for all plans under the contract. When the weighted average deductible exactly matches a deductible category listed in Table 2 of this section, the value associated with that deductible is the deductible factor. The deductible factor for a weighted average deductible between the values shown in Table 2 of section is determined by linear interpolation.

TABLE 1 TO § 422.2440—BASE CREDIBILITY FACTORS FOR MA CONTRACTS

Member months	Base credibility factor (additional percentage points)
<2,400	N/A (Non-credible).
2,400	8.4%.
6,000	5.3%.
12,000	3.7%.
24,000	2.6%.
60,000	1.7%.
120,000	1.2%.
180,000	1.0%.
>180,000	0.0% (Fully credible).

TABLE 2 TO § 422.2440—DEDUCTIBLE FACTORS FOR MA MSA CONTRACTS

Weighted average deductible	Deductible factor
<$2,500	1.000
$2,500	1.164
$5,000	1.402
≥$10,000	1.736

[85 FR 33908, June 2, 2020]

§ 422.2450 [Reserved]

§ 422.2460 Reporting requirements.

(a) Except as provided in paragraph (b) of this section, for each contract year, each MA organization must submit to CMS, in a timeframe and manner specified by CMS, a report that includes the data needed by the MA organization to calculate and verify the medical loss ratio (MLR) and remittance amount, if any, for each contract under this part, including the amount of incurred claims for original Medicare covered benefits, supplemental benefits, and prescription drugs; total revenue; expenditures on quality improving activities; non-claims costs; taxes; licensing and regulatory fees; and any remittance owed to CMS under § 422.2410.

(b) For contract years 2018 through 2022, each MA organization must submit to CMS, in a timeframe and manner specified by CMS, the following information:

(1) *Fully credible and partially credible contracts.* For each contract under this part that has fully credible or partially

credible experience, as determined in accordance with § 422.2440(d), the MA organization must report to CMS the MLR for the contract and the amount of any remittance owed to CMS under § 422.2410.

(2) *Non-credible contracts.* For each contract under this part that has non-credible experience, as determined in accordance with § 422.2440(d), the MA organization must report to CMS that the contract is non-credible.

(c) Total revenue included as part of the MLR calculation must be net of all projected reconciliations.

(d) Subject to paragraph (e) of this section, the MLR is reported once, and is not reopened as a result of any payment reconciliation processes.

(e) With respect to an MA organization that has already submitted to CMS the MLR report or MLR data required under paragraph (a) or (b) of this section, respectively, for a contract for a contract year, paragraph (d) of this section does not prohibit resubmission of the MLR report or MLR data for the purpose of correcting the prior MLR report or data submission. Such resubmission must be authorized or directed by CMS, and upon receipt and acceptance by CMS, is regarded as the contract's MLR report or data submission for the contract year for purposes of this subpart.

[83 FR 16736, Apr. 16, 2018, as amended at 87 FR 27899, May 9, 2022]

§ 422.2470 Remittance to CMS if the applicable MLR requirement is not met.

(a) *General requirement.* For each contract year, an MA organization must provide a remittance to CMS if the contract's MLR does not meet the minimum MLR requirement required by § 422.2410(b) of this subpart.

(b) *Amount of remittance.* For each contract that does not meet the MLR requirement for a contract year, the MA organization must remit to CMS the amount by which the MLR requirement exceeds the contract's actual MLR multiplied by the total revenue of the contract, as provided in § 422.2420(c), for the contract year.

(c) *Timing of remittance.* CMS deducts the remittance from plan payments in a timely manner after the MLR is reported, on a schedule determined by CMS.

(d) *Treatment of remittance.* Payment to CMS must not be included in the numerator or denominator of any year's MLR.

§ 422.2480 MLR review and non-compliance.

To ensure the accuracy of MLR reporting, CMS conducts selected review of data submitted under § 422.2460 to determine that that the MLRs and remittance amounts under § 422.2410(b) and sanctions under § 422.2410(c) and (d), were accurately calculated, reported, and applied.

(a) The reviews include a validation of amounts included in both the numerator and denominator of the MLR calculation reported to CMS.

(b) MA organizations are required to maintain evidence of the amounts reported to CMS and to validate all data necessary to calculate MLRs.

(c)(1) Documents and records must be maintained for 10 years from the date such calculations were reported to CMS with respect to a given MLR reporting year.

(2) MA organizations must require any third party vendor supplying drug or medical cost contracting and claim adjudication services to the MA organization to provide all underlying data associated with MLR reporting to that MA organization in a timely manner, when requested by the MA organization, regardless of current contractual limitations, in order to validate the accuracy of MLR reporting.

(d) Data submitted under § 422.2460, calculations, or any other MLR submission required by this subpart found to be materially incorrect or fraudulent—

(1) Is noted by CMS;

(2) Appropriate remittance amounts are recouped by CMS; and

(3) Sanctions may be imposed by CMS as provided in § 422.752.

[78 FR 31307, May 23, 2013, as amended at 83 FR 16736, Apr. 16, 2018]

§ 422.2490 Release of Part C MLR data.

(a) *Terminology.* Subject to the exclusions in paragraph (b) of this section, Part C MLR data consists of the information submitted under § 422.2460.

(b) *Exclusions from Part C MLR data.* For the purpose of this section, the following items are excluded from Part C MLR data:

(1) Narrative descriptions that MA organizations submit to support the information reported to CMS pursuant to the reporting requirements at § 422.2460, such as descriptions of expense allocation methods.

(2)(i) Information that is reported at the plan level, such as the number of member months associated with each plan under a contract, including information submitted for a contract consisting of only one plan.

(ii) Amounts that are reported as expenditures for a specific type of supplemental benefit, where the entire amount that is reported represents costs incurred by the only plan under the contract that offers that benefit.

(3) Any information that could be used to identify Medicare beneficiaries or other individuals.

(4) MLR review correspondence.

(5) Any information for a contract for those contract years for which the contract is determined to be non-credible, as defined in accordance with § 422.2440(d).

(c) *Data release.* CMS releases to the public Part C MLR data, for each contract for each contract year, no earlier than 18 months after the end of the applicable contract year.

[81 FR 80557, Nov. 15, 2016, as amended at 83 FR 16736, Apr. 16, 2018; 87 FR 27899, May 9, 2022]

Subpart Y [Reserved]

Subpart Z—Part C Recovery Audit Contractor Appeals Process

SOURCE: 79 FR 29961, May 23, 2014, unless otherwise noted.

§ 422.2600 Payment appeals.

If the Part C RAC did not apply its stated payment methodology correctly, an MA organization may appeal the findings of the applied methodology. The payment methodology itself is not subject to appeal.

§ 422.2605 Request for reconsideration.

(a) *Time for filing a request.* The request for reconsideration must be filed with the designated independent reviewer within 60 calendar days from the date of the demand letter received by the MA organization.

(b) *Content of request.* (1) The request for reconsideration must be in writing and specify the findings or issues with which the MA organization disagrees.

(2) The MA organization must include with its request all supporting documentary evidence it wishes the independent reviewer to consider.

(i) This material must be submitted in the format requested by CMS.

(ii) Documentation, evidence, or substantiation submitted after the filing of the reconsideration request will not be considered.

(c) *CMS rebuttal.* CMS may file a rebuttal to the MA organization's reconsideration request.

(1) The rebuttal must be submitted within 30 calendar days of the review entity's notification to CMS that it has received the MA organization's reconsideration request.

(2) CMS sends its rebuttal to the MA organization at the same time it is submitted to the independent reviewer.

(d) *Review entity.* An independent reviewer conducts the reconsideration. The independent reviewer reviews the demand for repayment, the evidence and findings upon which it was based and any supporting documentation that the MA organization or CMS submitted in accordance with this section.

(e) *Notification of decision.* The independent reviewer informs the CMS and the MA organization of its decision in writing.

(f) *Effect of decision.* A reconsideration decision is final and binding unless the MA organization requests a hearing official review in accordance with § 422.2610.

(g) *Right to hearing official review.* An MA organization that is dissatisfied with the independent reviewer's reconsideration decision is entitled to a hearing official review as provided in § 422.2610.

§ 422.2610 Hearing official review.

(a) *Time for filing a request.* A MA organization must file with CMS a request for a hearing official review within 30 calendar days from the date of the independent reviewer's issuance of a reconsideration determination.

(b) *Content of the request.* (1) The request must be in writing and must specify the findings or issues in the reconsideration decision with which the MA organization disagrees and the reasons for the disagreements.

(2) The MA organization must submit with its request all supporting documentation, evidence, and substantiation that it wants to be considered.

(3) No new evidence may be submitted.

(4) Documentation, evidence, or substantiation submitted after the filing of the request will not be considered.

(c) *CMS rebuttal.* CMS may file a rebuttal to the MA organization's hearing official review request.

(1) The rebuttal must be submitted within 30 calendar days of the MA organization's submission of its hearing official review request.

(2) CMS sends its rebuttal to the MA organization at the same time it is submitted to the hearing official.

(d) *Conducting a review.* A CMS-designated hearing official conducts the hearing on the record.

(1) The hearing is not to be conducted live or via telephone unless the hearing official, in his or her sole discretion, requests a live or telephonic hearing.

(2) In all cases, the hearing official's review is limited to information that meets one or more of the following:

(i) The Part C RAC used in making its determinations.

(ii) The independent reviewer used in making its determinations.

(iii) The MA organization submits with its hearing request.

(iv) CMS submits in accordance with paragraph (c) of this section.

(3) Neither the MA organization nor CMS may submit new evidence.

(e) *Hearing official decision.* The CMS hearing official decides the case within 60 days and sends a written decision to the MA organization and CMS, explaining the basis for the decision.

(f) *Effect of hearing official decision.* The hearing official's decision is final and binding, unless the decision is reversed or modified by the CMS Administrator in accordance with § 422.2615.

§ 422.2615 Review by the Administrator.

(a) *Request for review by Administrator.* If an MA organization is dissatisfied with the hearing official's decision, it may request that the CMS Administrator review the decision.

(1) The request must be filed with the CMS Administrator within 30 calendar days of the date of the hearing official's decision.

(2) The request must provide evidence or reasons to substantiate the request.

(b) *Content of request.* The MA organization must submit with its request all supporting documentation, evidence, and substantiation that it wants to be considered.

(1) Documentation, evidence, or substantiation submitted after the filing of the request will not be considered.

(2) Neither the MA organization, nor CMS may submit new evidence.

(c) *Discretionary review.* After receiving a request for review, the CMS Administrator has the discretion to review the hearing official's decision in accordance with paragraph (e) of this section or to decline to review said decision.

(d) *Notification of decision whether to review.* The Administrator notifies the MA organization within 45 days of receiving the MA organization's hearing request of whether he or she intends to review the hearing official's decision.

(1) If the Administrator agrees to review the hearing official's decision, CMS may file a rebuttal statement within 30 days of the Administrator's notice to the plan that the request for review has been accepted. CMS sends its rebuttal statement to the plan at the same time it is submitted to the Administrator.

(2) If the CMS Administrator declines to review the hearing official's decision, the hearing official's decision is final and binding.

(e) *CMS Administrator's review.* If the CMS Administrator agrees to review the hearing official's decision, he or

she determines, based upon this decision, the hearing record, and any arguments submitted by the MA organization or CMS in accordance with this section, whether the determination should be upheld, reversed, or modified. The Administrator furnishes a written decision, which is final and binding, to the MA organization and to CMS.

PART 423—VOLUNTARY MEDICARE PRESCRIPTION DRUG BENEFIT

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AUTHORITY: 42 U.S.C. 1302, 1306, 1395w–101 through 1395w–152, and 1395hh.

SOURCE: 70 FR 4525, Jan. 28, 2005, unless otherwise noted.

Subpart A—General Provisions

§ 423.1 Basis and scope.

(a) *Basis.* (1) This part is based on the indicated provisions of the following sections of the Social Security Act:

1106. Disclosure of Information in Possession of Agency.

1128J(d). Reporting and Returning of Overpayments.

1860D–1. Eligibility, enrollment, and information.

1860D–2. Prescription drug benefits.

1860D–3. Access to a choice of qualified prescription drug coverage.

1860D–4. Beneficiary protections for qualified prescription drug coverage.

1860D–11. PDP regions; submission of bids; plan approval.

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1860D–13. Premiums; late enrollment penalty.

1860D–14. Premium and cost-sharing subsidies for low-income individuals.

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1860D–16. Medicare Prescription Drug Account in the Federal Supplementary Medical Insurance Trust Fund.

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1860D–23. State pharmaceutical assistance programs.

1860D–24. Coordination requirements for plans providing prescription drug coverage.

1860D–31. Medicare prescription drug discount card and transitional assistance program.

1860D–41. Definitions; treatment of references to provisions in Part C.

1860D–42. Miscellaneous provisions.

1860D–43. Condition for coverage of drugs under this part.

(2) The following specific sections of the Medicare Modernization Act also address the prescription drug benefit program:

Sec. 102 Medicare Advantage conforming amendments.

Sec. 103 Medicaid amendments.

Sec. 104 Medigap.

Sec. 109 Expanding the work of Medicare Quality Improvement Organizations to include Parts C and D.

(3) Section 1611 of Title 8 of the United States Code regarding individuals who are not lawfully present and ineligible for Federal public benefits.

(b) *Scope*. This part establishes standards for beneficiary eligibility, access, benefits, protections, and low-income subsidies in Part D, as well as establishes standards and sets forth requirements, limitations, procedures and payments for organizations participating in the Voluntary Medicare Prescription Drug Program.

[70 FR 4525, Jan. 28, 2005, as amended at 73 FR 30683, May 28, 2008; 79 FR 29962, May 23, 2014; 80 FR 7962, Feb. 12, 2015]

§ 423.4 Definitions.

The following definitions apply to this part, unless the context indicates otherwise:

Actuarial equivalence means a state of equivalent value demonstrated through the use of generally accepted actuarial principles and in accordance with section 1860D–11(c) of the Act and with CMS actuarial guidelines.

Authorized generic drug means a drug as defined in section 505(t)(3) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(t)).

Biological product means a product licensed under section 351 of the Public Health Service Act (42 U.S.C. 262).

Biosimilar biological product means a biological product licensed under section 351(k) of the Public Health Service Act (42 U.S.C. 262(k)) that, in accordance with section 351(i)(2) of the Public Health Service Act (42 U.S.C. 262(i)(2)), is highly similar to the reference product, notwithstanding minor differences in clinically inactive components, and has no clinically meaningful differences between the biological product and the reference product, in terms of the safety, purity, and potency of the product.

Brand name biological product means a product licensed under section 351(a) (42 U.S.C. 262(a)) or 351(k) (42 U.S.C. 262(k)) of the Public Health Service Act and marketed under a brand name.

Brand name drug means a drug for which an application is approved under section 505(c) of the Federal Food, Drug, and Cosmetic Act (21 USC 355(c)), including an application referred to in section 505(b)(2) of the Federal Food, Drug and Cosmetic Act (21 USC 355(b)(2)).

Cost plan means a plan operated by a Health Maintenance Organization (HMO) or Competitive Medical Plan (CMP) in accordance with a cost-reimbursement contract under section 1876(h) of the Act.

Credible allegation of fraud means an allegation from any source, including but not limited to the following:

(1) Fraud hotline tips verified by further evidence.

(2) Claims data mining.

(3) Patterns identified through provider audits, civil false claims cases, and law enforcement investigations. Allegations are considered to be credible when they have indicia of reliability.

Downstream entity means any party that enters into a written arrangement, acceptable to CMS, with persons or entities involved with the Part D benefit, below the level of the arrangement between a Part D plan sponsor (or applicant) and a first tier entity. These written arrangements continue down to the level of the ultimate provider of both health and administrative services.

Eligible fallback entity or fallback entity is defined at § 423.855.

Fallback prescription drug plan is defined at § 423.855.

First tier entity means any party that enters into a written arrangement, acceptable to CMS, with a Part D plan sponsor or applicant to provide administrative services or health care services for a Medicare eligible individual under Part D.

Fiscally sound operation means an operation which at least maintains a positive net worth (total assets exceed total liabilities).

Formulary means the entire list of Part D drugs covered by a Part D plan.

Fraud hotline tip is a complaint or other communications that are submitted through a fraud reporting phone number or a website intended for the same purpose, such as the Federal Government's HHS OIG Hotline or a health plan's fraud hotline.

Full-benefit dual eligible individual has the meaning given the term at § 423.772, except where otherwise provided.

Generic drug means a drug for which an application under section 505(j) of the Federal Food, Drug, and Cosmetic Act (21 USC 355(j)) is approved.

Group health plan is defined at § 423.882.

Immediate need individual means a beneficiary whose enrollment into LI NET is on the basis of presumed low income subsidy eligibility and immediate need of a Part D drug.

Inappropriate prescribing means that, after consideration of all the facts and circumstances of a particular situation identified through investigation or other information or actions taken by Medicare Advantage (MA) organizations and Part D plan sponsors, there is an established pattern of potential fraud, waste, and abuse related to prescribing of opioids, as reported by the plan sponsors. Beneficiaries with cancer and sickle-cell disease, as well as those patients receiving hospice and long term care (LTC) services are excluded, when determining inappropriate prescribing. Plan sponsors may consider any number of factors including, but not limited, to the following:

(1) Documentation of a patient's medical condition.

(2) Identified instances of patient harm or death.

(3) Medical records, including claims (if available).

(4) Concurrent prescribing of opioids with an opioid potentiator in a manner that increases risk of serious patient harm.

(5) Levels of morphine milligram equivalent (MME) dosages prescribed.

(6) Absent clinical indication or documentation in the care management plan or in a manner that may indicate diversion.

(7) State-level prescription drug monitoring program (PDMP) data.

(8) Geography, time, and distance between a prescriber and the patient.

(9) Refill frequency and factors associated with increased risk of opioid overdose.

Insurance risk means, for a participating pharmacy, risk of the type commonly assumed only by insurers licensed by a State and does not include payment variations designed to reflect performance-based measures of activities within the control of the pharmacy, such as formulary compliance and generic drug substitutions, nor does it include elements potentially in the control of the pharmacy (for example, labor costs or productivity).

Interchangeable biological product means a product licensed under section 351(k) of the Public Health Service Act (42 U.S.C. 262(k)) that FDA has determined meets the standards described in section 351(k)(4) of the Public Health Service Act (42 U.S.C. 262(k)(4)), which in accordance with section 351(i)(3) of the Public Health Service Act (42 U.S.C. 262(i)(3)), may be substituted for the reference product without the intervention of the health care provider who prescribed the reference product.

Limited Income Newly Eligible Transition (LI NET) sponsor means a Part D

sponsor selected by CMS to administer the LI NET program.

MA stands for Medicare Advantage, which refers to the program authorized under Part C of title XVIII of the Act.

MA plan has the meaning given the term in § 422.2 of this chapter.

MA-PD plan means an MA plan that provides qualified prescription drug coverage.

Medicare prescription drug account means the account created within the Federal Supplementary Medical Insurance Trust Fund for purposes of Medicare Part D.

Monthly beneficiary premium means the amount calculated under § 423.286 for Part D plans other than fallback prescription drug plans, and § 423.867(a) for fallback prescription drug plans.

MTM program means a medication therapy management program described at § 423.153(d).

PACE Plan means a plan offered by a PACE organization.

PACE organization is defined in § 460.6 of this chapter.

Parent organization means the legal entity that exercises a controlling interest, through the ownership of shares, the power to appoint voting board members, or other means, in a Part D sponsor or MA organization, directly or through a subsidiary or subsidiaries, and which is not itself a subsidiary of any other legal entity.

Part D eligible individual means an individual who meets the requirements at § 423.30(a).

Part D plan (or Medicare Part D plan) means a prescription drug plan, an MA-PD plan, a PACE Plan offering qualified prescription drug coverage, or a cost plan offering qualified prescription drug coverage.

Part D plan sponsor or Part D sponsor refers to a PDP sponsor, MA organization offering a MA-PD plan, a PACE organization offering a PACE plan including qualified prescription drug coverage, and a cost plan offering qualified prescription drug coverage.

PDP region means a prescription drug plan region as determined by CMS under § 423.112.

PDP sponsor means a nongovernmental entity that is certified under this part as meeting the requirements and standards of this part that apply to entities that offer prescription drug plans. This includes fallback entities.

Pharmacist means any individual who holds a current valid license to practice pharmacy in a State or territory of the United States or the District of Columbia.

Prescription drug plan or PDP means prescription drug coverage that is offered under a policy, contract, or plan that has been approved as specified in § 423.272 and that is offered by a PDP sponsor that has a contract with CMS that meets the contract requirements under subpart K of this part. This includes fallback prescription drug plans.

Reference product means a product as defined in section 351(i)(4) of the Public Health Service Act (42 U.S.C. 262(i)(4)).

Related entity means any entity that is related to the Part D sponsor by common ownership or control and

(1) Performs some of the Part D plan sponsor's management functions under contract or delegation;

(2) Furnishes services to Medicare enrollees under an oral or written agreement; or

(3) Leases real property or sells materials to the Part D plan sponsor at a cost of more than $2,500 during a contract period.

Service area (Service area does not include facilities in which individuals are incarcerated.) means for—

(1) A prescription drug plan, an area established in § 423.112(a) within which access standards under § 423.120(a) are met;

(2) An MA-PD plan, an area that meets the definition of MA service area as described in § 422.2 of this chapter, and within which access standards under § 423.120(a) are met;

(3) A fallback prescription drug plan, the service area described in § 423.859(b);

(4) A PACE plan offering qualified prescription drug coverage, the service area described in § 460.12(c) of this chapter; and

(5) A cost plan offering qualified prescription drug coverage, the service area defined in § 417.1 of this chapter.

Subsidy-eligible individual means a full subsidy eligible individual (as defined at § 423.772) or other subsidy eligible individual (as defined at § 423.772).

Substantiated or suspicious activities of fraud, waste, or abuse means and includes, but is not limited to, allegations that a provider of services (including a prescriber) or supplier;

(1) Engaged in a pattern of improper billing;

(2) Submitted improper claims with suspected knowledge of their falsity;

(3) Submitted improper claims with reckless disregard or deliberate ignorance of their truth or falsity; or

(4) Is the subject of a fraud hotline tip verified by further evidence.

Tiered cost-sharing means a process of grouping Part D drugs into different cost sharing levels within a Part D sponsor's formulary.

Unbranded biological product means a product licensed under a biologics license application (BLA) under section 351(a) or 351(k) of the Public Health Service Act (42 U.S.C. 262(a) or 262(k)) and marketed without a brand name. It is licensed under the same BLA as the corresponding brand name biological product.

[70 FR 4525, Jan. 28, 2005, as amended at 72 FR 68731, Dec. 5, 2007; 76 FR 21570, Apr. 15, 2011; 84 FR 25671, June 3, 2019; 86 FR 6114, Jan. 19, 2021; 88 FR 22337, Apr. 12, 2023; 89 FR 30829, Apr. 23, 2024]

§ 423.6 Cost-sharing in beneficiary education and enrollment-related costs.

The requirements of section 1857(e)(2) of the Act and § 422.6 of this chapter with regard to the payment of fees established by CMS for cost sharing of enrollment related costs apply to PDP sponsors under Part D.

Subpart B—Eligibility and Enrollment

§ 423.30 Eligibility and enrollment.

(a) *General rule.* (1) An individual is eligible for Part D if he or she does all of the following:

(i) Is entitled to Medicare benefits under Part A or enrolled in Medicare Part B (but not including an individual enrolled solely for coverage of immunosuppressive drugs under § 407.1(a)(6)) of this subchapter.

(ii) Lives in the service area of a Part D plan, as defined under § 423.4.

(iii) Is a United States citizen or is lawfully present in the United States as determined in 8 CFR 1.3.

(2) Except as provided in paragraphs (b), (c), and (d) of this section, an individual is eligible to enroll in a PDP if:

(i) The individual is eligible for Part D in accordance with paragraph (a)(1) of this section;

(ii) The individual resides in the PDP's service area; and

(iii) The individual is not enrolled in another Part D plan.

(3) Retroactive Part A or Part B determinations. Individuals who become entitled to Medicare Part A or enrolled in Medicare Part B for a retroactive effective date are Part D eligible as of the month in which a notice of entitlement Part A or enrollment in Part B is provided.

(b) *Coordination with MA plans.* A Part D eligible individual enrolled in a MA-PD plan must obtain qualified prescription drug coverage through that plan. MA enrollees are not eligible to enroll in a PDP, except as follows:

(1) A Part D eligible individual is eligible to enroll in a PDP if the individual is enrolled in a MA private fee-for-service plan (as defined in section 1859(b)(2) of the Act) that does not provide qualified prescription drug coverage; and

(2) A Part D eligible individual is eligible to enroll in a PDP if the individual is enrolled in a MSA plan (as defined in section 1859(b)(3) of the Act).

(c) *Enrollment in a PACE plan.* A Part D eligible individual enrolled in a PACE plan that offers qualified prescription drug coverage under this Part must obtain such coverage through that plan.

(d) *Enrollment in a cost-based HMO or CMP.* A Part D eligible individual enrolled in a cost-based HMO or CMP (as defined under part 417 of this chapter) that elects to receive qualified prescription drug coverage under such plan is ineligible to enroll in another Part D plan. A Part D eligible individual enrolled in a cost-based HMO or CMP offering qualified prescription drug coverage is eligible to enroll in a PDP if the individual does not elect to receive qualified prescription drug coverage under the cost-based HMO or

CMP and otherwise meets the requirements of paragraph (a)(2) of this section.

[70 FR 4525, Jan. 28, 2005, as amended at 80 FR 7962, Feb. 12, 2015; 87 FR 66510, Nov. 3, 2022]

§ 423.32 Enrollment process.

(a) *General rule.* A Part D eligible individual who wishes to enroll in a PDP may enroll during the enrollment periods specified in § 423.38, by filing the appropriate enrollment form with the PDP or through other mechanisms CMS determines are appropriate.

(b) *Enrollment form or CMS-approved enrollment mechanism.* The enrollment form or CMS-approved enrollment mechanism must comply with CMS instructions regarding content and format and must have been approved by CMS as described in § 423.2262.

(1) The enrollment must be completed by the individual and include an acknowledgement by the beneficiary for disclosure and exchange of necessary information between the U.S. Department of Health and Human Services (or its designees) and the PDP sponsor. Individuals who assist beneficiaries in completing the enrollment, including authorized representatives, must indicate they have provided assistance and their relationship to the beneficiary.

(2) Part D eligible individuals enrolling or enrolled in a Part D plan must provide information regarding reimbursement for Part D costs through other insurance, group health plan or other third-party payment arrangement, and consent to the release of the information provided by the individual on other insurance, group health plan or other third-party payment arrangements, as well as any other information on reimbursement of Part D costs collected or obtained from other sources, in a form and manner approved by CMS.

(c) *Timely process an individual's enrollment request.* A PDP sponsor must timely process an individual's enrollment request in accordance with CMS enrollment guidelines and enroll Part D eligible individuals who are eligible to enroll in its plan under § 423.30(a) and who elect to enroll or are enrolled in the plan during the periods specified in § 423.38.

(d) *Notice requirement.* The PDP sponsor must provide the individual with prompt notice of acceptance or denial of the individual's enrollment request, in a format and manner specified by CMS.

(e) *Maintenance of enrollment.* An individual who is enrolled in a PDP remains enrolled in that PDP until one of the following occurs:

(i) The individual successfully enrolls in another PDP or MA-PD plan;

(ii) The individual voluntarily disenrolls from the PDP;

(iii) The individual is involuntary disenrolled from the PDP in accordance with § 423.44(b)(2);

(iv) The PDP is discontinued within the area in which the individual resides; or

(iv) The individual is enrolled after the initial enrollment, in accordance with § 423.34(c).

(f) *Enrollees of cost-based HMOs or CMPs and PACE.* Individuals enrolled in a cost-based HMO or CMP plan (as defined in part 417 of this chapter) or PACE (as defined in § 460.6 of this chapter) that offers prescription drug coverage under this part as of December 31, 2005, remain enrolled in that plan as of January 1, 2006, and receive Part D benefits offered by that plan until one of the conditions in § 423.32(e) are met.

(g) *Passive enrollment by CMS.* In situations involving either immediate terminations as provided in § 423.509(a)(5) or § 422.510(a)(5) of this chapter, or other situations in which CMS determines that remaining enrolled in a plan poses potential harm to plan members, CMS may implement passive enrollment procedures.

(1) *Passive enrollment procedures.* Individuals will be considered to have enrolled in the plan selected by CMS unless individuals—

(i) Decline the plan selected by CMS, in a form and manner determined by CMS; or

(ii) Request enrollment in another plan.

(2) *Beneficiary notification.* The organization that receives the enrollment must provide notification that describes the costs and benefits of the new plan and the process for accessing

care under the plan and the beneficiary's ability to decline the enrollment or choose another plan. Such notification must be provided to all potential enrollees prior to the enrollment effective date (or as soon as possible after the effective date if prior notice is not practical), in a form and manner determined by CMS.

(3) *Special election period.* All individuals will be provided with a special enrollment period, as described in § 423.38(c)(8)(ii).

(h) *Notification of reinstatement based on beneficiary cancellation of new enrollment.* When an individual is disenrolled from a Part D plan due to the election of a new plan, the Part D plan sponsor must reinstate the individual's enrollment in that plan if the individual cancels the election in the new plan within timeframes established by CMS. The Part D plan sponsor offering the plan from which the individual was disenrolled must send the member notification of the reinstatement within 10 calendar days of receiving confirmation of the individual's reinstatement.

(i) *Exception for employer group health plans.* (1) In cases when a PDP sponsor has both a Medicare contract and a contract with an employer, and in which the PDP sponsor arranges for the employer to process election forms for Part D eligible group members who wish to enroll under the Medicare contract, the effective date of the election may be retroactive. Consistent with § 423.343(a), payment adjustments based on a retroactive effective date may be made for up to a 90-day period.

(2) In order to obtain the effective date described in paragraph (i)(1) of this section, the beneficiary must certify that, at the time of enrollment in the PDP, he or she received the disclosure statement specified in § 423.128.

(3) Upon receipt of the election from the employer, the PDP sponsor must submit the enrollment to CMS within timeframes specified by CMS.

(j) *Authorized representatives.* As used in this subpart, an authorized representative is an individual who is the legal representative or otherwise legally able to act on behalf of an enrollee, as the law of the State in which the beneficiary resides may allow, in order to execute an enrollment or disenrollment request.

(1) The authorized representative would constitute the ''beneficiary'' or the ''enrollee'' for the purpose of making an election.

(2) Authorized representatives may include court-appointed legal guardians, persons having durable power of attorney for health care decisions, or individuals authorized to make health care decisions under state surrogate consent laws, provided they have the authority to act for the beneficiary in this capacity.

[70 FR 4525, Jan. 28, 2005, as amended at 74 FR 1543, Jan. 12, 2009; 83 FR 16736, Apr. 16, 2018; 89 FR 30830, Apr. 23, 2024]

§ 423.34 Enrollment of low-income subsidy eligible individuals.

(a) *General rule.* CMS must ensure the enrollment into Part D plans of low-income subsidy eligible individuals who fail to enroll in a Part D plan.

(b) *Definitions—Full-benefit dual-eligible individual.* For purposes of this section, a full-benefit dual eligible individual means an individual who is—

(1) Determined eligible by the State for—

(i) Medical assistance for full-benefits under Title XIX of the Act for the month under any eligibility category covered under the State plan or comprehensive benefits under a demonstration under section 1115 of the Act; or

(ii) Medical assistance under section 1902(a)(10(C) of the Act (medically needy) or section 1902(f) of the Act (States that use more restrictive eligibility criteria than are used by the SSI program) for any month if the individual was eligible for medical assistance in any part of the month.

(2) Eligible for Part D in accordance with § 423.30(a) of this subpart.

Low-income subsidy-eligible individual. For purposes of this section, a low-income subsidy eligible individual means an individual who meets the definition of full subsidy eligible (including full benefit dual eligible individuals as set forth in this section) or other subsidy eligible in § 423.772 of this part.

(c) *Reassigning low income subsidy eligible individuals*—(1) *General rule.* Notwithstanding § 423.32(e) of this subpart, during the annual coordinated election

period, CMS may reassign certain low income subsidy eligible individuals in another PDP if CMS determines that the further enrollment is warranted, except as specified in paragraph (c)(2) of this section.

(2) *Part D prescription drug plans that waive a de minimis premium amount.* If a Part D plan offering basic prescription drug coverage in the area where the beneficiary resides has a monthly beneficiary premium amount that exceeds the low-income subsidy amount by a de minimis amount, and the Part D plan volunteers to waive that de minimis amount in accordance with §423.780, then CMS does not reassign low income subsidy individuals who would otherwise be enrolled under paragraph (d)(1) of this section on the basis that the monthly beneficiary premium exceeds the low-income subsidy by a de minimis amount. A Part D plan that volunteers to waive such a de minimis amount agrees to do so for each month during the contract year for which a beneficiary qualifies for 100 percent low-income premium subsidy as provided in §423.780(f).

(d) *Automatic enrollment rules*—(1) *General rule.* Except for low income subsidy eligible individuals who are qualifying covered retirees with a group health plan sponsor, as specified in paragraph (d)(3) of this section, CMS enrolls those individuals who fail to enroll in a Part D plan into a PDP offering basic prescription drug coverage in the area where the beneficiary resides that has a monthly beneficiary premium amount that does not exceed the low income subsidy amount (as defined in §423.780(b) of this part). In the event that there is more than one PDP in an area with a monthly beneficiary premium at or below the low income premium subsidy amount, individuals are enrolled in such PDPs on a random basis.

(2) *Individuals enrolled in an MSA plan or one of the following that does not offer a Part D benefit.* Low-income subsidy eligible individuals enrolled in an MA private fee-for-service plan or cost-based HMO or CMP that does not offer qualified prescription drug coverage or an MSA plan and who fail to enroll in a Part D plan must be enrolled into a PDP plan as described in paragraph (d)(1) of this section.

(3) *Exception for individuals who are qualifying covered retirees.* (i) Full benefit dual eligible individuals who are qualifying covered retirees as defined in §423.882 of this part, and for whom CMS has approved the group health plan sponsor to receive the retirement drug subsidy described in subpart R of this part, also are automatically enrolled in a Part D plan, consistent with this paragraph, unless they elect to decline that enrollment.

(ii) Before effectuating such an enrollment, CMS provides notice to such individuals of their choices and advises them to discuss the potential impact of Medicare Part D coverage on their group health plan coverage. The notice informs individuals that they will be deemed to have declined to enroll in Part D unless they affirmatively enroll in a Part D plan or contact CMS and confirm that they wish to be auto-enrolled in a PDP. Individuals who elect not to be auto-enrolled, may enroll in Medicare Part D at a later time if they choose to do so.

(iii) All other low income subsidy eligible beneficiaries who are qualified covered retirees are not enrolled by CMS into PDPs.

(4) *Enrollment in PDP plans that voluntarily waive a de minimis premium amount.* CMS may include in the process specified in paragraph (d)(1) of this section that PDPs that voluntarily waive a de minimis amount as specified in §423.780, if CMS determines that such inclusion is warranted.

(e) *Declining enrollment and disenrollment.* Nothing in this section prevents a low income subsidy eligible individual from—

(1) Affirmatively declining enrollment in Part D; or

(2) Disenrolling from the Part D plan in which the individual is enrolled and electing to enroll in another Part D plan during the special enrollment period provided under §423.38.

(f) *Effective date of enrollment for full-benefit dual eligible individuals.* Enrollment of full-benefit dual eligible individuals under this section must be effective as follows:

(1) January 1, 2006 for individuals who are full-benefit dual-eligible individuals as of December 31, 2005.

(2) The first day of the month the individual is eligible for Part D under § 423.30(a)(1) for individuals who are Medicaid eligible and subsequently become newly eligible for Part D under § 423.30(a)(1) on or after January 1, 2006.

(3) For individuals who are eligible for Part D under § 423.30(a)(1) of this subpart and subsequently become newly eligible for Medicaid on or after January 1, 2006, enrollment is effective with the first day of the month when the individuals become eligible for both Medicaid and Part D.

(g) *Effective date of enrollment for non-full-benefit dual-eligible individuals who are low-income subsidy-eligible individuals.* The effective date for non-full-benefit dual-eligible individuals who are low-income subsidy-eligible individuals is no later than the first day of the second month after CMS determines that they meet the criteria for enrollment under this section.

[75 FR 19815, Apr. 15, 2010, as amended at 76 FR 21570, Apr. 15, 2011]

§ 423.36 Disenrollment process.

(a) *General rule.* An individual may disenroll from a PDP during the periods specified in § 423.38 by enrolling in a different PDP plan, submitting a disenrollment request to the PDP in the form and manner prescribed by CMS, or filing the appropriate disenrollment request through other mechanisms as determined by CMS.

(b) *Responsibilities of the PDP sponsor.* The PDP sponsor must—

(1) Submit a disenrollment notice to CMS within timeframes CMS specifies;

(2) Provide the enrollee with a notice of disenrollment as CMS determines and approves; and

(3) File and retain disenrollment requests for the period specified in CMS instructions.

(4) In the case of an incomplete disenrollment request—

(i) Document its efforts to obtain information to complete the disenrollment request;

(ii) Notify the individual (in writing or verbally) within 10 calendar days of receipt of the disenrollment request; and

(iii) The organization must deny the request if any additional information needed to make the disenrollment request ''complete'' is not received within the following timeframes:

(A) For disenrollment requests received during the AEP by December 7, or within 21 calendar days of the request for additional information, whichever is later; and

(B) For disenrollment requests received during all other election periods, by the end of the month in which the disenrollment request was initially received, or within 21 calendar days of the request for additional information, whichever is later.

(c) *Retroactive disenrollment.* CMS may grant retroactive disenrollment in the following cases:

(1) There never was a legally valid enrollment; or

(2) A valid request for disenrollment was properly made but not processed or acted upon.

(d) *Incomplete disenrollment.* A disenrollment request is considered to be incomplete if the required but missing information is not received by the PDP sponsor within the timeframe specified in paragraph (b)(4)(iii) of this section.

(e) *Exception for employer group health plans.* (1) In cases when a PDP sponsor has both a Medicare contract and a contract with an employer, and in which the PDP sponsor arranges for the employer to process election forms for Part D eligible group members who wish to disenroll from the Medicare contract, the effective date of the election may be retroactive. Consistent with § 423.343(a), payment adjustments based on a retroactive effective date may be made for up to a 90-day period.

(2) Upon receipt of the election from the employer, the PDP sponsor must submit the disenrollment to CMS within timeframes specified by CMS.

(f) *Effect of failure to submit disenrollment notice to CMS promptly.* If the PDP sponsor fails to submit the correct and complete notice required in paragraph (b)(1) of this section, the PDP sponsor must reimburse CMS for any capitation payments received after the month in which payment would

have ceased if the requirement had been met timely.

[70 FR 4525, Jan. 28, 2005, as amended at 89 FR 30830, Apr. 23, 2024]

§ 423.38 Enrollment periods.

(a) *Initial enrollment period for Part D—Basic rule.* The initial enrollment period is the period during which an individual is first eligible to enroll in a Part D plan.

(1) *In 2005.* An individual who is first eligible to enroll in a Part D plan on or prior to January 31, 2006, has an initial enrollment period from November 15, 2005 through May 15, 2006.

(2) *February 2006.* An individual who is first eligible to enroll in a Part D plan in February 2006 has an initial enrollment period from November 15, 2005 through May 31, 2006.

(3) *March 2006 and subsequent months.* (i) Except as provided in paragraph (a)(3)(ii) and (a)(3)(iii) of this section, the initial enrollment period for an individual who is first eligible to enroll in a Part D plan on or after March 2006 is the same as the initial enrollment period for Medicare Part B under § 407.14 of this chapter.

(ii) Exception. For those individuals who are not eligible to enroll in a Part D plan at any time during their initial enrollment period for Medicare Part B, their initial enrollment period under this Part is the 3 months before becoming eligible for Part D, the month of eligibility, and the three months following eligibility to Part D.

(iii) An individual who becomes entitled to Medicare Part A or enrolled in Part B for a retroactive effective date has an initial enrollment period under this Part beginning with the month in which notification of the Medicare determination is received and ending on the last day of the third month following the month in which the notification was received.

(b) *Annual coordinated election period*—(1) *For 2006.* This period begins on November 15, 2005 and ends on May 15, 2006.

(2) *For 2007 through 2010.* The annual coordinated election period for the following calendar year is November 15 through December 31.

(3) *For 2011 and subsequent years.* Beginning with 2011, the annual coordinated election period for the following calendar year is October 15 through December 7.

(c) *Special enrollment periods.* A Part D eligible individual may enroll in a PDP or disenroll from a PDP and enroll in another PDP or MA–PD plan (as provided at § 422.62(b) of this chapter), as applicable, under any of the following circumstances:

(1) The individual involuntarily loses creditable prescription drug coverage or such coverage is involuntarily reduced so that it is no longer creditable coverage as defined under § 423.56(a). Loss of credible prescription drug coverage due to failure to pay any required premium is not considered involuntary loss of the coverage.

(2) The individual was not adequately informed, as required by standards established by CMS under § 423.56, that he or she has lost his or her creditable prescription drug coverage, that he or she never had credible prescription drug coverage, or the coverage is involuntarily reduced so that it is no longer creditable prescription drug coverage.

(3) The individual's enrollment or non-enrollment in a Part D plan is unintentional, inadvertent, or erroneous because of the error, misrepresentation, or inaction of a Federal employee, or any person authorized by the Federal government to act on its behalf.

(4)(i) Except as provided in paragraph (ii) of this section, the individual is a full-subsidy eligible individual or other subsidy-eligible individual as defined in § 423.772, who is making a one-time-per month election into a PDP.

(ii) An individual described in paragraph (i) is not eligible for this special enrollment period if he or she has been notified that he or she has been identified as a ''potential at-risk beneficiary'' or ''at-risk beneficiary'' as defined in § 423.100 and such identification has not been terminated in accordance with § 423.153(f)).

(5) The individual elects to disenroll from a MA-PD plan and elects coverage under Medicare Part A and Part B in accordance with § 422.62(c) of this chapter.

(6) The PDP sponsor's contract is terminated by the PDP sponsor or by CMS, as provided under § 423.507

through § 423.510, or the PDP plan is no longer offered in the area when the individual resides.

(7)(i) The individual is no longer eligible for the PDP because of a change in his or her place of residence to a location outside of the PDP region(s) in which the PDP is offered; or

(ii) The individual who, as a result of a change in permanent residence, has new Part D plan options available to them.

(8) The individual demonstrates to CMS, in accordance with guidelines issued by CMS, that the PDP sponsor offering the PDP substantially violated a material provision of its contract under this part in relation to the individual, including, but not limited to any of the following:

(i) Failure to provide the individual on a timely basis benefits available under the plan.

(ii) Failure to provide benefits in accordance with applicable quality standards.

(iii) The PDP (or its agent, representative, or plan provider) materially misrepresented the plan's provisions in communications as outlined in subpart V of this part.

(9) The individual is making an election within 3 months after a gain, loss, or change to Medicaid or LIS eligibility, or notification of such a change, whichever is later.

(10) The individual is making an election within 3 months after notification of a CMS or State-initiated enrollment action or that enrollment action's effective date, whichever is later.

(11) The individual is making an enrollment request into or out of an employer sponsored Part D plan, is disenrolling from a Part D plan to take employer sponsored coverage of any kind, or is disenrolling from employer sponsored coverage (including Consolidated Omnibus Budget Reconciliation Act (COBRA) coverage) to elect a Part D plan.

(i) This special election period (SEP) is available to individuals who have (or are enrolling in) an employer or union sponsored Part D plan and ends 2 months after the month the employer or union coverage of any type ends.

(ii) The individual may choose an effective date that is not earlier than the first of the month following the month in which the election is made and no later than up to 3 months after the month in which the election is made.

(12) The individual is enrolled in a Part D plan offered by a Part D plan sponsor that has been sanctioned by CMS and elects to disenroll from that plan in connection with the matter(s) that gave rise to that sanction.

(i) Consistent with the disclosure requirements at § 423.128(f), CMS may require the sponsor to notify current enrollees that if the enrollees believe they are affected by the matter(s) that gave rise to the sanction, the enrollees are eligible for a SEP to elect another PDP.

(ii) The SEP starts with the imposition of the sanction and ends when the sanction ends or when the individual makes an election, whichever occurs first.

(13) The individual is enrolled in a section 1876 cost contract that is nonrenewing its contract for the area in which the enrollee resides.

(i) Individuals eligible for this SEP must meet Part D plan eligibility requirements.

(ii) This SEP begins December 8 of the then-current contract year and ends on the last day of February of the following year.

(14) The individual is disenrolling from a PDP to enroll in a Program of All-inclusive Care for the Elderly (PACE) organization or is enrolling in a PDP after disenrolling from a PACE organization.

(i) An individual who disenrolls from PACE has a SEP for 2 months after the effective date of PACE disenrollment to elect a PDP.

(ii) An individual who disenrolls from a PDP has a SEP for 2 months after the effective date of PDP disenrollment to elect a PACE plan.

(15) The individual moves into, resides in, or moves out of an institution, as defined by CMS, and elects to enroll in, or disenroll from, a Part D plan.

(16) The individual who is not entitled to premium free Part A and enrolls in Part B during the General Enrollment Period for Part B that starts January 1, 2023, is eligible to request enrollment in a Part D plan. The special enrollment period begins when the

individual submits their Part B application and continues for the first 2 months of Part B enrollment. The Part D plan enrollment is effective the first of the month following the month the Part D sponsor receives the enrollment request.

(17) The individual belongs to a qualified State Pharmaceutical Assistance Program (SPAP) and is requesting enrollment in a Part D plan.

(i) The individual is eligible to make one enrollment election per year.

(ii) This SEP is available while the individual is enrolled in the SPAP and, upon loss of eligibility for SPAP benefits, for an additional 2 calendar months after either the month of the loss of eligibility or notification of the loss, whichever is later.

(18) The individual is enrolled in a Part D plan and elects to disenroll from that Part D plan to enroll in or maintain other creditable prescription drug coverage.

(19)(i) The individual is enrolled in a section 1876 cost contract and an optional supplemental Part D benefit under that contract and elects a Part D plan upon disenrolling from the cost contract.

(ii) The SEP begins the month the individual requests disenrollment from the cost contract and ends when the individual makes an enrollment election or on the last day of the second month following the month the cost contract enrollment ended, whichever is earlier.

(20) The individual is requesting enrollment in a Part D plan offered by a Part D plan sponsor with a Star Rating of 5 Stars. An individual may use this SEP only once for the contract year in which the Part D plan was assigned a 5-star overall performance rating, beginning the December 8 before that contract year through November 30 of that contract year.

(21)(i) The individual is a non-U.S. citizen who becomes lawfully present in the United States.

(ii) This SEP begins the month the enrollee attains lawful presence status and ends the earlier of when the individual makes an enrollment election or 2 calendar months after the month the enrollee attains lawful presence status.

(22) The individual was adversely affected by having requested, but not received, required notices or information in an accessible format, as outlined in section 504 of the Rehabilitation Act of 1973, within the same timeframe that the Part D plan sponsor or CMS provided the same information to individuals who did not request an accessible format.

(i) The SEP begins at the end of the election period during which the individual was seeking to make an election and the length is at least as long as the time it takes for the information to be provided to the individual in an accessible format.

(ii) Part D plan sponsors may determine eligibility for this SEP when the criterion is met, ensuring adequate documentation of the situation, including records indicating the date of the individual's request, the amount of time taken to provide accessible versions of materials and the amount of time it takes for the same information to be provided to an individual who does not request an accessible format.

(23) Individuals affected by an emergency or major disaster declared by a Federal, State or local government entity are eligible for an SEP to make a Part D enrollment or disenrollment election. The SEP starts as of the date the declaration is made, the incident start date or, if different, the start date identified in the declaration, whichever is earlier. The SEP ends 2 full calendar months following the end date identified in the declaration or, if different, the date the end of the incident is announced, the date the incident automatically ends under applicable state or local law, or, if the incident end date is not otherwise identified, the incident end date specified in paragraph (c)(23)(i) of this section.

(i) If the incident end date of an emergency or major disaster is not otherwise identified, the incident end date is 1 year after the SEP start date or, if applicable, the date of a renewal or extension of the emergency or disaster declaration, whichever is later. Therefore, the maximum length of this SEP, if the incident end date is not otherwise identified, is 14 full calendar months after the SEP start date or, if

applicable, the date of a renewal or extension of the emergency or disaster declaration.

(ii)(A) Resides, or resided at the start of the SEP eligibility period described in this paragraph (c)(23), in an area for which a Federal, state or local government entity has declared an emergency or major disaster; or

(B) Does not reside in an affected area but relies on help making healthcare decisions from one or more individuals who reside in an affected area;

(iii) Was eligible for another election period at the time of SEP eligibility period described in this paragraph (c)(23); and

(iv) Did not make an election during that other election period due to the emergency or major disaster.

(24) The individual is using the SEP at §422.62(b)(8) of this chapter to disenroll from a MA plan that includes Part D benefits.

(i) This SEP permits a one-time election to enroll in a Part D plan.

(ii) This SEP begins upon disenrollment from the MA plan and continues for 2 calendar months.

(25)(i) An individual using the MA Open Enrollment Period for Institutionalized Individuals (OEPI) to disenroll from a MA plan that includes Part D benefits plan is eligible for a SEP to request enrollment in a Part D plan.

(ii) The SEP begins with the month the individual requests disenrollment from the MA plan and ends on the last day of the second month following the month MA enrollment ended.

(26) An individual using the Medicare Advantage Open Enrollment Period (MA OEP) to elect original Medicare is eligible for a SEP to make a Part D enrollment election.

(27)(i) The individual is enrolled in a MA special needs plan (SNP) and is no longer eligible for the SNP because he or she no longer meets the specific special needs status.

(ii) The individual may request enrollment in a Part D plan that begins the month the individual's special needs status changes and ends the earlier of when he or she makes an election or 3 months after the effective date of involuntary disenrollment from the SNP.

(28) The individual is found, after enrollment into a Chronic Care SNP, not to have the required qualifying condition.

(i) This individual is eligible to enroll prospectively in a Part D plan.

(ii) This SEP begins when the MA organization notifies the individual of the lack of eligibility for the Chronic Care SNP and extends through the end of that month and the following 2 calendar months.

(iii) The SEP ends when the individual makes an enrollment election or on the last day of the second of the 2 calendar months following notification of the lack of eligibility, whichever occurs first.

(29) The individual uses the SEP at §422.62(b)(15) of this chapter to enroll in a MA Private Fee-for-Service plan without Part D benefits, or enrolls in a section 1876 cost plan, is eligible to request enrollment in a PDP or the cost plan's optional supplemental Part D benefit, if offered.

(i) This SEP begins the month the individual uses the SEP at §422.62(b)(15) of this chapter and continues for 2 additional months.

(ii) [Reserved]

(30) An individual who uses the SEP at §422.62(b)(23) of this chapter to disenroll from a MA plan is eligible to request enrollment in a PDP.

(i) This SEP begins the month the individual is notified of eligibility for the SEP at §422.62(b)(23) of this chapter and continues for an additional 2 calendar months.

(ii) This SEP permits one enrollment into a PDP.

(iii) This SEP ends when the individual has enrolled in the PDP.

(iv) An individual may use this SEP to request enrollment in a PDP subsequent to having submitted a disenrollment to the MA plan or may simply request enrollment in the PDP, resulting in automatic disenrollment from the MA plan.

(31) The individual is enrolled in a plan offered by a Part D plan sponsor that has been placed into receivership by a state or territorial regulatory authority. The SEP begins the month the receivership is effective and continues

until it is no longer in effect or until the enrollee makes an election, whichever occurs first. When instructed by CMS, the MA plan that has been placed under receivership must notify its enrollees, in the form and manner directed by CMS, of the enrollees' eligibility for this SEP and how to use the SEP.

(32) The individual is enrolled in a plan that has been identified with the low performing icon in accordance with § 423.186(h)(1)(ii). This SEP exists while the individual is enrolled in the low performing Part D plan.

(33) The individual was involuntarily disenrolled from an MA–PD plan due to loss of Part B but continues to be entitled to Part A. This SEP begins when the individual is advised of the loss of Part B and continues for 2 additional months.

(34) The individual enrolls in Medicare premium-Part A or Part B using an exceptional condition SEP, as described in 42 CFR parts 406.27 and 407.23. The SEP begins when the individual submits their premium-Part A or Part B application and continues for the first 2 months of enrollment in premium Part A or Part B. The Part D plan enrollment is effective the first of the month following the month the Part D plan receives the enrollment request.

(35)(i) The individual is a full-benefit dual eligible individual (as defined in § 423.772) making a one-time-per month election into a fully integrated dual eligible special needs plan as defined in § 422.2 of this chapter, a highly integrated dual eligible special needs plan as defined in § 422.2 of this chapter, or an applicable integrated plan as defined in § 422.561 of this chapter.

(ii) The SEP is available only to facilitate aligned enrollment as defined in § 422.2 of this chapter.

(36) The individual meets other exceptional circumstances as CMS may provide.

(d) *Enrollment period to coordinate with MA annual 45-day disenrollment period.* Through 2018, an individual enrolled in an MA plan who elects Original Medicare from January 1 through February 14, as described in § 422.62(a)(5) of this chapter, may also elect a PDP during this time.

(e) *Enrollment period to coordinate with MA open enrollment period.* For 2019 and subsequent years, an individual who makes an election as described in § 422.62(a)(3) of this chapter, may make an election to enroll in or disenroll from Part D coverage. An individual who elects Original Medicare during the MA open enrollment period may elect to enroll in a PDP during this time.

[70 FR 4525, Jan. 28, 2005, as amended at 75 FR 19816, Apr. 15, 2010; 76 FR 21570, Apr. 15, 2011; 83 FR 16737, Apr. 16, 2018; 85 FR 33909, June 2, 2020; 88 FR 22337, Apr. 12, 2023; 89 FR 30830, Apr. 23, 2024]

§ 423.40 Effective dates.

(a) *Initial enrollment period.* (1) An enrollment made prior to the month of entitlement to Part A or enrollment in Part B is effective the first day of the month the individual is entitled to or enrolled in Part A or enrolled in Part B.

(2) Except as otherwise provided under § 423.34(f), an enrollment made during or after the month of entitlement to Part A or enrollment in Part B is effective the first day of the calendar month following the month in which the enrollment in Part D is made.

(3) If the individual is not eligible to enroll in Part D on the first day of the calendar month following the month in which the election to enroll in Part D is made, the enrollment in Part D is effective the first day of the month the individual is eligible for Part D.

(4) In no case is an enrollment in Part D effective before January 1, 2006 or before entitlement to Part A or enrollment Part B.

(b) *Annual coordinated election periods*—(1) *General rule.* Except as provided under paragraph (b)(2) of this section, for an enrollment or change of enrollment in Part D made during an annual coordinated election period as described in § 423.38(b), the coverage or change in coverage is effective as of the first day of the following calendar year.

(2) *Exception for January 1, 2006 through May 15, 2006.* Enrollment elections made during the annual coordinated election period between January 1, 2006 and May 15, 2006 are effective the

first day of the calendar month following the month in which the enrollment in Part D is made.

(c) *Special enrollment periods.* For an enrollment or change of enrollment in Part D made during a special enrollment period specified in § 423.38(c), the coverage or change in coverage is effective the first day of the calendar month following the month in which the election is made, unless otherwise noted.

(d) *PDP enrollment period to coordinate with the MA annual disenrollment period.* Through 2018, an enrollment made from January 1 through February 14 by an individual who has disenrolled from an MA plan as described in § 422.62(a)(5) of this chapter will be effective the first day of the month following the month in which the enrollment in the PDP is made.

(e) *PDP enrollment period to coordinate with the MA open enrollment period.* For 2019 and subsequent years, an enrollment made by an individual who elects Original Medicare during the MA open enrollment period as described in § 422.62(a)(3) of this chapter, will be effective the first day of the month following the month in which the election is made.

(f) *Beneficiary choice of effective date.* If a beneficiary is eligible for more than one election period, resulting in more than one possible effective date, the Part D plan sponsor must allow the beneficiary to choose the election period that results in the individual's desired effective date.

(1) To determine the beneficiary's choice of election period and effective date, the Part D plan sponsor must attempt to contact the beneficiary and must document its attempts.

(2) If the Part D plan sponsor is unable to obtain the beneficiary's desired enrollment effective date, the Part D plan sponsor must assign an election period using the following ranking of election periods:

(i) ICEP/Part D IEP.

(ii) MA–OEP.

(iii) SEP.

(iv) AEP.

(v) OEPI.

(3) If the Part D plan sponsor is unable to obtain the beneficiary's desired disenrollment effective date, the Part D plan sponsor must assign an election period that results in the earliest disenrollment.

[70 FR 4525, Jan. 28, 2005, as amended at 76 FR 21570, Apr. 15, 2011; 83 FR 16737, Apr. 16, 2018; 85 FR 33911, June 2, 2020; 89 FR 30831, Apr. 23, 2024]

§ 423.44 Involuntary disenrollment from Part D coverage.

(a) *General rule.* Except as provided in paragraphs (b) through (d) of this section, a PDP sponsor may not—

(1) Involuntarily disenroll an individual from any PDP it offers; or

(2) Orally or in writing, or by any action or inaction, request or encourage an individual to disenroll.

(b) *Basis for disenrollment*—(1) *Optional involuntary disenrollment.* A PDP sponsor may disenroll an individual from a PDP it offers in any of the following circumstances:

(i) Any monthly premium is not paid on a timely basis, as specified under paragraph (d)(1) of this section; or

(ii) The individual has engaged in disruptive behavior, as specified under paragraph (d)(2) of this section.

(iii) The individual provides fraudulent information on his or her election form or permits abuse of his or her enrollment card as specified in paragraph (d)(9) of this section.

(2) *Required involuntary disenrollment.* A PDP sponsor must disenroll an individual from a PDP it offers in any of the following circumstances:

(i) The individual no longer resides in the PDP's service area.

(ii) The individual loses eligibility for Part D.

(iii) Death of the individual.

(iv) The PDP sponsor's contract is terminated by CMS or by a PDP or through mutual consent. The PDP sponsor must disenroll affected enrollees in accordance with the procedures for disenrollment set forth at § 423.507 through § 423.510.

(v) The individual materially misrepresents information, as determined by CMS, to the PDP sponsor that the individual has or expects to receive reimbursement for third-party coverage.

(vi) The individual is not lawfully present in the United States.

(c) *Notice requirement.* (1) If the disenrollment is for any of the reasons

specified in paragraphs (b)(1), (b)(2)(i), or (b)(2)(iv) of this section (that is, other than death or loss of Part D eligibility, the PDP sponsor must give the individual timely notice of the disenrollment with an explanation of why the PDP is planning to disenroll the individual.

(2) Notices for reasons specified in paragraphs (b)(1) through (b)(2)(i) and (b)(2)(iii) of this section must—

(i) Be provided to the individual before submission of the disenrollment notice to CMS; and

(ii) Include an explanation of the individual's right to file a grievance under the PDP's grievance procedures.

(d) *Process for disenrollment*—(1) Except as specified in paragraph (d)(1)(v) of this section, a PDP sponsor may disenroll an individual from the PDP for failure to pay any monthly premium under the following circumstances:

(i) The PDP sponsor can demonstrate to CMS that it made reasonable efforts to collect the unpaid premium amount.

(ii) The PDP sponsor gives the enrollee notice of disenrollment that meets the requirements set forth in paragraph (c) of this section.

(iii) The PDP sponsor provides the individual with a grace period, that is, an opportunity to pay past due premiums in full. The grace period must—

(A) Be at least 2 whole calendar months; and

(B) Begin on the first day of the month for which the premium is unpaid or the first day of the month following the date on which premium payment is requested, whichever is later.

(iv) *Reenrollment in the PDP.* If an individual is disenrolled from the PDP for failure to pay monthly PDP premiums, the PDP sponsor has the option to decline future enrollment by the individual in any of its PDPs until the individual has paid any past premiums due to the PDP sponsor.

(v) A PDP sponsor may not disenroll either of the following:

(A) An individual who had monthly premiums withheld per §423.293(a) and (e) of this part or who is in premium withhold status, as defined by CMS.

(B) A member or initiate the disenrollment process if the sponsor has been notified that an SPAP, or other payer, is paying the Part D portion of the premium, and the sponsor has not yet coordinated receipt of the premium payments with the SPAP or other payer.

(vi) *Extension of grace period for good cause and reinstatement.* When an individual is disenrolled for failure to pay the plan premium, CMS (or a third party to which CMS has assigned this responsibility, such as a Part D sponsor) may reinstate enrollment in the PDP, without interruption of coverage, if the individual does all of the following:

(A) Submits a request for reinstatement for good cause within 60 calendar days of the disenrollment effective date.

(B) Has not previously requested reinstatement for good cause during the same 60-day period following the involuntary disenrollment.

(C) Shows good cause for failure to pay within the initial grace period.

(D) Pays all overdue premiums within 3 calendar months after the disenrollment date.

(E) Establishes by a credible statement that failure to pay premiums within the initial grace period was due to circumstances for which the individual had no control, or which the individual could not reasonably have been expected to foresee.

(vii) *No extension of grace period.* A beneficiary's enrollment in the PDP may not be reinstated if the only basis for such reinstatement is a change in the individual's circumstances subsequent to the involuntary disenrollment for non-payment of premiums.

(2) *Disruptive behavior*—(i) *Definition.* A PDP enrollee is disruptive if his or her behavior substantially impairs the plans ability to arrange or provide for services to the individual or other plan members. An individual cannot be considered disruptive if the behavior is related to the use of medical services or compliance (or noncompliance) with medical advice or treatment.

(ii) *Basis of disenrollment for disruptive behavior.* A PDP may disenroll an individual whose behavior is disruptive as defined in §423.44(d)(2)(i) only after the PDP sponsor meets the requirements described in this section and after CMS has reviewed and approved the request.

(iii) *Effort to resolve the problem.* The PDP sponsor must make a serious effort to resolve the problems presented by the individual, including providing reasonable accommodations, as determined by CMS, for individuals with mental or cognitive conditions, including mental illness, Alzheimer's disease, and developmental disabilities. In addition, the PDP sponsor must inform the individual of the right to use the PDP's grievance procedures, through the notices described in paragraph (d)(2)(viii) of this section. The individual has a right to submit any information or explanation that he or she may wish to the PDP.

(iv) *Documentation.* The PDP sponsor—

(A) Must document the enrollee's behavior, its own efforts to resolve any problems, as described in paragraph (d)(2)(iii) of this section, and any extenuating circumstances;

(B) May request from CMS the ability to decline future enrollment by the individual; and

(C) Must submit the following:

(*1*) The information specified in paragraph (d)(2)(iv)(A) of this section.

(*2*) Any documentation received by the individual to CMS.

(*3*) Dated copies of the notices required in paragraph (d)(2)(viii) of this section.

(v) *CMS review of the proposed disenrollment.* CMS reviews the information submitted by the PDP sponsor and any information submitted by the individual (which the PDP sponsor has submitted to CMS) to determine if the PDP sponsor has fulfilled the requirements to request disenrollment for disruptive behavior. If the PDP sponsor has fulfilled the necessary requirements, CMS reviews the information and make a decision to approve or deny the request for disenrollment, including conditions on future enrollment, within 20 working days. During the review, CMS ensures that staff with appropriate clinical or medical expertise reviews the case before making a final decision. The PDP sponsor is required to provide a reasonable accommodation, as determined by CMS, for the individual in exceptional circumstances that CMS deems necessary. CMS notifies the PDP sponsor within 5 working days after making its decision.

(vi) *Exception for fallback prescription drug plans.* CMS reserves the right to deny a request from a fallback prescription drug plan as defined in *§ 423.855* to disenroll an individual for disruptive behavior.

(vii) *Effective date of disenrollment.* If CMS permits a PDP to disenroll an individual for disruptive behavior, the termination is effective the first day of the calendar month after the month in which the PDP gives the individual written notice of the disenrollment that meets the requirements set forth in paragraph (c) of this section.

(viii) *Required notices.* The PDP sponsor must provide the individual two notices prior to submitting the request for disenrollment to CMS.

(A) The first notice, the advance notice, informs the member that continued disruptive behavior could lead to involuntary disenrollment and provides the individual an opportunity to cease the behavior in order to avoid the disenrollment action.

(*1*) If the disruptive behavior ceases after the member receives the advance notice and then later resumes, the sponsor must begin the process again.

(*2*) The sponsor must wait at least 30 days after sending the advance notice before sending the second notice, during which 30-day period the individual has the opportunity to cease their behavior.

(B) The second notice, the notice of intent to request CMS permission to disenroll the member, notifies the member that the PDP sponsor requests CMS permission to involuntarily disenroll the member.

(*1*) This notice must be provided prior to submission of the request to CMS.

(*2*) These notices are in addition to the disenrollment submission notice required under § 423.44(c).

(3) *Loss of Part D eligiblity.* If an individual is no longer eligible for Part D, CMS notifies the PDP that the disenrollment is effective the first day of the calendar month following the last month of Part D eligibility.

(4) *Death of the individual.* If the individual dies, disenrollment is effective the first day of the calendar month following the month of death.

(5) *Individual no longer resides in the PDP service area—Basis for disenrollment.* (i) *Basis for disenrollment.* The PDP must disenroll an individual, and must document the basis for such action, if the PDP establishes, on the basis of a written statement from the individual or other evidence acceptable to CMS, that the individual has permanently moved out of the PDP service area and must give the individual a written notice of the disenrollment that meets the requirements set forth in paragraph (c) of this section within 10 calendar days of the plan's confirmation of the individual's residence outside of the plan service area.

(ii) *Special rule.* If the individual has not moved from the PDP service area, but has been determined by the PDP sponsor to be absent from the service area for more than 12 consecutive months, the PDP sponsor must disenroll the individual from the plan, and document the basis for such action, effective on the first day of the 13th month after the individual left the service area and must give the individual a written notice of the disenrollment that meets the requirements set forth in paragraph (c) of this section within the first 10 calendar days of the 12th month of an individual's temporary absence from the plan service area or, if the sponsor learns of the individual's temporary absence from the plan service area after the expiration of the 12 month period, within 10 calendar days of the sponsor learning of the absence. The individual is considered to be temporarily absent from the plan service area when one or more of the required materials and content referenced in §423.2267(e), if provided by mail, is returned to the Part D plan sponsor by the U.S. Postal Service as undeliverable and a forwarding address is not provided.

(iii) *Incarceration.* The PDP must disenroll an individual if the PDP establishes, on the basis of evidence acceptable to CMS, that the individual is incarcerated and does not reside in the service area of the PDP as specified at §423.4 or when notified of an incarceration by CMS as specified in paragraph (d)(5)(iv) of this section.

(iv) *Notification by CMS of incarceration.* When CMS notifies the PDP of the disenrollment due to the individual being incarcerated and not residing in the service area of the PDP as per §423.4, disenrollment is effective the first of the month following the start of incarceration, unless otherwise specified by CMS.

(6) *Plan termination.* (i) When a PDP contract terminates as provided in §423.507 through §423.510, the PDP sponsor must give each affected PDP enrollee notice of the effective date of the plan termination and a description of alternatives for obtaining prescription drug coverage under Part D, as specified by CMS.

(ii) The notice must be sent before the effective date of the plan termination or area reduction, and in the timeframes specified by CMS.

(7) *Misrepresentation of third-party reimbursement.* (i) If CMS determines an individual has materially misrepresented information to the PDP sponsor as described under §423.44(b)(2)(v), the termination is effective the first day of the calendar month after the month in which the PDP sponsor gives the individual written notice of the disenrollment that meets the requirements set forth in paragraph (c) of this section.

(ii) *Reenrollment in the PDP.* Once an individual is disenrolled from the PDP for misrepresentation of third party reimbursement, the PDP sponsor has the option to decline future enrollment by the individual in any of its PDPs for a period of time CMS specifies.

(8) *Individual is not lawfully present in the United States.* Disenrollment is effective the first day of the month following notice by CMS that the individual is ineligible in accordance with §423.30(a)(1)(iii).

(9) *Individual commits fraud or permits abuse of enrollment card*—(i) *Basis for disenrollment.* A PDP may disenroll the individual from a Part D plan if the individual—

(A) Knowingly provides, on the election form, fraudulent information that materially affects the individual's eligibility to enroll in the PDP; or

(B) Intentionally permits others to use his or her enrollment card to obtain drugs under the PDP.

(ii) *Notice of disenrollment.* The Part D plan must give the individual a written

notice of the disenrollment that meets the requirements set forth in paragraph (c) of this section.

(iii) *Report to CMS.* The Part D plan must report to CMS any disenrollment based on fraud or abuse by the individual.

(e) *Involuntary disenrollment by CMS*—(1) *General rule.* CMS will disenroll individuals who fail to pay the Part D income related monthly adjustment amount (Part D—IRMAA) specified in § 423.286(d)(4) and § 423.293(d) of this part.

(2) *Initial grace period.* For all Part D—IRMAA amounts directly billed to an enrollee in accordance with § 423.293(d)(2), the grace period ends with the last day of the third month after the billing month.

(3) *Extension of grace period for good cause and reinstatement.* When an individual is disenrolled for failing to pay the Part D—IRMAA within the initial grace period specified in paragraph (e)(2) of this section, CMS (or an entity acting on behalf of CMS) may reinstate enrollment, without interruption of coverage, if the individual shows good cause as specified in § 423.44(d)(1)(vi), pays all Part D—IRMAA arrearages, and any overdue premiums due the Part D plan sponsor within 3 calendar months after the disenrollment date.

(4) *Notice of termination.* Where CMS has disenrolled an individual in accordance with paragraph (e)(1) of this section, the Part D plan sponsor must provide notice of termination in a form and manner determined by CMS.

(5) *Effective date of disenrollment.* After a grace period and notice of termination has been provided in accordance with paragraphs (e)(2) and (4) of this section, the effective date of disenrollment is the first day following the last day of the initial grace period.

[70 FR 4525, Jan. 28, 2005, as amended at 74 FR 1543, Jan. 12, 2009; 75 FR 19816, Apr. 15, 2010; 76 FR 21570, Apr. 15, 2011; 79 FR 29962, May 23, 2014; 80 FR 7962, Feb. 12, 2015; 89 FR 30831, Apr. 23, 2024; 89 FR 63827, Aug. 6, 2024]

§ 423.46 Late enrollment penalty.

(a) *General.* A Part D eligible individual must pay the late penalty described under § 423.286(d)(3), except as described at § 423.780(e), if there is a continuous period of 63 days or longer at any time after the end of the individual's initial enrollment period during which the individual meets all of the following conditions:

(1) The individual was eligible to enroll in a Part D plan;

(2) The individual was not covered under any creditable prescription drug coverage; and

(3) The individual was not enrolled in a Part D plan.

(b) *Role of Part D plan in determination of the penalty.* Part D sponsors must obtain information on prior creditable coverage from all enrolled or enrolling beneficiaries and report this information to CMS in a form and manner determined by CMS.

(c) *Reconsideration.* Individuals determined to be subject to a late enrollment penalty may request reconsideration of this determination, consistent with § 423.56(g) of this part. Such review will be conducted by CMS, or an independent review entity contracted by CMS, in accordance with guidance issued by CMS. Decisions made through this review are not subject to appeal, but may be reviewed and revised at the discretion of CMS.

(d) *Record retention.* Part D plan sponsors must retain all information collected concerning a creditable coverage period determination in accordance with the enrollment records retention requirements described in § 423.505(e)(1)(iii).

[70 FR 4525, Jan. 28, 2005, as amended at 73 FR 54251, Sept. 18, 2008; 74 FR 1543, Jan. 12, 2009]

§ 423.48 Information about Part D.

Each Part D plan must provide, on an annual basis, and in a format and using standard terminology that CMS may specify in guidance, the information necessary to enable CMS to provide to current and potential Part D eligible individuals the information they need to make informed decisions among the available choices for Part D coverage.

§ 423.56 Procedures to determine and document creditable status of prescription drug coverage.

(a) *Definition*. Creditable prescription drug coverage means any of the following types of coverage listed in paragraph (b) of this section only if the actuarial value of the coverage equals or exceeds the actuarial value of defined standard prescription drug coverage under Part D in effect at the start of such plan year, not taking into account the value of any discount or coverage provided during the coverage gap, and demonstrated through the use of generally accepted actuarial principles and in accordance with CMS guidelines.

(b) *Types of coverage*. The following coverage is considered creditable if it meets the definition provided in paragraph (a) of this section:

(1) Prescription drug coverage under a PDP or MA-PD plan.

(2) Medicaid coverage under title XIX of the Act or under a waiver under section 1115 of the Act.

(3) Coverage under a group health plan, including the Federal employees health benefits program, and qualified retiree prescription drug plans as defined in section 1860D–22(a)(2) of the Act.

(4) Coverage under State Pharmaceutical

Assistance Programs (SPAP) as defined at § 423.454.

(5) Coverage of prescription drugs for veterans, survivors and dependents under chapter 17 of title 38, U.S.C.

(6) Coverage under a Medicare supplemental policy (Medigap policy) as defined at § 403.205 of this chapter.

(7) Military coverage under chapter 55 of title 10,

U.S.C., including TRICARE.

(8) Individual health insurance coverage (as defined in section 2791(b)(5) of the Public Health Service Act) that includes coverage for outpatient prescription drugs and that does not meet the definition of an excepted benefit (as defined in section 2791(c) of the Public Health Service Act).

(9) Coverage provided by the medical care program of the Indian Health Service, Tribe or Tribal organization, or Urban Indian organization (I/T/U).

(10) Coverage provided by a PACE organization.

(11) Coverage provided by a cost-based HMO or CMP under part 417 of this chapter.

(12) Coverage provided through a State High-Risk Pool as defined under 42 CFR 146.113(a)(1)(vii).

(13) Other coverage as the Secretary may determine appropriate.

(c) *General disclosure requirements*. With the exception of PDPs and MA-PD plans under § 423.56(b)(1) and PACE or cost-based HMO or CMP that provide qualified prescription drug coverage under this Part, each entity that offers prescription drug coverage under any of the types described in § 423.56(b), must disclose to all Part D eligible individuals enrolled in or seeking to enroll in the coverage whether the coverage is creditable prescription drug coverage.

(d) *Disclosure of non-creditable coverage*. In the case that the coverage of the type described in § 423.56(b) is not creditable prescription drug, the disclosure described in paragraph (c) of this section to Part D eligible individuals must also include:

(1) The fact that the coverage is not creditable prescription drug coverage, as provided by CMS;

(2) That there are limitations on the periods in a year in which the individual may enroll in Part D plans; and

(3) That the individual may be subject to a late enrollment penalty, as described under § 423.46.

(e) *Disclosure to CMS*. With the exception of PDPs and MA-PD plans under § 423.56(b)(1) and PACE or cost-based HMO or CMP that provide qualified prescription drug coverage under this Part, all other entities listed under paragraph (b) of this section must disclose whether the coverage they provide is creditable prescription drug coverage to CMS in a form and manner described by CMS.

(f) *Notification content and timing requirements*. The disclosure notification to Part-D eligible individuals required in § 423.56(c) and (d) must be provided in a form and manner prescribed by CMS. Notices must be provided, at minimum, at the following times:

(1) Prior to an individual's initial enrollment period for Part D, as described under § 423.38(a);

(2) Prior to the effective date of enrollment in the prescription drug coverage and upon any change that affects whether the coverage is creditable prescription drug coverage;

(3) Prior to the commencement of the Annual Coordinated Election Period as defined in § 423.38(b); and

(4) Upon request by the individual.

(g) *When an individual is not adequately informed of coverage.* If an individual establishes to CMS that he or she was not adequately informed that his or her prescription drug coverage was not creditable prescription drug coverage, the individual may apply to CMS to have the coverage treated as creditable prescription drug coverage for purposes of applying the late penalty described in § 423.46.

[70 FR 4525, Jan. 28, 2005, as amended at 73 FR 20505, Apr. 15, 2008; 77 FR 22168, Apr. 12, 2012]

Subpart C—Benefits and Beneficiary Protections

§ 423.100 Definitions.

As used in this part, unless otherwise specified—

ACIP-recommended adult vaccine means a covered Part D drug, as defined in this section, that is a vaccine licensed by the U.S. Food and Drug Administration (FDA) under section 351 of the Public Health Service Act for use by adult populations and administered in accordance with recommendations of the Advisory Committee on Immunization Practices (ACIP) of the Centers for Disease Control and Prevention (CDC) as adopted by the CDC Director.

Actual cost means the negotiated price for a covered Part D drug when the drug is purchased at a network pharmacy, and the usual and customary price when a beneficiary purchases the drug at an out-of-network pharmacy consistent with § 423.124(a).

Affected enrollee, as used in this subpart, means a Part D enrollee who is currently taking a covered Part D drug that is subject to a negative formulary change that affects the Part D enrollee's access to the drug during the current plan year.

Alternative prescription drug coverage means coverage of Part D drugs, other than standard prescription drug coverage that meets the requirements of § 423.104(e). The term alternative prescription drug coverage must be either—

(1) *Basic alternative coverage* (alternative coverage that is actuarially equivalent to defined standard coverage, as determined through processes and methods established under § 423.265(d)(2)); or

(2) *Enhanced alternative coverage* (alternative coverage that meets the requirements of § 423.104(f)(1)).

Applicable beneficiary means an individual who, on the date of dispensing a covered Part D drug—

(1) Is enrolled in a prescription drug plan or an MA–PD plan;

(2) Is not enrolled in a qualified retiree prescription drug plan;

(3) Is not entitled to an income-related subsidy under section 1860D–14(a) of the Act;

(4) Has reached or exceeded the initial coverage limit under section 1860D–2(b)(3) of the Act during the year;

(5) Has not incurred costs for covered part D drugs in the year equal to the annual out-of-pocket threshold specified in section 1860D–2(b)(4)(B) of the Act; and

(6) Has a claim that—

(i) Is within the coverage gap;

(ii) Straddles the initial coverage period and the coverage gap;

(iii) Straddles the coverage gap and the annual out-of-pocket threshold; or

(iv) Spans the coverage gap from the initial coverage period and exceeds the annual out-of-pocket threshold.

Applicable drug means a Part D drug that is—

(1)(i) Approved under a new drug application under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA); or

(ii) In the case of a biological product, licensed under section 351 of the Public Health Service Act (other than, with respect to a plan year before 2019, a product licensed under subsection (k) of such section 351); and

(2)(i) If the PDP sponsor of the prescription drug plan or the MA organization offering the MA–PD plan uses a

formulary, which is on the formulary of the prescription drug plan or MA–PD plan that the applicable beneficiary is enrolled in;

(ii) If the PDP sponsor of the prescription drug plan or the MA organization offering the MA–PD plan does not use a formulary, for which benefits are available under the prescription drug plan or MA–PD plan that the applicable beneficiary is enrolled in; or

(iii) Is provided to a particular applicable beneficiary through an exception or appeal for that particular applicable beneficiary.

At-risk beneficiary means a Part D eligible individual—

(1) Who is—

(i) Identified using clinical guidelines (as defined in this section);

(ii) Not an exempted beneficiary; and

(iii) Determined to be at-risk for misuse or abuse of such frequently abused drugs by a Part D plan sponsor under its drug management program in accordance with the requirements of § 423.153(f); or

(2) With respect to whom a Part D plan sponsor receives a notice upon the beneficiary's enrollment in such sponsor's plan that the beneficiary was identified as an at-risk beneficiary (as defined in the paragraph (1) of this definition) under the prescription drug plan in which the beneficiary was most recently enrolled and such identification had not been terminated upon disenrollment.

Basic prescription drug coverage means coverage of Part D drugs that is either standard prescription drug coverage or basic alternative coverage.

Bioequivalent has the meaning given such term in section 505(j)(8) of the Food, Drug, and Cosmetic Act.

Clinical guidelines, for the purposes of a drug management program under § 423.153(f), are criteria—

(1) To identify potential at-risk beneficiaries who may be determined to be at-risk beneficiaries under such programs; and

(2) That are developed in accordance with the standards in § 423.153(f)(16) and, beginning with contract year 2020, will be published in guidance annually.

Contracted pharmacy network means licensed pharmacies, including retail, mail-order, and institutional pharmacies under contract with a Part D sponsor to provide covered Part D drugs at negotiated prices to Part D enrollees.

Corresponding drug means, respectively, a generic or authorized generic of a brand name drug, an interchangeable biological product of a reference product, or an unbranded biological product marketed under the same biologics license application (BLA) as a brand name biological product.

Coverage gap means the period in prescription drug coverage that occurs between the initial coverage limit and the out-of-pocket threshold. For purposes of applying the initial coverage limit, Part D sponsors must apply their plan specific initial coverage limit under basic alternative, enhanced alternative or actuarially equivalent Part D benefit designs.

Covered insulin product means, for purposes of § 423.120(h), an insulin product, including a product that is a combination of more than one type of insulin or a product that is a combination of both insulin and a non-insulin drug or biological product, that—

(1) Is a covered Part D drug covered under a PDP or MA–PD plan—

(i) Is licensed under section 351 of the Public Health Service Act; and

(ii) Is marketed under the license described in paragraph (1)(i) of this definition.

(2) Is not a compounded drug product that contains insulin (as described in § 423.120(d)).

Covered insulin product applicable cost-sharing amount means, with respect to a covered insulin product, as defined in this section, covered under a PDP or an MA–PD plan prior to an enrollee reaching the annual out-of-pocket threshold during plan year 2026 and each subsequent plan year, the lesser of the following:

(1) $35.

(2) An amount equal to 25 percent of the maximum fair price established for the covered insulin product in accordance with Part E of title XI of the Act.

(3) An amount equal to 25 percent of the negotiated price (as defined in this section) of the covered insulin product under the PDP or MA–PD plan.

Covered Part D drug means a Part D drug that is included in a Part D plan's

formulary, or treated as being included in a Part D plan's formulary as a result of a coverage determination or appeal under §§ 423.566, 423.580, and 423.600, 423.610, 423,620, and 423.630, and obtained at a network pharmacy or an out-of-network pharmacy in accordance with § 423.124.

Daily cost-sharing rate means, as applicable, the established—

(1) Monthly copayment under the enrollee's Part D plan, divided by the number of days in the approved month's supply for the drug dispensed and rounded to the nearest cent; or

(2) Coinsurance percentage under the enrollee's Part D plan.

Dispensing fees means costs that-

(1) Are incurred at the point of sale and pay for costs in excess of the ingredient cost of a covered Part D drug each time a covered Part D drug is dispensed;

(2) Include only pharmacy costs associated with ensuring that possession of the appropriate covered Part D drug is transferred to a Part D enrollee. Pharmacy costs include, but are not limited to, any reasonable costs associated with a pharmacist's time in checking the computer for information about an individual's coverage, performing quality assurance activities consistent with § 423.153(c)(2), measurement or mixing of the covered Part D drug, filling the container, physically providing the completed prescription to the Part D enrollee, delivery, special packaging, and salaries of pharmacists and other pharmacy workers as well as the costs associated with maintaining the pharmacy facility and acquiring and maintaining technology and equipment necessary to operate the pharmacy. Dispensing fees should take into consideration the number of dispensing events in a billing cycle, the incremental costs associated with the type of dispensing methodology, and with respect to Part D drugs dispensed in LTC facilities, the techniques to minimize the dispensing of unused drugs. Dispensing fees may also take into account costs associated with data collection on unused Part D drugs and restocking fees associated with return for credit and reuse in long-term care pharmacies, when return for credit and reuse is permitted under the State in law and is allowed under the contract between the Part D sponsor and the pharmacy.

(3) Do not include administrative costs incurred by the Part D plan in the operation of the Part D benefit, including systems costs for interfacing with pharmacies.

Effective date of the ACIP recommendation means the date specified on the CDC website noting the date the CDC Director adopted the ACIP recommendation.

Exempted beneficiary means with respect to a drug management program, an enrollee who—

(1) Has elected to receive hospice care or is receiving palliative or end-of-life care;

(2) Is a resident of a long-term care facility, of a facility described in section 1905(d) of the Act, or of another facility for which frequently abused drugs are dispensed for residents through a contract with a single pharmacy;

(3) Is being treated for cancer-related pain or

(4) Has sickle cell disease.

Frequently abused drug means a controlled substance under the Federal Controlled Substances Act that the Secretary determines is frequently abused or diverted, taking into account all of the following factors:

(1) The drug's schedule designation by the Drug Enforcement Administration.

(2) Government or professional guidelines that address that a drug is frequently abused or misused.

(3) An analysis of Medicare or other drug utilization or scientific data.

Government-funded health program means any program established, maintained, or funded, in whole or in part, by the Government of the United States, by the government of any State or political subdivision of a State, or by any agency or instrumentality of any of the foregoing, which uses public funds, in whole or in part, to provide to, or pay on behalf of, an individual the cost of Part D drugs, including any of the following:

(1) An approved State child health plan under title XXI of the Act providing benefits for child health assistance that meets the requirements of section 2103 of the Act;

(2) The Medicaid program under title XIX of the Act or a waiver under section 1115 of the Act;

(3) The veterans' health care program under Chapter 17 of title 38 of the United States Code;

(4) The Indian Health Service program under the Indian Health Care Improvement Act under Chapter 18 of title 25 of the United States Code; and

(5) Any other government-funded program whose principal activity is the direct provision of health care to persons.

Group health plan, for purposes of applying the definition of incurred costs in § 423.100, has the meaning given such term in 29 U.S.C. 1167(1), but specifically excludes a personal health savings vehicle, as used in this subpart.

Immediate negative formulary change means an immediate substitution or market withdrawal that meets the requirements of § 423.120(e)(2)(i) or (ii) respectively.

Incurred costs means costs incurred by a Part D enrollee for—

(1)(i) Covered Part D drugs that are not paid for under the Part D plan as a result of application of any annual deductible or other cost-sharing rules for covered Part D drugs prior to the Part D enrollee satisfying the out-of-pocket threshold under § 423.104(d)(5)(iii), including any price differential for which the Part D enrollee is responsible under § 423.124(b); or

(ii) Nominal cost-sharing paid by or on behalf of an enrollee, which is associated with drugs that would otherwise be covered Part D drugs, as defined in § 423.100, but are instead paid for, with the exception of said nominal cost-sharing, by a patient assistance program providing assistance outside the Part D benefit, provided that documentation of such nominal cost-sharing has been submitted to the Part D plan consistent with the plan processes and instructions for the submission of such information; and

(2) That are paid for—

(i) By the Part D enrollee or on behalf of the Part D enrollee by another person, and the Part D enrollee (or person paying on behalf of the Part D enrollee) is not reimbursed through insurance or otherwise, a group health plan, or other third party payment arrangement, or the person paying on behalf of the Part D enrollee is not paying under insurance or otherwise, a group health plan, or third party payment arrangement;

(ii) Under State Pharmaceutical Assistance Program (as defined in § 423.464); by the Indian Health Service, an Indian tribe or tribal organization, or urban Indian organization (as defined in section 4 of the Indian Health Care Improvement Act) or under an AIDS Drug Assistance Program (as defined in part B of title XXVI of the Public Health Service); or by a manufacturer as payment for an applicable discount (as defined in § 423.2305) or under the Medicare Coverage Gap Discount Program (as defined in § 423.2305); or

(iii) Under § 423.782 of this part.

Insurance means a health plan that provides, or pays the cost of Part D drugs, including, but not limited to, any of the following:

(1) Health insurance coverage (as defined in 42 U.S.C. 300gg–91(b)(1));

(2) A Medicare Advantage plan (as described under section 1851(a)(2) of the Act); and

(3) A PACE organization (as defined under sections 1894(a)(3) and 1934(a)(13) of the Act) but specifically excluding a personal health savings vehicle.

I/T/U pharmacy means a pharmacy operated by the Indian Health Service, an Indian tribe or tribal organization, or an urban Indian organization, all of which are defined in section 4 of the Indian Health Care Improvement Act, 25 U.S.C. 1603.

Long-term care facility means a skilled nursing facility as defined in section 1819(a) of the Act, or a medical institution or nursing facility for which payment is made for an institutionalized individual under section 1902(q)(1)(B) of the Act.

Long-term care pharmacy means a pharmacy owned by or under contract with a long-term care facility to provide prescription drugs to the facility's residents.

Long-term care network pharmacy means a long-term care pharmacy that is a network pharmacy.

Maintenance change means one of the following negative formulary changes with respect to a covered Part D drug:

(1) Making any negative formulary changes to a drug within 90 days of adding a corresponding drug to the same or a lower cost-sharing tier and with the same or less restrictive prior authorization (PA), step therapy (ST), or quantity limit (QL) requirements (other than immediate substitutions that meet the requirements of § 423.120(e)(2)(i)).

(2) Making any negative formulary changes to a reference product within 90 days of adding a biosimilar biological product other than an interchangeable biological product of that reference product to the same or a lower cost-sharing tier and with the same or less restrictive PA, ST, or QL requirements.

(3) Removing a non-Part D drug.

(4) Adding or making more restrictive PA, ST, or QL requirements based upon a new FDA-mandated boxed warning.

(5) Removing a drug withdrawn from sale by the manufacturer or that FDA determines to be withdrawn for safety or effectiveness reasons if the Part D sponsor chooses not to treat it as an immediate negative formulary change.

(6) Removing a drug based on long term shortage and market availability.

(7) Making negative formulary changes based upon new clinical guidelines or information or to promote safe utilization.

(8) Adding PA to help determine Part B versus Part D coverage.

Negative formulary change means one of the following changes with respect to a covered Part D drug:

(1) Removing a drug from a formulary.

(2) Moving a drug to a higher cost-sharing tier.

(3) Adding or making more restrictive prior authorization (PA), step therapy (ST), or quantity limit (QL) requirements. Negative formulary changes do not include safety-based claim edits which are not submitted to CMS as part of the formulary.

Negotiated price means the price for a covered Part D drug that—

(1) The Part D sponsor (or other intermediary contracting organization) and the network dispensing pharmacy or other network dispensing provider have negotiated as the lowest possible reimbursement such network entity will receive, in total, for a particular drug;

(2) Meets all of the following:

(i) Includes all price concessions (as defined in this section) from network pharmacies or other network providers;

(ii) Includes any dispensing fees; and

(iii) Excludes additional contingent amounts, such as incentive fees, if these amounts increase prices; and

(3) Is reduced by non-pharmacy price concessions and other direct or indirect remuneration that the Part D sponsor passes through to Part D enrollees at the point of sale.

Network pharmacy means a licensed pharmacy that is under contract with a Part D sponsor to provide covered Part D drugs at negotiated prices to its Part D plan enrollees.

Non-maintenance change means a negative formulary change that is not a maintenance change or an immediate negative formulary change.

Non-preferred pharmacy means a network pharmacy that offers covered Part D drugs at negotiated prices to Part D enrollees at higher cost-sharing levels than apply at a preferred pharmacy.

Or otherwise means through a government-funded health program.

Other specified entities means State Pharmaceutical Assistance Programs (as defined in § 423.454), entities providing other prescription drug coverage (as described in § 423.464(f)(1)), authorized prescribers, network pharmacies, and pharmacists.

Out-of-network pharmacy means a licensed pharmacy that is not under contract with a Part D sponsor to provide negotiated prices to Part D plan enrollees.

Part D drug means—

(1) Unless excluded under paragraph (2) of this definition, any of the following if used for a medically accepted indication (as defined in section 1860D–2(e)(4) of the Act)—

(i) A drug that may be dispensed only upon a prescription and that is described in sections 1927(k)(2)(A)(i) through (iii) of the Act.

(ii) A biological product described in sections 1927(k)(2)(B)(i) through (iii) of the Act.

(iii) Insulin described in section 1927(k)(2)(C) of the Act.

(iv) Medical supplies associated with the injection of insulin, including syringes, needles, alcohol swabs, and gauze.

(v) A vaccine licensed under section 351 of the Public Health Service Act and for vaccine administration on or after January 1, 2008, its administration.

(vi) Supplies that are directly associated with delivering insulin into the body, such as an inhalation chamber used to deliver the insulin through inhalation.

(vii) A combination product approved and regulated by the FDA as a drug, vaccine, or biologic described in paragraphs (1)(i), (ii), (iii), or (v) of this definition.

(2) Does not include any of the following:

(i) Drugs for which payment as so prescribed and dispensed or administered to an individual is available for that individual under Part A or Part B (even though a deductible may apply, or even though the individual is eligible for coverage under Part A or Part B but has declined to enroll in Part A or Part B).

(ii) Drugs or classes of drugs, or their medical uses, which may be excluded from coverage or otherwise restricted under Medicaid under sections 1927(d)(2) or (d)(3) of the Act, except for smoking cessation agents.

(iii) Medical foods, defined as a food that is formulated to be consumed or administered enterally under the supervision of a physician and which is intended for the specific dietary management of a disease or condition for which distinctive nutritional requirements, based on recognized scientific principles, are established by medical evaluation, and that are not regulated as drugs under section 505 of the Federal Food, Drug, and Cosmetic Act.

Person means a natural person, corporation, mutual company, unincorporated association, partnership, joint venture, limited liability company, trust, estate, foundation, not-for-profit corporation, unincorporated organization, government or governmental subdivision or agency.

Personal health savings vehicle means a vehicle through which individuals can set aside their own funds to pay for health care expenses, including covered Part D drugs, on a tax-free basis including any of the following—

(1) A Health Savings Account (as defined under section 220 of the Internal Revenue Code);

(2) A Flexible Spending Account (as defined in section 106(c)(2) of the Internal Revenue Code) offered in conjunction with a cafeteria plan under section 125 of the Internal Revenue Code; and

(3) An Archer Medical Savings Account (as defined under section 223 of the Internal Revenue Code); but specifically excluding a Health Reimbursement Arrangement (as described under Internal Revenue Ruling 2002–41 and Internal Revenue Notice 2002–45)

Plan allowance means the amount Part D plans that offer coverage other than defined standard coverage may use to determine their payment and Part D enrollees' cost-sharing for covered Part D drugs purchased at an out-of-network pharmacy or in a physician's office in accordance with the requirements of § 423.124(b).

Potential at-risk beneficiary means a Part D eligible individual who is not an exempted beneficiary (as defined in this section) and—

(1) Who is identified using clinical guidelines (as defined in this section); or

(2) With respect to whom a Part D plan sponsor receives a notice upon the beneficiary's enrollment in such sponsor's plan that the beneficiary was identified as a potential at-risk beneficiary (as defined in paragraph (1) of this definition) under the prescription drug plan in which the beneficiary was most recently enrolled and such identification had not been terminated upon disenrollment.

Preclusion list means a CMS compiled list of prescribers who—

(1) Meet all of the following requirements:

(i) The prescriber is currently revoked from Medicare for a reason other than that stated in § 424.535(a)(3) of this chapter.

(ii) The prescriber is currently under a reenrollment bar under § 424.535(c) of this chapter.

(iii) CMS determines that the underlying conduct that led to the revocation is detrimental to the best interests of the Medicare program. In making this determination under this paragraph (1)(iii), CMS considers the following factors:

(A) The seriousness of the conduct underlying the prescriber's revocation;

(B) The degree to which the prescriber's conduct could affect the integrity of the Part D program; and

(C) Any other evidence that CMS deems relevant to its determination; or

(2) Meet both of the following requirements:

(i) The prescriber has engaged in behavior, other than that described in § 424.535(a)(3) of this chapter, for which CMS could have revoked the individual to the extent applicable had he or she been enrolled in Medicare.

(ii) CMS determines that the underlying conduct that would have led to the revocation is detrimental to the best interests of the Medicare program. In making this determination under this paragraph, CMS considers all of the following factors:

(A) The seriousness of the conduct involved.

(B) The degree to which the prescriber's conduct could affect the integrity of the Part D program.

(C) Any other evidence that CMS deems relevant to its determination; or

(3) The prescriber, regardless of whether he or she is or was enrolled in Medicare, has been convicted of a felony under Federal or State law within the previous 10 years that CMS deems detrimental to the best interests of the Medicare program. Factors that CMS considers in making such a determination under this paragraph are as follows:

(i) The severity of the offense.

(ii) When the offense occurred.

(iii) Any other information that CMS deems relevant to its determination.

Preferred drug means a covered Part D drug on a Part D plan's formulary for which beneficiary cost-sharing is lower than for a non-preferred drug in the plan's formulary.

Preferred pharmacy means a network pharmacy that offers covered Part D drugs at negotiated prices to Part D enrollees at lower levels of cost-sharing than apply at a non-preferred pharmacy under its pharmacy network contract with a Part D plan.

Price concession means any form of discount, direct or indirect subsidy, or rebate received by the Part D sponsor or its intermediary contracting organization from any source that serves to decrease the costs incurred under the Part D plan by the Part D sponsor. Examples of price concessions include but are not limited to: Discounts, chargebacks, rebates, cash discounts, free goods contingent on a purchase agreement, coupons, free or reduced-price services, and goods in kind.

Program size means the estimated population of potential at-risk beneficiaries in drug management programs (described in § 423.153(f)) operated by Part D plan sponsors that the Secretary determines can be effectively managed by such sponsors as part of the process to develop clinical guidelines.

Qualified prescription drug coverage means any standard prescription drug coverage or alternative prescription drug coverage

Required prescription drug coverage means coverage of Part D drugs under an MA-PD plan that consists of either—

(1) Basic prescription drug coverage; or

(2) Enhanced alternative coverage, provided there is no MA monthly supplemental beneficiary premium (as defined under section 1854(b)(2)(C) of the Act) applied under the plan due to the application of a credit against the premium of a rebate under § 422.266(b) of this chapter.

Retail pharmacy means any licensed pharmacy that is open to dispense prescription drugs to the walk-in general public from which Part D enrollees could purchase a covered Part D drug without being required to receive medical services from a provider or institution affiliated with that pharmacy.

Rural means a five-digit ZIP code in which the population density is less than 1,000 individuals per square mile.

Standard prescription drug coverage means coverage of Part D drugs that meets the requirements of § 423.104(d). The term standard prescription drug coverage must be either—

(1) *Defined standard coverage* (standard prescription drug coverage that provides for cost-sharing as described in § 423.104(d)(2)(i)(A) and (d)(5)(i)); or

(2) *Actuarially equivalent standard coverage* (standard prescription drug coverage that provides for cost-sharing as described in § 423.104(d)(2)(i)(B) or cost-sharing as described in § 423.104(d)(5)(ii), or both).

Suburban means a five-digit ZIP code in which the population density is between 1,000 and 3,000 individuals per square mile.

Supplemental benefits means benefits offered by Part D plans, other than employer group health or waiver plans, that meet the requirements of § 423.104(f)(1)(ii).

Therapeutically equivalent refers to drugs that are rated as therapeutic equivalents under the Food and Drug Administration's most recent publication of ''Approved Drug Products with Therapeutic Equivalence Evaluations.''

Third party payment arrangement means any contractual or similar arrangement under which a person has a legal obligation to pay for covered Part D drugs.

Urban means a five-digit ZIP code in which the population density is greater than 3,000 individuals per square mile.

Usual and customary (U&C) price means the price that an out-of-network pharmacy or a physician's office charges a customer who does not have any form of prescription drug coverage for a covered Part D drug.

Valid prescription means a prescription that complies with all applicable State law requirements constituting a valid prescription.

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§ 423.104 Requirements related to qualified prescription drug coverage.

(a) *General.* Subject to the conditions and limitations set forth in this subpart, a Part D sponsor must provide enrollees with coverage of the benefits described in paragraph (c) of this section. The benefits may be provided directly by the Part D sponsor or through arrangements with other entities. CMS reviews and approves these benefits consistent with § 423.272, and using written policy guidelines and requirements in this part and other CMS instructions.

(b) *Availability of prescription drug plan.* A PDP sponsor offering a prescription drug plan must offer the plan—

(1) To all Part D eligible beneficiaries residing in the plan's service area; and

(2) At a uniform premium, with uniform benefits and level of cost-sharing throughout the plan's service area.

(c) *Types of benefits.* The coverage provided by a Part D plan must be qualified prescription drug coverage.

(d) *Standard prescription drug coverage.* Standard prescription drug coverage includes access to negotiated prices as described under paragraph (g)(1) of this section, provides coverage of Part D drugs, and must meet the following requirements

(1) *Deductible.* An annual deductible equal to—

(i) *For 2006.* $250; or

(ii) *For years subsequent to 2006.* The amount specified in this paragraph for the previous year, increased by the annual percentage increase specified in paragraph (d)(5)(iv) of this section, and rounded to the nearest multiple of $5.

(2) *Cost-sharing under the initial coverage limit.* (i) Subject to paragraph (d)(4) of this section, coinsurance for actual costs for covered Part D drugs covered under the Part D plan above the annual deductible specified in paragraph (d)(1) of this section, and up to the initial coverage limit under paragraph (d)(3) of this section, that is—

(A) Equal to 25 percent of actual cost; or

(B) Actuarially equivalent to an average expected coinsurance of no more than 25 percent of actual cost, as determined through processes and methods established under § 423.265(c) and (d).

(ii) *Tiered copayments.* A Part D plan providing actuarially equivalent standard coverage may apply tiered copayments, provided that any tiered copayments are consistent with paragraphs

(d)(2)(i)(B) and (d)(4) of this section and are approved as described in § 423.272(b)(2).

(iii) Tiered cost sharing under paragraph (d)(2)(ii) of this section may not exceed levels annually determined by CMS to be discriminatory.

(iv) Specialty tier means a formulary cost sharing tier dedicated to high-cost Part D drugs with ingredient costs for a 30-day equivalent supply (as described in paragraph (d)(2)(iv)(A)(*2*) of this section) that are greater than the specialty tier cost threshold specified in paragraph (d)(2)(iv)(A) of this section.

(A) *Specialty-tier cost threshold*. CMS sets the specialty-tier cost threshold for a plan year in accordance with this paragraph (d)(2)(iv)(A), using the following steps:

(*1*) *30-day equivalent ingredient cost*. Using the PDE data as specified in paragraph (d)(2)(iv)(C) of this section, CMS uses the ingredient cost reflected on the prescription drug event (PDE) to determine the ingredient cost in dollars for a 30-day equivalent supply of the Part D drug.

(*2*) *30-day equivalent supply*. CMS determines the 30-day equivalent supply as follows: If the days' supply reported on a PDE is less than or equal to 34, the number of 30-day equivalent supplies equals one. If the days' supply reported on a PDE is greater than 34, the number of 30-day equivalent supplies is equal to the number of days' supply reported on each PDE divided by 30.

(*3*) *Top 1 percent*. CMS determines the amount that equals the lowest 30-day equivalent ingredient cost that is within the top 1 percent of all 30-day equivalent ingredient costs reflected in the PDE data.

(*4*) *Determination*. Except as provided in paragraph (d)(2)(iv)(B) of this section, the amount determined in paragraph (d)(2)(iii) of this section is the specialty-tier cost threshold for the plan year.

(*5*) *Claims history*. Except for newly FDA-approved Part D drugs only recently available on the market for which Part D sponsors would have little or no claims data, CMS approves placement of a Part D drug on a specialty tier when that Part D sponsor's claims data from the time period specified in paragraph (d)(2)(iv)(C) of this section demonstrates that greater than 50 percent of the Part D sponsor's PDEs for a given Part D drug, when adjusted for 30-day equivalent supplies, have ingredient costs for 30-day equivalent supplies, as described in paragraph (d)(2)(iv)(A)(*2*) of this section, that exceed the specialty-tier cost threshold.

(*6*) *No claims history*. For newly FDA-approved Part D drugs only recently available on the market for which Part D sponsors would have little or no claims data, CMS approves placement of a Part D drug on a specialty tier when that Part D sponsor estimates that ingredient cost portion of their negotiated prices for a 30-day equivalent supply, as defined in subparagraph (d)(2)(iv)(A)(*2*), is anticipated to exceed the specialty-tier cost threshold more than 50 percent of the time, subject to the requirements at §§ 423.120(b), (e), and (f).

(B) *Limit on specialty-tier cost threshold adjustment*. (*1*) CMS increases the specialty-tier cost threshold for a plan year only if the amount determined in paragraph (d)(2)(iv)(A)(*3*) of this section for a plan year is at least 10 percent above the specialty tier cost threshold for the prior plan year.

(*2*) If an increase is made in accordance with this paragraph (d)(2)(iv)(B), CMS rounds the amount determined in paragraph (d)(2)(iv)(A)(*3*) of this section to the nearest $10, and the resulting dollar amount is the specialty-tier cost threshold for the plan year.

(C) *Data used to determine the specialty-tier cost threshold*. CMS uses PDEs from the plan year that ended 12 months prior to the applicable plan year.

(D) *Maximum number of specialty tiers and maximum allowable cost sharing*. A Part D plan may maintain up to two specialty tiers. CMS sets the maximum allowable cost sharing for a single specialty tier, or, in the case of a plan with two specialty tiers, the higher cost sharing specialty tier as follows:

(*1*) For Part D plans with the full deductible provided under the Defined Standard benefit, as specified in paragraph (d)(1) of this section, 25 percent coinsurance.

(*2*) For Part D plans with no deductible, 33 percent coinsurance.

(*3*) For Part D plans with a deductible that is greater than $0 and less than the deductible provided under the Defined Standard benefit, a coinsurance percentage that is determined by subtracting the plan's deductible from 33 percent of the initial coverage limit (ICL) under section 1860D–2(b)(3) of the Act, dividing this difference by the difference between the ICL and the plan's deductible, and rounding to the nearest 1 percent.

(3) *Initial coverage limit.* Except as provided in paragraphs (d)(4) and (d)(5) of this section, the initial coverage limit is equal to—

(i) *For 2006.* $2,250.

(ii) *For years subsequent to 2006.* The amount specified in this paragraph for the previous year, increased by the annual percentage increase specified in paragraph (d)(5)(iv) of this section, and rounded to the nearest multiple of $10.

(4) *Cost-sharing in the coverage gap for applicable beneficiaries.* (i) Coinsurance in the coverage gap (as defined in § 423.100) for costs for covered Part D drugs that are not applicable drugs (as defined in § 423.100) under the Medicare coverage gap discount program that is—

(A) Equal to the generic gap coinsurance percentage described in paragraph (d)(4)(iii) of this section; or

(B) Actuarially equivalent to an average expected coinsurance for covered Part D drugs that are not applicable drugs under the Medicare coverage gap discount program, as determined through processes and methods established under § 423.265 (c) and (d).

(ii) Coinsurance in the coverage gap for the actual cost minus the dispensing fee and any vaccine administration fee for covered Part D drugs that are applicable drugs under the Medicare coverage gap discount program that is—

(A) Equal to the difference between the applicable gap coinsurance percentage described in paragraph (d)(4)(iv) of this section and the discount percentage determined under the Medicare coverage gap discount program; or

(B) Actuarially equivalent to an average expected coinsurance for covered Part D drugs that are applicable drugs under the Medicare coverage gap discount program, as determined through processes and methods established under § 423.265 (c) and (d).

(iii) *Generic gap coinsurance percentage.* The generic gap coinsurance percentage is equal to—

(A) For 2011, 93 percent.

(B) For years 2012 through 2019, the amount specified in this paragraph for the previous year, decreased by 7 percentage points.

(C) For 2020 and each subsequent year, 25 percent.

(iv) *Applicable gap coinsurance percentage.* The applicable gap coinsurance percentage is equal to—

(A) For 2013 and 2014, 97.5 percent.

(B) For 2015 and 2016, 95 percent.

(C) For 2017, 90 percent.

(D) For 2018, 85 percent.

(E) For 2019, 80 percent.

(F) For 2020 and subsequent years, 75 percent.

(5) *Protection against high out-of-pocket expenditures.* (i) After an enrollee's incurred costs exceed the annual out-of-pocket threshold described in paragraph (d)(5)(iii) of this section, cost-sharing equal to the greater of—

(A) *Copayments.* (*1*) In 2006, $2 for a generic drug or preferred drug that is a multiple source drug (as defined in section 1927(k)(7)(A)(i) of the Act) and $5 for any other drug; and

(*2*) For subsequent years, the copayment amounts specified in this paragraph for the previous year increased by the annual percentage increase described in paragraph (d)(5)(iv) of this section and rounded to the nearest multiple of 5 cents; or

(B) *Coinsurance.* Coinsurance of five percent of actual cost.

(ii) As determined through processes and methods established under § 423.265(c) and (d), a Part D plan may substitute for cost-sharing under paragraph (d)(5)(i) of this section an amount that is actuarially equivalent to expected cost-sharing under paragraph (d)(5)(i) of this section.

(iii) *Annual out-of-pocket threshold.* For purposes of this part, the annual out-of-pocket threshold equals—

(A) *For 2006.* $3,600.

(B) *For each year 2007 through 2013.* The amount specified in this paragraph for the previous year, increased by the annual percentage increase specified in

paragraph (d)(5)(iv) of this section, and rounded to the nearest multiple of $50.

(C) *For years 2014 and 2015.* The amount specified in this paragraph for the previous year, increased by the annual percentage increase specified in paragraph (d)(5)(iv) of this section, minus 0.25 percentage point.

(D) *For each year 2016 through 2019.* The amount specified in this paragraph for the previous year, increased by the lesser of—

(*1*) The annual percentage increase specified in (d)(5)(v) of this section plus 2 percentage points; or

(*2*) The annual percentage increase specified in (d)(5)(iv) of this section.

(E) *For 2020.* The amount specified in this paragraph for 2013 increased by the annual percentage increases specified in paragraph (d)(5)(iv) of this section for 2014 through 2020, and rounded to the nearest $50.

(F) *For 2021 and subsequent years.* The amount specified in this paragraph for the previous year, increased by the annual percentage increase specified in paragraph (d)(5)(iv) of this section, and rounded to the nearest $50.

(iv) *Annual percentage increase.* The annual percentage increase for each year is equal to the annual percentage increase in average per capita aggregate expenditures for Part D drugs in the United States for Part D eligible individuals and is based on data for the 12-month period ending in July of the previous year.

(v) *Additional annual percentage increase.* The annual percentage increase for each year is equal to the annual percentage increase in the consumer price index for all urban consumers (United States city average) for the 12-month period ending in July of the previous year.

(e) *Alternative prescription drug coverage.* Alternative prescription drug coverage includes access to negotiated prices as described under paragraph (g)(1) of this section, provides coverage of Part D drugs, and must meet the following requirements—

(1) Has an annual deductible that does not exceed the annual deductible specified in paragraph (d)(1) of this section;

(2) Imposes cost-sharing no greater than that specified in paragraphs (d)(5)(i) or (ii) of this section once the annual out-of-pocket threshold described in paragraph (d)(5)(iii) of this section is met;

(3) Has a total or gross value that is at least equal to the total or gross value of defined standard coverage.

(4) Has an unsubsidized value that is at least equal to the unsubsidized value of standard prescription drug coverage. For purposes of this subparagraph, the unsubsidized value of coverage is the amount by which the actuarial value of the coverage exceeds the actuarial value of the subsidy payments under § 423.782 for the coverage; and

(5) Provides coverage that is designed, based upon an actuarially representative pattern of utilization, to provide for the payment, for costs incurred for covered Part D drugs, that are equal to the initial coverage limit under paragraph (d)(3) of this section, of an amount equal to at least the product of -

(i) The amount by which the initial coverage limit described in paragraph (d)(3) of this section for the year exceeds the deductible described in paragraph (d)(1) of this section; and

(ii) 100 percent minus the coinsurance percentage specified in paragraph (d)(2)(i) of this section.

(f) *Enhanced alternative coverage.* (1) Enhanced alternative coverage must meet the requirements under paragraph (e) of this section and includes-

(i) Basic prescription drug coverage, as defined in § 423.100; and

(ii) Supplemental benefits, which include-

(A) Coverage of drugs that are specifically excluded as Part D drugs under paragraph (2)(ii) of the definition of Part D drug under § 423.100; or

(B) Any of the following changes or combination of changes that increase the actuarial value of benefits under the Part D plan above the actuarial value of defined standard prescription drug coverage, as determined through processes and methods established under § 423.265—

(*1*) A reduction in the annual deductible described in paragraph (d)(1) of this section;

(*2*) A reduction in the cost-sharing described in paragraphs (d)(2) or (d)(5) of this section, or

(*3*) An increase in the initial coverage limit described in paragraph (d)(3) of this section.

(C) Both the coverage described in paragraph (f)(1)(ii)(A) of this section and the changes or combination of changes described in paragraph (f)(1)(ii)(B) of this section.

(2) *Restrictions on the offering of enhanced alternative coverage by PDP sponsors.* A PDP sponsor may not offer enhanced alternative coverage in a service area unless the PDP sponsor also offers a prescription drug plan in that service area that provides basic prescription drug coverage.

(3) *Restrictions on the offering of enhanced alternative coverage by MA organization*s. Effective January 1, 2006, an MA organization—

(i) May not offer an MA coordinated care plan, as defined in §422.4 of this chapter, in an area unless either that plan (or another MA plan offered by the MA organization in that same service area) includes required prescription drug coverage; and

(ii) May not offer prescription drug coverage (other than that required under Parts A and B of title XVIII of the Act) to an enrollee—

(A) Under an MSA plan, as defined in §422.2 of this chapter; or

(B) Under another MA plan (including a private fee-for-service plan, as defined in §422.4 of this chapter) unless the drug coverage under the other plan provides qualified prescription drug coverage and unless the requirements of paragraph (f)(3)(i) of this section are met.

(4) *Restrictions on the offering of enhanced alternative coverage by cost plans.* (i) A cost plan that elects to offer qualified prescription drug coverage may offer enhanced alternative coverage as an optional supplemental benefit under §417.440(b)(2)(ii) of this chapter only if the cost plan also offers basic prescription drug coverage. An enrollee in the cost plan may, at the individual's option, elect whether to receive qualified prescription drug coverage under the cost plan and, if so, whether to receive basic prescription drug coverage or, if offered by the cost plan, enhanced alternative coverage.

(ii) A cost plan that offers qualified prescription drug coverage as an optional supplemental benefit under §417.440(b)(2)(ii) of this chapter may not offer prescription drug coverage that is not qualified prescription drug coverage. A cost plan that does not offer qualified prescription drug coverage under §417.440(b)(2)(ii) of this chapter may offer prescription drug coverage that is not qualified prescription drug coverage under §417.440(b)(2)(i) of this chapter.

(g) *Negotiated prices*—(1) *Access to negotiated prices.* A Part D sponsor is required to provide its Part D enrollees with access to negotiated prices for covered Part D drugs included in its Part D plan's formulary. Negotiated prices must be provided even if no benefits are payable to the beneficiary for covered Part D drugs because of the application of any deductible or 100 percent coinsurance requirement following satisfaction of any initial coverage limit. Negotiated prices must be provided when the negotiated price for a covered Part D drug under a Part D sponsor's benefit package is less than the applicable cost-sharing before the application of any deductible, before any initial coverage limit, before the annual out-of-pocket threshold, and after the annual out-of-pocket threshold.

(2) *Interaction with Medicaid best price.* Prices negotiated with a pharmaceutical manufacturer, including discounts, subsidies, rebates, and other price concessions, for covered Part D drugs by the following entities are not taken into account in establishing Medicaid's best price under section 1927(c)(1)(C) of the Act—

(i) A Part D plan, as defined in §423.4; or

(iii) A qualified retiree prescription drug plan (as defined in §423.882) for Part D eligible individuals.

(3) *Disclosure.* (i) A Part D sponsor is required to disclose to CMS data on aggregate negotiated price concessions obtained from pharmaceutical manufacturers, as well as data on aggregate negotiated price concessions obtained from pharmaceutical manufacturers that are passed through to beneficiaries, via pharmacies and other dispensers, in the form of lower subsidies paid by CMS on behalf of low-income individuals described in §423.782, or in

the form of lower monthly beneficiary premiums or lower covered Part D drug prices at the point of sale.

(ii) Information on negotiated prices disclosed to CMS under paragraph (g)(3) of this section is protected under the confidentiality provisions applicable under section 1927(b)(3)(D) of the Act.

(4) *Audits.* CMS and the Office of the Inspector General may conduct periodic audits of the financial statements and all records of Part D sponsors pertaining to any qualified prescription drug coverage they may offer under a Part D plan.

(h) *Valid prescription.* A Part D sponsor may only provide benefits for Part D drugs that require a prescription if those drugs are dispensed upon a valid prescription.

(i) *Daily cost-sharing rate.* Beginning January 1, 2014, a Part D sponsor is required to provide its enrollees access to a daily cost-sharing rate in accordance with § 423.153(b)(4).

[70 FR 4525, Jan. 28, 2005, as amended at 74 FR 1544, Jan. 12, 2009; 75 FR 19816, Apr. 15, 2010; 76 FR 21571, Apr. 15, 2011; 77 FR 22169, Apr. 12, 2012; 80 FR 7963, Feb. 12, 2015; 86 FR 6115, Jan. 19, 2021; 89 FR 30833, Apr. 23, 2024]

§ 423.112 Establishment of prescription drug plan service areas.

(a) *Service area for prescription drug plan sponsors.* The service area for a prescription drug plan sponsor other than a fallback prescription drug plan sponsor consists of one or more PDP regions as established under paragraphs (b) and (c) of this section.

(b) *Establishment of PDP regions*—(1) *General.* CMS establishes PDP regions in a manner consistent with the requirements for the establishment of MA regions as described at § 422.455 of this chapter.

(2) *Relation to MA regions.* To the extent practicable, PDP regions are the same as MA regions. CMS may establish PDP regions that are not the same as MA regions if CMS determines that the establishment of these regions improves access to prescription drug plan benefits for Part D eligible individuals.

(c) *Authority for territories.* CMS establishes a PDP region or regions for States that are not within the 50 States and the District of Columbia.

(d) *Revision of PDP regions.* CMS may revise the PDP regions established under paragraphs (b) and (c) of this section.

(e) *Regional or national plan.* Nothing in this section prevents a prescription drug plan from being offered in two or more PDP regions in their entirety or in all PDP regions in their entirety.

[70 FR 4525, Jan. 28, 2005, as amended at 75 FR 19816, Apr. 15, 2010]

§ 423.120 Access to covered Part D drugs.

(a) *Assuring pharmacy access*—(1) *Standards for convenient access to network pharmacies.* Except as provided in paragraph (a)(7) of this section, a Part D sponsor (as defined in § 423.4 of this part) must have a contracted pharmacy network consisting of retail pharmacies sufficient to ensure that, for beneficiaries residing in each State in a PDP sponsor's service area (as defined in § 423.112(a) of this part), each State in a regional MA-organization's service area (as defined in § 422.2 of this part), the entire service area of a local MA organization (as defined in § 422.2 of this chapter) or the entire geographic area of a cost contract (as defined in § 417.401 of this chapter) all of the following requirements are satisfied:

(i) At least 90 percent of Medicare beneficiaries, on average, in urban areas served by the Part D sponsor live within 2 miles of a network pharmacy that is a retail pharmacy or a pharmacy described under paragraph (a)(2) of this section.

(ii) At least 90 percent of Medicare beneficiaries, on average, in suburban areas served by the Part D sponsor live within 5 miles of a network pharmacy that is a retail pharmacy or a pharmacy described under paragraph (a)(2) of this section.

(iii) At least 70 percent of Medicare beneficiaries, on average, in rural areas served by the Part D sponsor live within 15 miles of a network pharmacy that is a retail pharmacy or a pharmacy described under paragraph (a)(2) of this section.

(2) *Applicability of some non-retail pharmacies to standards for convenient access.* Part D sponsors may count I/T/U pharmacies and pharmacies operated by Federally Qualified Health Centers

and Rural Health Centers toward the standards for convenient access to network pharmacies in paragraph (a)(1) of this section.

(3) *Access to non-retail pharmacies.* A Part D sponsor's contracted pharmacy network may be supplemented by non-retail pharmacies, including pharmacies offering home delivery via mail-order and institutional pharmacies, provided the requirements of paragraph (a)(1) of this section are met.

(4) *Access to home infusion pharmacies.* A Part D sponsor's contracted pharmacy network must provide adequate access to home infusion pharmacies consistent with written policy guidelines and other CMS instructions. A Part D plan must ensure that such network pharmacies, at a minimum meet all the following requirements:

(i) Are capable of delivering home-infused drugs in a form that can be administered in a clinically appropriate fashion.

(ii) Are capable of providing infusible Part D drugs for both short-term acute care and long-term chronic care therapies.

(iii) Ensure that the professional services and ancillary supplies necessary for home infusion therapy are in place before dispensing Part D home infusion drugs.

(iv) Provide delivery of home infusion drugs within 24 hours of discharge from an acute care setting, or later if so prescribed.

(5) *Access to long-term care pharmacies.* A Part D sponsor must offer standard contracting terms and conditions, including performance and service criteria for long-term care pharmacies that CMS specifies, to all long-term care pharmacies in its service area. The sponsor must provide convenient access to long-term care pharmacies consistent with written policy guidelines and other CMS instructions.

(6) *Access to I/T/U pharmacies.* A Part D sponsor must offer standard contracting terms and conditions conforming to the model addendum that CMS develops, to all I/T/U pharmacies in its service area. The sponsor must provide convenient access to I/T/U pharmacies consistent with written policy guidelines and other CMS instructions.

(7) *Waiver of pharmacy access requirements.* CMS waives the requirements under paragraph (a)(1) of this section in the case of either of the following:

(i) An MA organization or cost contract (as described in section 1876(h) of the Act) that provides its enrollees with access to covered Part D drugs through pharmacies owned and operated by the MA organization or cost contract, provided the organization's or plan's pharmacy network meets the access standard set forth—

(A) At § 422.112 of this chapter for an MA organization; or

(B) At § 417.416(e) of this chapter for a cost contract.

(ii) An MA organization offering a private fee-for-service plan described in § 422.4 of this chapter that—

(A) Offers qualified prescription drug coverage; and

(B) Provides plan enrollees with access to covered Part D drugs dispensed at all pharmacies, without regard to whether they are contracted network pharmacies and without charging cost-sharing in excess of that described in § 423.104(d)(2) and (d)(5).

(8) Pharmacy network contracting requirements. In establishing its contracted pharmacy network, a Part D sponsor offering qualified prescription drug coverage—

(i) Must contract with any pharmacy that meets the Part D sponsor's standard terms and conditions;

(ii) May not require a pharmacy to accept insurance risk as a condition of participation in the Part D sponsor's contracted pharmacy network; and

(iii) May not prohibit a pharmacy from, nor penalize a pharmacy for, informing a Part D plan enrollee of the availability at that pharmacy of a prescribed medication at a cash price that is below the amount that the enrollee would be charged to obtain the same medication through the enrollee's Part D plan.

(9) *Differential cost-sharing for preferred pharmacies.* A Part D sponsor offering a Part D plan that provides coverage other than defined standard coverage may reduce copayments or coinsurance for covered Part D drugs obtained through a preferred pharmacy

relative to the copayments or coinsurance applicable for such drugs when obtained through a non-preferred pharmacy. Such differentials are taken into account in determining whether the requirements under § 423.104(d)(2) and (d)(5) and § 423.104(e) are met. Any cost-sharing reduction under this section must not increase CMS payments to the Part D plan under § 423.329.

(10) *Level playing field between mail-order and network pharmacies.* A Part D sponsor must permit its Part D plan enrollees to receive benefits, which may include a 90-day supply of covered Part D drugs, at any of its network pharmacies that are retail pharmacies. A Part D sponsor may require an enrollee obtaining a covered Part D drug at a network pharmacy that is a retail pharmacy to pay any higher cost-sharing applicable to that covered Part D drug at the network pharmacy that is a retail pharmacy instead of the cost-sharing applicable to that covered Part D drug at the network pharmacy that is a mail-order pharmacy.

(b) *Formulary requirements.* A Part D sponsor that uses a formulary under its qualified prescription drug coverage must meet the following requirements—

(1) *Development and revision by a pharmacy and therapeutic committee.* A Part D sponsor's formulary must be developed and reviewed by a pharmacy and therapeutic committee that—

(i) Includes a majority of members who are practicing physicians and/or practicing pharmacists.

(ii) Includes at least one practicing physician and at least one practicing pharmacist who are independent and free of conflict relative to-

(A) The Part D sponsor and Part D plan; and

(B) Pharmaceutical manufacturers.

(iii) Includes at least one practicing physician and one practicing pharmacist who are experts regarding care of elderly or disabled individuals.

(iv) Clearly articulates and documents processes to determine that the requirements under paragraphs (b)(1)(i) through (iii) of this section have been met, including the determination by an objective party of whether disclosed financial interests are conflicts of interest and the management of any recusals due to such conflicts.

(v) Bases clinical decisions on the strength of scientific evidence and standards of practice, including assessing peer-reviewed medical literature, pharmacoeconomic studies, outcomes research data, and other such information as it determines appropriate.

(vi) Considers whether the inclusion of a particular Part D drug in a formulary or formulary tier has any therapeutic advantages in terms of safety and efficacy.

(vii) Reviews policies that guide exceptions and other utilization management processes, including drug utilization review, quantity limits, generic substitution, and therapeutic interchange.

(viii) Evaluates and analyzes treatment protocols and procedures related to the plan's formulary at least annually consistent with written policy guidelines and other CMS instructions.

(ix) Documents in writing its decisions regarding formulary development and revision and utilization management activities.

(x) Reviews and approves all clinical prior authorization criteria, step therapy protocols, and quantity limit restrictions applied to each covered Part D drug.

(xi) Meets other requirements consistent with written policy guidelines and other CMS instructions.

(2) Provision of an Adequate Formulary. A Part D plan's formulary must—

(i) Except as provided in paragraphs (b)(2)(ii) and (v) of this section, include within each therapeutic category and class of Part D drugs at least two Part D drugs that are not therapeutically equivalent and bioequivalent, with different strengths and dosage forms available for each of those drugs, except that only one Part D drug must be included in a particular category or class of covered Part D drugs if the category or class includes only one Part D drug.

(ii) Include at least one Part D drug within a particular category or class of Part D drugs to the extent the Part D plan demonstrates, and CMS approves, the following-

(A) That only two drugs are available in that category or class of Part D drugs; and

(B) That one drug is clinically superior to the other drug in that category or class of Part D drugs.

(iii) Include adequate coverage of the types of drugs most commonly needed by Part D enrollees, as recognized in national treatment guidelines.

(iv) Be approved by CMS consistent with § 423.272(b)(2).

(v) Until such time as there are established, through notice and comment rulemaking, criteria to identify, as appropriate, categories and classes of clinical concern, the categories and classes of clinical concern are as specified in section 1860D–4(b)(3)(G)(iv) of the Act.

(vi) Exceptions to paragraph (b)(2)(v) of this section are as follows:

(A) Drug or biological products that are rated as either of the following:

(*1*) Therapeutically equivalent (under the Food and Drug Administration's most recent publication of ''Approved Drug Products with Therapeutic Equivalence Evaluations,'' also known as the Orange Book).

(*2*) Interchangeable (under the Food and Drug Administration's most recent publication of the Purple Book: Lists of Licensed Biological Products with Reference Product Exclusivity and Biosimilarity or Interchangeability Evaluations).

(B) Utilization management processes that limit the quantity of drugs due to safety.

(C) Subject to CMS review and approval, for enrollees that are not on existing therapy on the protected class Part D drug, and except for antiretroviral medications, prior authorization and step therapy requirements to confirm intended use is for a protected class indication, to ensure clinically appropriate use, to promote utilization of preferred formulary alternatives, or a combination thereof.

(D) Other drugs that CMS specifies through a process that is based upon scientific evidence and medical standards of practice (and, in the case of antiretroviral medications, is consistent with the Department of Health and Human Services Guidelines for the Use of Antiretroviral Agents in HIV–1–Infected Adults and Adolescents) and which permits public notice and comment.

(3) *Transition process.* A Part D sponsor must provide for an appropriate transition process for enrollees prescribed Part D drugs that are not on its Part D plan's formulary (including Part D drugs that are on a sponsor's formulary but require prior authorization or step therapy under a plan's utilization management rules). The transition process must:

(i)(A) Be applicable to all of the following:

(*1*) New enrollees into Part D plans following the annual coordinated election period.

(*2*) Newly eligible Medicare enrollees from other coverage.

(*3*) Individuals who switch from one plan to another after the start of the contract year.

(*4*) Current enrollees remaining in the plan affected by formulary changes.

(B) Not apply in cases of immediate changes as permitted under paragraph (e)(2) of this section.

(ii) Ensure access to a temporary supply of drugs within the first 90 days of coverage under a new plan. This 90 day timeframe applies to retail, home infusion, long-term care and mail-order pharmacies,

(iii) Ensure the provision of a temporary fill when an enrollee requests a fill of a non-formulary drug during the time period specified in paragraph (b)(3)(ii) of this section (including Part D drugs that are on a plan's formulary but require prior authorization or step therapy under a plan's utilization management rules) by providing a one-time, temporary supply of at least an approved month's supply of medication, unless the prescription is written by a prescriber for less than an approved month's supply and requires the Part D sponsor to allow multiple fills to provide up to a total of an approved month's supply of medication.

(iv) Ensure written notice is provided to each affected enrollee within 3 business days after adjudication of the temporary fill. For long-term care residents dispensed multiple supplies of a Part D drug, in increments of 14-days-

or-less, consistent with the requirements under § 423.154, the written notice must be provided within 3 business days after adjudication of the first temporary fill.

(v) Ensure that reasonable efforts are made to notify prescribers of affected enrollees who receive a transition notice under paragraph (b)(3)(iv) of this section.

(vi) A Part D sponsor must charge cost sharing for a temporary supply of drugs provided under its transition process such that the following conditions are met:

(A) For low-income subsidy (LIS) enrollees, a sponsor must not charge higher cost sharing for transition supplies than the statutory maximum copayment amounts.

(B) For non-LIS enrollees, a sponsor must charge—

(*1*) The same cost sharing for non-formulary Part D drugs provided during the transition that would apply for non-formulary drugs approved through a formulary exception in accordance with § 423.578(b); and

(*2*) The same cost sharing for formulary drugs subject to utilization management edits provided during the transition that would apply once the utilization management criteria are met.

(4) *Limitation on changes in therapeutic classification.* Except as CMS may permit to account for new therapeutic uses and newly approved Part D drugs, a Part D sponsor may not change the therapeutic categories and classes in a formulary other than at the beginning of each plan year.

(5) Notice of formulary changes. Part D sponsors must provide notice of changes to CMS-approved formularies as specified in § 423.120(f).

(6) Changes to CMS-approved formularies. Changes to CMS-approved formularies may be made only in accordance with paragraph (e) of this section.

(7) *Provider and patient education.* A Part D sponsor must establish policies and procedures to educate and inform health care providers and enrollees concerning its formulary.

(c) *Use of standardized technology.* (1) A Part D sponsor must issue and reissue, as necessary, a card or other type of technology that its enrollees may use to access negotiated prices for covered Part D drugs as provided under § 423.104(g). The card or other technology must comply with standards CMS establishes.

(2) When processing Part D claims, a Part D sponsor or its intermediary must comply with the electronic transaction standards established by 45 CFR 162.1102. CMS will issue guidance on the use of conditional fields within such standards.

(3) A Part D sponsor must require its network pharmacies to submit claims to the Part D sponsor or its intermediary whenever the card described in paragraph (c)(1) of this section is presented or on file at the pharmacy unless the enrollee expressly requests that a particular claim not be submitted to the Part D sponsor or its intermediary.

(4) Beginning January 1, 2012, a part D sponsor must assign and exclusively use a unique—

(i) Part D BIN or RxBIN and Part D processor control number (RxPCN) combination in its Medicare line of business; and

(ii) Part D cardholder identification number (RxID) to each Medicare Part D enrollee to clearly identify Medicare Part D beneficiaries.

(5)(i) A Part D plan sponsor must reject, or must require its pharmacy benefit manager (PBM) to reject, a pharmacy claim for a Part D drug unless the claim contains the active and valid National Provider Identifier (NPI) of the prescriber who prescribed the drug.

(ii) The sponsor must communicate at point-of sale whether or not a submitted NPI is active and valid in accordance with this paragraph (c)(5)(ii).

(A) If the sponsor communicates that the NPI is not active and valid, the sponsor must permit the pharmacy to—

(*1*) Confirm that the NPI is active and valid; or

(*2*) Correct the NPI.

(B) If the pharmacy confirms that the NPI is active and valid or corrects the NPI, the sponsor must pay the claim if it is otherwise payable.

(iii) A Part D sponsor must not later recoup payment from a network pharmacy for a claim that does not contain

an active and valid individual prescriber NPI on the basis that it does not contain one, unless the sponsor—

(A) Has complied with paragraph (c)(5)(ii) of this section;

(B) Has verified that a submitted NPI was not in fact active and valid; and

(C) The agreement between the parties explicitly permits such recoupment.

(iv) With respect to requests for reimbursement submitted by Medicare beneficiaries, a Part D sponsor may not make payment to a beneficiary dependent upon the sponsor's acquisition of an active and valid individual prescriber NPI, unless there is an indication of fraud. If the sponsor is unable to retrospectively acquire an active and valid individual prescriber NPI, the sponsor may not seek recovery of any payment to the beneficiary solely on that basis.

(6)(i) Except as provided in paragraph (c)(6)(iv) of this section, a Part D sponsor must reject, or must require its PBM to reject, a pharmacy claim for a Part D drug if the individual who prescribed the drug is included on the preclusion list, defined in § 423.100.

(ii) Except as provided in paragraph (c)(6)(iv) of this section, a Part D sponsor must deny, or must require its PBM to deny, a request for reimbursement from a Medicare beneficiary if the request pertains to a Part D drug that was prescribed by an individual who is identified by name in the request and who is included on the preclusion list, defined in § 423.100.

(iii) A Part D plan sponsor may not submit a prescription drug event (PDE) record to CMS unless it includes on the PDE record the active and valid individual NPI of the prescriber of the drug, and the prescriber is not included on the preclusion list, defined in § 423.100, for the date of service.

(iv) With respect to Part D prescribers who have been added to an updated preclusion list but are not currently excluded by the OIG, the Part D plan sponsor must do all of the following:

(A) Subject to all other Part D rules and plan coverage requirements, and no later than 30 days after the posting of this updated preclusion list, must provide an advance written notice to any beneficiary who has received a Part D drug prescribed by an individual added to the preclusion list in this update and whom the plan sponsor has identified during the applicable 30-day period.

(B)(*1*) Subject to paragraph (c)(6)(iv)(B)(*2*) of this section, must ensure that reasonable efforts are made to notify the individual described in paragraph (c)(6)(iv) of this section of a beneficiary who was sent a notice under paragraph (c)(6)(iv)(A) of this section.

(*2*) Paragraph (c)(6)(iv)(B)(*1*) of this section applies only upon a prescriber writing a prescription in Medicare Part D when:

(*i*) The plan sponsor has enough information on file to either copy the prescriber on the notification previously sent to the beneficiary or send a new notice informing the prescriber that they may not see plan beneficiaries due to their preclusion status; and

(*ii*) The claim is received after the claim denial or reject date in the preclusion file.

(C) Must not reject a pharmacy claim or deny a beneficiary request for reimbursement for a Part D drug prescribed by the prescriber, solely on the ground that they have been included in the updated preclusion list, in the 60-day period after the date it sent the notice described in paragraph (c)(6)(iv)(A) of this section.

(v)(A) CMS sends written notice to the prescriber via letter of his or her inclusion on the preclusion list. The notice must contain the reason for the inclusion on the preclusion list and inform the prescriber of his or her appeal rights. A prescriber may appeal his or her inclusion on the preclusion list under this section in accordance with part 498 of this chapter.

(B) If the prescriber's inclusion on the preclusion list is based on a contemporaneous Medicare revocation under § 424.535 of this chapter:

(*1*) The notice described in paragraph (c)(6)(v)(A) of this section must also include notice of the revocation, the reason(s) for the revocation, and a description of the prescriber's appeal rights concerning the revocation.

(*2*) The appeals of the prescriber's inclusion on the preclusion list and the

prescriber's revocation must be filed jointly by the prescriber and, as applicable, considered jointly under part 498 of this chapter.

(C)(*1*) Except as provided in paragraph (c)(6)(v)(C)(*2*) of this section, a prescriber will only be included on the preclusion list after the expiration of either of the following:

(*i*) If the prescriber does not file a reconsideration request under § 498.5(n)(1) of this chapter, the prescriber will be added to the preclusion list upon the expiration of the 60-day period in which the prescriber may request a reconsideration.

(*ii*) If the prescriber files a reconsideration request under § 498.5(n)(1) of this chapter, the prescriber will be added to the preclusion list effective on the date on which CMS, if applicable, denies the prescriber's reconsideration.

(*2*) An OIG excluded prescriber is added to the preclusion list effective on the date of the exclusion.

(vi) CMS has the discretion not to include a particular individual on (or if warranted, remove the individual from) the preclusion list should it determine that exceptional circumstances exist regarding beneficiary access to prescriptions. In making a determination as to whether such circumstances exist, CMS takes into account—

(A) The degree to which beneficiary access to Part D drugs would be impaired; and

(B) Any other evidence that CMS deems relevant to its determination.

(vii)(A) Except as provided in paragraphs (c)(6)(vii)(C) and (D) of this section, a prescriber who is revoked under § 424.535 of this chapter will be included on the preclusion list for the same length of time as the prescriber's reenrollment bar.

(B) Except as provided in paragraphs (c)(6)(vii)(C) and (D) of this section, a prescriber who is not enrolled in Medicare will be included on the preclusion list for the same length of time as the reenrollment bar that CMS could have imposed on the prescriber had the prescriber been enrolled and then revoked.

(C) Except as provided in paragraph (c)(6)(vii)(D) of this section, an individual, regardless of whether the individual is or was enrolled in Medicare, that is included on the preclusion list because of a felony conviction will remain on the preclusion list for a 10-year period, beginning on the date of the felony conviction, unless CMS determines that a shorter length of time is warranted. Factors that CMS considers in making such a determination are—

(*1*) The severity of the offense;

(*2*) When the offense occurred; and

(*3*) Any other information that CMS deems relevant to its determination.

(D) In cases where an individual is excluded by the OIG, the individual must remain on the preclusion list until the expiration of the CMS-imposed preclusion list period or reinstatement by the OIG, whichever occurs later.

(viii) Payment denials under paragraph (c)(6) of this section that are based upon the prescriber's inclusion on the preclusion list are not appealable by beneficiaries.

(d) *Treatment of compounded drug products.* With respect to multi-ingredient compounds, a Part D sponsor must—

(1) Make a determination as to whether the compound is covered under Part D.

(i) A compound that contains at least one ingredient covered under Part B as prescribed and dispensed or administered is considered a Part B compound, regardless of whether other ingredients in the compound are covered under Part B as prescribed and dispensed or administered.

(ii) Only compounds that contain at least one ingredient that independently meets the definition of a Part D drug, and that do not meet the criteria under paragraph (d)(1)(i) of this section, may be covered under Part D. For purposes of this paragraph (d) these compounds are referred to as Part D compounds.

(iii) For a Part D compound to be considered on-formulary, all ingredients that independently meet the definition of a Part D drug must be considered on-formulary (even if the particular Part D drug would be considered off-formulary if it were provided separately—that is, not as part of the Part D compound).

(iv) For a Part D compound that is considered off-formulary—

(A) Transition rules apply such that all ingredients in the Part D compound that independently meet the definition of a Part D drug must become payable in the event of a transition fill under § 423.120(b)(3); and

(B) All ingredients that independently meet the definition of a Part D drug must be covered if an exception under § 423.578(b) is approved for coverage of the compound.

(2) Establish consistent rules for beneficiary payment liabilities for both ingredients of the Part D compound that independently meet the definition of a Part D drug and non-Part D ingredients.

(i) For low income subsidy beneficiaries the copayment amount is based on whether the most expensive ingredient that independently meets the definition of a Part D drug in the Part D compound is a generic or brand name drug (as described under § 423.782).

(ii) For any non-Part D ingredient of the Part D compound (including drugs described under § 423.104(f)(1)(ii)(A)), the Part D sponsor's contract with the pharmacy must prohibit balance billing the beneficiary for the cost of any such ingredients.

(e) *Approval of changes to CMS-approved formularies.* A Part D sponsor may not make any negative formulary changes to its CMS-approved formulary except as specified in this section.

(1) *Negative change request.* Except as provided in paragraph (e)(2) of this section, prior to implementing a negative formulary change, Part D sponsors must submit to CMS, at a time and in a form and manner specified by CMS, a negative formulary change request.

(2) *Exception for immediate negative formulary changes.* A negative change request is not required in the following circumstances:

(i) *Immediate substitutions.* A Part D sponsor may make negative formulary changes to a brand name drug, a reference product, or a brand name biological product within 30 days of adding a corresponding drug to its formulary on the same or lower cost sharing tier and with the same or less restrictive formulary prior authorization (PA), step therapy (ST), or quantity limit (QL) requirements, so long as the Part D sponsor previously could not have included such corresponding drug on its formulary when it submitted its initial formulary for CMS approval consistent with paragraph (b)(2) of this section because such drug was not yet available on the market, and the Part D sponsor has provided advance general notice as specified in paragraph (f)(2) of this section.

(ii) *Market withdrawals.* A Part D sponsor may immediately remove from its formulary any Part D drugs withdrawn from sale by their manufacturer or that the Food and Drug Administration (FDA) determines to be withdrawn for safety or effectiveness reasons.

(3) *Approval process for negative formulary changes*—(i) *Maintenance changes.* Negative change requests for maintenance changes are deemed approved 30 days after submission unless CMS notifies the Part D sponsor otherwise.

(ii) *Non-maintenance changes.* Part D sponsors must not implement non-maintenance changes until they receive notice of approval from CMS. Affected enrollees are exempt from non-maintenance changes for the remainder of the contract year.

(4) *Limitation on formulary changes prior to the beginning of a contract year.* Except as provided in paragraph (e)(2) of this section, a Part D sponsor may not make a negative formulary change that takes effect between the beginning of the annual coordinated election period described in § 423.38(b) and 60 days after the beginning of the contract year associated with that annual coordinated election period.

(f) *Provision of notice regarding changes to CMS-approved formularies*—

(1) *Notice of negative formulary changes.* Except as specified in paragraphs (f)(2) and (3) of this section, prior to making any negative formulary change, a Part D sponsor must provide notice to CMS and other specified entities at least 30 days prior to the date such change becomes effective, and must either: provide written notice to affected enrollees at least 30 days prior to the date the change becomes effective, or when an affected enrollee requests a refill of the Part D drug, provide such enrollee with an approved month's supply of the Part D

drug under the same terms as previously allowed and written notice of the formulary change. The requirement to provide notice to CMS is satisfied upon a Part D sponsor's submission of a negative change request described in paragraph (e) of this section. The requirement to provide notice to other specified entities is satisfied by the Part D sponsor's compliance with § 423.128(d)(2).

(2) *Advance general notice of immediate negative formulary changes.* In the case of immediate negative formulary changes described in paragraph (e)(2) of this section, a Part D sponsor must provide advance general notice to all current and prospective enrollees and other specified entities in its formulary and other applicable beneficiary communication materials advising that the Part D sponsor may make immediate negative formulary changes consistent with the requirements of paragraph (e)(2) at any time. Such advance general notice must include information about how to access the plan's online formulary; about how to contact the plan; and that written notice of any change made will describe the specific drugs involved. Advance general notice of immediate substitutions must also specify that the written notice will contain information on the steps that enrollees may take to request coverage determinations and exceptions. Advance general notice of immediate substitutions is provided to CMS during bid submission. Advance general notice of market withdrawals is provided to CMS in the advance notice of immediate negative formulary changes that Part D sponsors provide to enrollees and other specified entities required earlier in this paragraph (f)(2).

(3) *Retrospective notice and update.* In the case of a negative formulary change described in paragraph (e)(2) of this section, the Part D sponsor must provide notice to other specified entities and written notice to affected enrollees as soon as possible, but no later than by the end of the month following any month in which the change takes effect. The requirement to provide notice to other specified entities is satisfied by the Part D sponsor's compliance with § 423.128(d)(2). Part D sponsors also must submit such changes to CMS, in a form and manner specified by CMS, in their next required or scheduled formulary update.

(4) *Content of written notice:* Any written notice required under this paragraph (other than advance general notice) must contain all of the following information:

(i) The name of the affected covered Part D drug.

(ii) Whether the plan is removing the covered Part D drug from the formulary, moving it to a higher cost-sharing tier, or adding or making more restrictive PA, ST, or QL requirements.

(iii) The reason for the negative formulary change.

(iv) Appropriate alternative drugs on the formulary in the same or a lower cost-sharing tier and the expected cost sharing for those drugs.

(v) For formulary changes other than those described in paragraph (e)(2)(ii) of this section, the means by which enrollees may obtain a coverage determination under § 423.566, including an exception to a coverage rule under § 423.578.

(5) *Notice of other formulary changes.* Part D sponsors provide appropriate notice of all formulary changes other than negative formulary changes by providing—

(i) Advance general notice to all current and prospective enrollees, CMS, and other specified entities in formulary and other applicable beneficiary communication materials advising them that the Part D sponsor may make formulary changes other than negative formulary changes at any time and providing information about how to access the plan's online formulary and how to contact the plan; and

(ii) Notice of specific formulary changes to other specified entities by complying with § 423.128(d)(2) and to CMS by submitting such changes to CMS in their next required or scheduled formulary update.

(g) *Coverage of ACIP-recommended adult vaccines.* With respect to an ACIP-recommended adult vaccine, a Part D sponsor must—

(1) Not apply any deductible nor charge any cost sharing; and

(2) Once a new or revised recommendation is posted on the CDC website, provide coverage consistent with paragraph (g)(1) of this section for dates of service on or after the effective date of the ACIP recommendation, as defined at § 423.100.

(3) Apply the requirements in paragraphs (g)(1) and (2) of this section to ACIP-recommended adult vaccines obtained from either an in-network or out-of-network pharmacy or provider in accordance with § 423.124(a) and (c).

(h) *Cost sharing for covered insulin products.* With respect to a covered insulin product, as defined at § 423.100, covered under a PDP or an MA–PD plan prior to an enrollee reaching the annual out-of-pocket threshold, a Part D sponsor must do all of the following:

(1) Not apply a deductible.

(2) Ensure any enrollee cost sharing for each prescription fill up to a one-month supply does not exceed the covered insulin product applicable cost-sharing amount defined at § 423.100.

(3) Ensure any enrollee cost sharing for each prescription fill greater than a 1-month supply does not exceed the cumulative covered insulin product applicable cost-sharing amount (as defined in § 423.100) that would apply if the same days' supply was dispensed in the fewest number of 1-month supply increments necessary.

(4) Apply the requirements in paragraphs (h)(1) through (3) of this section to covered insulin products obtained from either an in-network or out-of-network pharmacy or provider.

[70 FR 4525, Jan. 28, 2005, as amended at 73 FR 20506, Apr. 15, 2008; 74 FR 2888, Jan. 16, 2009; 75 FR 19816, Apr. 15, 2010; 75 FR 32860, June 10, 2010; 76 FR 21572, Apr. 15, 2011; 77 FR 22169, Apr. 12, 2012; 79 FR 29962, May 23, 2014; 80 FR 7963, Feb. 12, 2015; 80 FR 25966, May 6, 2015; 83 FR 16738, Apr. 16, 2018; 84 FR 15840, Apr. 16, 2019; 84 FR 23883, May 23, 2019; 84 FR 26579, June 7, 2019; 89 FR 30833, Apr. 23, 2024; 90 FR 15912, Apr. 15, 2025]

§ 423.124 Special rules for out-of-network access to covered Part D drugs at out-of-network pharmacies.

(a) *Out-of-network access to covered part D drugs*—(1) *Out-of-network pharmacy access.* A Part D sponsor must ensure that Part D enrollees have adequate access to covered Part D drugs dispensed at out-of-network pharmacies when the enrollees—

(i) Cannot reasonably be expected to obtain such drugs at a network pharmacy; and

(ii) Do not access covered Part D drugs at an out-of-network pharmacy on a routine basis.

(2) *Physician's office access.* A Part D sponsor must ensure that Part D enrollees have adequate access to vaccines and other covered Part D drugs appropriately dispensed and administered by a physician in a physician's office.

(b) *Financial responsibility for out-of-network access to covered Part D drugs.* A Part D sponsor that provides its Part D enrollees with coverage other than defined standard coverage may require its Part D enrollees accessing covered Part D drugs as provided in paragraph (a) of this section to assume financial responsibility for any differential between the out-of-network pharmacy's (or provider's) usual and customary price and the Part D sponsor's plan allowance, consistent with the requirements of §§ 423.104(d)(2)(i)(B) and 423.104(e).

(c) *Limits on out-of-network access to covered Part D.* A Part D sponsor must establish reasonable rules to appropriately limit out-of-network access to covered Part D drugs.

§ 423.128 Dissemination of Part D plan information.

(a) *Detailed description.* A Part D sponsor must disclose the information specified in paragraph (b) of this section in the manner specified by CMS—

(1) To each enrollee of a Part D plan offered by the Part D sponsor under this part, except as provided in paragraph (b)(11)(ii) of this section;

(2) In a clear, accurate, and standardized form; and

(3) At the time of enrollment and at least annually thereafter, by the first day of the annual coordinated election period.

(b) *Content of Part D plan description.* The Part D plan description must include the following information about the qualified prescription drug coverage offered under the Part D plan—

(1) *Service area.* The plan's service area.

(2) *Benefits.* The benefits offered under the plan, including—

(i) Applicable conditions and limitations.

(ii) Premiums.

(iii) Cost-sharing (such as copayments, deductibles, and coinsurance), and cost-sharing for subsidy eligible individuals.

(iv) Any other conditions associated with receipt or use of benefits.

(3) *Cost-sharing.* A description of how a Part D eligible individual may obtain more information on cost-sharing requirements, including tiered or other copayment levels applicable to each drug (or class of drugs), in accordance with paragraph (d) of this section.

(4) *Formulary.* Information about the plan's formulary, including-

(i) A list of drugs included on the plan's formulary;

(ii) The manner in which the formulary (including any tiered formulary structure and utilization management procedures used) functions;

(iii) The process for obtaining an exception to a plan's formulary or tiered cost-sharing structure; and

(iv) A description of how a Part D eligible individual may obtain additional information on the formulary, in accordance with paragraph (d) of this section.

(5) *Access.* The number, mix, and distribution (addresses) of network pharmacies from which enrollees may reasonably be expected to obtain covered Part D drugs and how the Part D sponsor meets the requirements of § 423.120(a)(1) for access to covered Part D drugs;

(6) *Out-of-network coverage.* Provisions for access to covered Part D drugs at out-of-network pharmacies, consistent with § 423.124(a).

(7) *Grievance, coverage determination, and appeal procedures.* All grievance, coverage determination, and appeal rights and procedures required under § 423.562 et. seq., including—

(i) Access to a uniform model form used to request a coverage determination under § 423.568 or § 423.570, and a uniform model form used to request a redetermination under § 423.582 or § 423.584, to the extent such uniform model forms have been approved for use by CMS;

(ii) Immediate access to the coverage determination and redetermination processes via an Internet Web site; and

(iii) A system that transmits codes to network pharmacies so that the network pharmacy is notified to populate and/or provide a printed notice at the point-of-sale to an enrollee explaining how the enrollee can request a coverage determination by contacting the plan sponsor's toll free customer service line or by accessing the plan sponsor's internet Web site.

(8) *Quality assurance policies and procedures.* A description of the quality assurance policies and procedures required under § 423.153(c), as well as the medication therapy management program required under § 423.153(d).

(9) *Disenrollment rights and responsibilities.*

(10) *Potential for contract termination.* The fact that a Part D sponsor may terminate or refuse to renew its contract, or reduce the service area included in its contract, and the effect that any of those actions may have on individuals enrolled in a Part D plan;

(11) *Opioid information.* (i) Beginning January 1, 2022, and subject to paragraph (b)(11)(ii) of this section, a Part D sponsor must disclose to each enrollee at least once per year the following:

(A) The risks associated with prolonged opioid use.

(B) Coverage of non-pharmacological therapies, devices, and non-opioid medications—

(*1*) In the case of an MA–PD, under such plan; and

(*2*) In the case of a PDP, under such plan and Medicare Parts A and B.

(ii) The Part D sponsor may elect to, in lieu of disclosing the information described in paragraph (b)(11)(i) of this section to each enrollee under each plan offered by the Part D sponsor under this part, disclose such information to a subset of enrollees, such as enrollees who have been prescribed an opioid in the previous 2-year period.

(c) *Disclosure upon request of general coverage information, utilization, and grievance information.* Upon request of a Part D eligible individual, a Part D sponsor must provide the following information—

(1) *General coverage information.* General coverage information, including—

(i) *Enrollment procedures.* Information and instructions on how to exercise election options under this part;

(ii) *Rights.* A general description of procedural rights (including grievance, coverage determination, reconsideration, exceptions, and appeals procedures) under this part;

(iii) *Benefits.* (A) Covered services under the Part D plan;

(B) Any beneficiary cost-sharing, such as deductibles, coinsurance, and copayment amounts, including cost-sharing for subsidy eligible individuals;

(C) Any maximum limitations on out-of-pocket expenses;

(D) The extent to which an enrollee may obtain benefits from out-of-network providers;

(E) The types of pharmacies that participate in the Part D plan's network and the extent to which an enrollee may select among those pharmacies; and

(F) The Part D plan's out-of-network pharmacy access policy.

(iv) Premiums;

(v) The Part D plan's formulary;

(vi) The Part D plan's service area; and

(vii) Quality and performance indicators for benefits under the Part D plan as determined by CMS.

(2) The procedures the Part D sponsor uses to control utilization of services and expenditures.

(3) The number of disputes, and the disposition in the aggregate, in a manner and form described by CMS. These disputes are categorized as—

(i) Grievances according to § 423.564;

(ii) Appeals according to § 423.580 et. seq.; and

(iii) Exceptions according to § 423.578.

(4) Financial condition of the Part D sponsor, including the most recently audited information regarding, at a minimum, a description of the financial condition of the Part D sponsor offering the Part D plan.

(d) *Provision of specific information.* Each Part D sponsor offering qualified prescription drug coverage under a Part D plan must have mechanisms for providing specific information on a timely basis to current and prospective enrollees upon request. These mechanisms must include—

(1) A toll-free customer call center that—

(i) Is open during usual business hours.

(A) For coverage beginning on and after January 1, 2022, is open at least from 8:00 a.m. to 8:00 p.m. in all regions served by the Part D plan, with the following exceptions:

(*1*) From October 1 through March 31 of the following year, a customer call center may be closed on Thanksgiving Day and Christmas Day so long as the interactive voice response (IVR) system or similar technology records messages from incoming callers and such messages are returned within one (1) business day.

(*2*) From April 1 through September 30, a customer call center may be closed any Federal holiday, Saturday, or Sunday, so long as the interactive voice response (IVR) system or similar technology records messages from incoming callers and such messages are returned within one (1) business day.

(B) For coverage beginning on and after January 1, 2022, any call center serving pharmacists or pharmacies must be open so long as any network pharmacy in that region is open.

(ii) Provides customer telephone service, including to pharmacists, in accordance with standard business practices.

(A) For coverage beginning on and after January 1, 2022, limits average hold time to 2 minutes. The hold time is defined as the time spent on hold by callers following the interactive voice response (IVR) system, touch-tone response system, or recorded greeting, before reaching a live person.

(B) For coverage beginning on and after January 1, 2022, answers 80 percent of incoming calls within 30 seconds after the interactive voice response (IVR), touch-tone response system, or recorded greeting interaction.

(C) For coverage beginning on and after January 1, 2022, limits the disconnect rate of all incoming calls to 5 percent. The disconnect rate is defined as the number of calls unexpectedly dropped divided by the total number of calls made to the customer call center.

(iii)(A) Provides interpreters for non-English speaking and limited English proficient (LEP) individuals.

(B) For coverage beginning on and after January 1, 2022, interpreters must be available for 80 percent of incoming calls requiring an interpreter within 8 minutes of reaching the customer service representative and be made available at no cost to the caller.

(iv) Provides immediate access to the coverage determination and redetermination processes.

(v) At a minimum, for coverage beginning on and after January 1, 2022:

(A) Provides effective real-time communication with individuals using auxiliary aids and services, including TTYs and all forms of Federal Communication Commission-approved telecommunications relay systems, when using automated-attendant systems. See 28 CFR 35.161 and 36.303(d).

(B) Establishes contact with a customer service representative within 7 minutes on no fewer than 80 percent of incoming calls requiring TTY services.

(vi) For coverage beginning on and after January 1, 2022, provides the information described in paragraph (d)(4) of this section to enrollees who call the customer service call center.

(2) An Internet website that—

(i) Includes, at a minimum, the information required in paragraph (b) of this section.

(ii) Includes a current formulary for its Part D plan, updated at least monthly.

(iii) Provides current and prospective Part D enrollees with notice that is timely under § 423.120(f) regarding any negative formulary changes on its Part D plan's formulary.

(3) The provision of information in writing, upon request.

(4) Beginning on January 1, 2023, a Part D sponsor must implement, and make available directly to enrollees, in an easy to understand manner, the following complete, accurate, timely, clinically appropriate, patient-specific formulary and benefit real-time information in their beneficiary-specific portal or computer application:

(i) Enrollee cost sharing amounts.

(ii) Formulary medication alternatives for a given condition.

(iii) Formulary status, including utilization management requirements applicable to each alternative medication, as appropriate for each enrollee and medication presented.

(5) The Part D sponsor may provide rewards and incentives to enrollees who use the beneficiary real time benefit tool (RTBT) described in paragraph (d)(4) of this section, provided the rewards and incentives comply with the requirements in paragraphs (d)(5)(i) through (vi) of this section, and the rewards and incentives information is made available to CMS upon request. Use is defined as logging into the RTBT, via portal or computer application, or calling the customer service call center to obtain the information described in paragraph (d)(4) of this section. The rewards and incentives must meet the following:

(i) Be of reasonable value, both individually and in the aggregate.

(ii) Be designed so that all enrollees are eligible to earn rewards and incentives, and that there is no discrimination based on race, color, national origin, including limited English proficiency, sex, age, disability, chronic disease, health status, or other prohibited basis.

(iii) Not be offered in the form of cash or other cash equivalents.

(iv) Not be used to target potential enrollees.

(v) Be earned solely for logging onto the beneficiary RTBT and not for any other purpose.

(vi) Otherwise comply with all relevant fraud and abuse laws, including, when applicable, the anti-kickback statute and civil money penalty prohibiting inducements to beneficiaries.

(e) *Claims information.* A Part D sponsor must furnish directly to enrollees, in the manner specified by CMS and in a form easily understandable to such enrollees, a written explanation of benefits when prescription drug benefits are provided under qualified prescription drug coverage. The explanation of benefits must—

(1) List the item or service for which payment was made and the amount of the payment for each item or service.

(2) Include a notice of the individual's right to request an itemized statement.

(3) Include the cumulative, year-to-date total amount of benefits provided, in relation to—

(i) The deductible for the current year.

(ii) The initial coverage limit for the current year.

(iii) The annual out-of-pocket threshold for the current year.

(4) Include the cumulative, year-to-date total of incurred costs to the extent practicable.

(5) For each prescription drug claim, must include the cumulative percentage increase (if any) in the negotiated price since the first claim of the current benefit year and therapeutic alternatives with lower cost-sharing, when available as determined by the plan, from the applicable approved plan formulary.

(6) Include any negative formulary changes applicable to an enrollee for which Part D plans are required to provide notice as described in § 423.120(f).

(7) Be provided no later than the end of the month following any month when prescription drug benefits are provided under this part, including the covered Part D spending between the initial coverage limit described in § 423.104(d)(3) and the out-of-pocket threshold described in § 423.104(d)(5)(iii).

(f) *Disclosure requirements.* CMS may require a Part D plan sponsor to disclose to its enrollees or potential enrollees, the Part D plan sponsor's performance and contract compliance deficiencies in a manner specified by CMS.

(g) *Changes in rules.* If a Part D sponsor intends to change its rules for a Part D plan, it must do all of the following:

(1) Submit the changes for CMS review under the procedures of Subpart V of this part.

(2) For changes that take effect on January 1, notify all enrollees at least 15 days before the beginning of the Annual Coordinated Election Period as defined in section 1860D–1(b)(1)(B) of the Act.

(3) Provide notice of all other changes in accordance with notice requirements as specified in this part.

[70 FR 4525, Jan. 28, 2005, as amended at 73 FR 54222, Sept. 18, 2008; 74 FR 1544, Jan. 12, 2009; 75 FR 19818, Apr. 15, 2010; 76 FR 21573, Apr. 15, 2011; 80 FR 7963, Feb. 12, 2015; 83 FR 16739, Apr. 16, 2018; 84 FR 23883, May 23, 2019; 86 FR 6115, Jan. 19, 2021; 89 FR 30834, Apr. 23, 2024]

§ 423.129 Resolution of complaints in complaints tracking module.

(a) *Definitions.* For the purposes of this regulation, the following terms have the following meanings:

Assignment date is the date CMS assigns a complaint to a particular Part D sponsor in the Complaints Tracking Module.

Complaints Tracking Module is an electronic system maintained by CMS to record and track complaints submitted to CMS about Medicare health and drug plans from beneficiaries and others.

Immediate need complaint is a complaint involving a situation that prevents a beneficiary from accessing care or a service for which they have an immediate need. This includes when the beneficiary currently has enough of the drug or supply to which they are seeking access to last for 2 or fewer days.

Urgent complaint is a complaint involving a situation that prevents a beneficiary from accessing care or a service for which they do not have an immediate need. This includes when the beneficiary currently has enough of the drug or supply to which they are seeking access to last for 3 to 14 days.

(b) *Timelines for complaint resolution*—(1) *Immediate need complaint*s. The Part D sponsor must resolve immediate need complaints within 2 calendar days of the assignment date.

(2) *Urgent complaints.* The Part D sponsor must resolve urgent complaints within 7 calendar days of the assignment date.

(3) *All other complaints.* The Part D sponsor must resolve all other complaints within 30 calendar days of the assignment date.

(4) *Extensions.* Except for immediate need complaints, urgent complaints, and any complaint that requires expedited treatment under § 423.564(f), if a

complaint is also a grievance within the scope of § 423.564 and the requirements for an extension of the time to provide a response in § 423.564(e)(2) are met, the Part D sponsor may extend the timeline to provide a response.

(5) *Coordination with timeframes for grievances, PACE service determination requests, and PACE appeals.* When a complaint under this section is also a grievance within the scope of §§ 423.564 or 460.120, a PACE service determination request within the scope of § 460.121, or a PACE appeal within the definition of § 460.122, the Part D sponsor must comply with the shortest applicable timeframe for resolution of the complaint.

(c) *Timeline for contacting individual filing a complaint.* Regardless of the type of complaint received, the Part D sponsor must attempt to contact the individual who filed a complaint within 7 calendar days of the assignment date.

[89 FR 30834, Apr. 23, 2024]

§ 423.132 Public disclosure of pharmaceutical prices for equivalent drugs.

(a) *General requirements.* Except as provided under paragraph (c) of this section, a Part D sponsor must require a pharmacy that dispenses a covered Part D drug to inform an enrollee of any differential between the price of that drug and the price of the lowest priced generic version of that covered Part D drug that is therapeutically equivalent and bioequivalent and available at that pharmacy, unless the particular covered Part D drug being purchased is the lowest-priced therapeutically equivalent and bioequivalent version of that drug available at that pharmacy.

(b) *Timing of notice.* Subject to paragraph (d) of this section, the information under paragraph (a) of this section must be provided after the drug is dispensed at the point of sale or, in the case of dispensing by mail order, at the time of delivery of the drug.

(c) *Waiver of public disclosure requirement.* CMS waives the requirement under paragraph (a) of this section in any of the following cases:

(1) An MA private fee-for-service plan described in § 422.4 of this chapter that—

(i) Offers qualified prescription drug coverage and provides plan enrollees with access to covered Part D drugs dispensed at all pharmacies, without regard to whether they are contracted network pharmacies; and

(ii) Does not charge additional cost-sharing for access to covered Part D drugs dispensed at out-of-network pharmacies.

(2) An out-of-network pharmacy.

(3) An I/T/U network pharmacy.

(4) A network pharmacy that is located in any of the U.S. territories.

(5) A long-term care network pharmacy.

(6) Other circumstances where CMS deems compliance with the requirements of paragraph (a) of this section to be impossible or impracticable.

(d) *Modification of timing requirement.* CMS modifies the requirement under paragraph (b) of this section under circumstances where CMS deems compliance with this requirement to be impossible or impracticable.

[70 FR 4525, Jan. 28, 2005, as amended at 75 FR 19818, Apr. 15, 2010]

§ 423.136 Privacy, confidentiality, and accuracy of enrollee records.

For any medical records or other health and enrollment information it maintains with respect to enrollees, a PDP sponsor must establish procedures to do the following—

(a) Abide by all Federal and State laws regarding confidentiality and disclosure of medical records, or other health and enrollment information. The PDP sponsor must safeguard the privacy of any information that identifies a particular enrollee and have procedures that specify—

(1) For what purposes the information is used within the organization; and

(2) To whom and for what purposes it discloses the information outside the organization.

(b) Ensure that medical information is released only in accordance with applicable Federal or State law, or under court orders or subpoenas.

(c) Maintain the records and information in an accurate and timely manner.

(d) Ensure timely access by enrollees to the records and information that pertain to them.

§ 423.137 Medicare Prescription Payment Plan.

(a) *General.* For plan years beginning on or after January 1, 2026, or, in the case of a plan operating on a non-calendar year basis, for the portion of the plan year starting on January 1, 2026, each PDP sponsor offering a prescription drug plan and each MA organization offering an MA–PD plan must provide to any enrollee of such plan, including an enrollee who is a subsidy eligible individual (as defined at § 423.4), the option to elect with respect to a plan year to pay $0 cost sharing at the point of sale and pay cost sharing under the plan in monthly amounts that are capped in accordance with this section.

(b) *Definitions.* For the purposes of this section, the following definitions apply:

(1) *OOP costs for the Medicare Prescription Payment Plan* means the out-of-pocket (OOP) cost sharing amount the Part D enrollee is directly responsible for paying.

(i) For the subsequent month calculation of the Part D cost sharing incurred by the Part D enrollee, it includes those Part D cost sharing amounts that the enrollee is responsible for paying after taking into account amounts paid by third-party payers.

(ii) It does not include the covered plan pay amount or other costs defined under section 1860D–2(b)(4)(C) of the Act.

(2) *Remaining OOP costs owed by the participant* means the sum of out-of-pocket costs for the Medicare Prescription Payment Plan that have not yet billed to the program participant. For example, if a Medicare Prescription Payment Plan participant incurs $2,000 in January 2025 and is billed $166.67, the remaining OOP costs for the Medicare Prescription Payment Plan are $2,000 − $166.67 = $1,833.33.

(c) *Calculation of the maximum monthly cap on cost-sharing payments.* For each month in the plan year for which an enrollee in a PDP or an MA–PD plan has made an election to participate in the Medicare Prescription Payment Plan, the PDP sponsor or MA organization must determine a maximum monthly cap (as defined in paragraph (c)(1) of this section) for such enrollee.

(1) *Enrollee monthly payments.* For each month an enrollee is participating in the Medicare Prescription Payment Plan, the PDP sponsor or MA organization shall bill such enrollee an amount (not to exceed the maximum monthly cap) for the out-of-pocket costs of such enrollee in such month.

(i) *First month maximum monthly cap calculation.* For the first month for which the enrollee has made an election to participate in the Medicare Prescription Payment Plan, the maximum monthly cap is an amount determined by calculating the annual out-of-pocket threshold specified in section 1860D–2(b)(4)(B) of the Act minus the incurred costs of the enrollee as described in section 1860D–2(b)(4)(C) of the Act; divided by the number of months remaining in the plan year.

(A) When the out-of-pocket costs incurred in the first month of program participation are less than the maximum monthly cap defined in this paragraph (c)(1)(i), the PDP sponsor or MA organization must bill the participant the lesser of the participant's actual out-of-pocket costs or the first month's maximum monthly cap.

(B) When an enrollee opts into the Medicare Prescription Payment Plan prior to the start of the plan year, the calculation described in this paragraph (c)(1)(i) applies to their first month of active coverage within the plan year.

(ii) *Calculation of maximum monthly cap in subsequent months.* For subsequent months in the plan year, the maximum monthly cap is an amount determined by calculating the sum of any remaining out-of-pocket costs owed by the enrollee from a previous month that have not yet been billed to the enrollee and any additional out-of-pocket costs incurred by the enrollee; divided by the number of months remaining in the plan year.

(2) *Eligible out-of-pocket costs.* The calculations described in paragraphs (c)(1)(i) and (ii) of this section apply only to covered Part D drugs, as defined at § 423.100.

(3) *Months remaining in the plan year.* For the calculations described in paragraphs (c)(1)(i) and (ii) of this section, the number of months remaining in the

plan year includes the month for which the cap is being calculated.

(4) *Impact on true out-of-pocket cost accumulation.* Participation in the Medicare Prescription Payment Plan must have no impact on true out-of-pocket cost accumulation. Costs defined under section 1860D–2(b)(4)(C) of the Act incurred under the Medicare Prescription Payment Plan must still be treated as incurred based on the date each Part D claim is adjudicated.

(5) *Prescriptions for an extended day supply.* For participants who fill prescriptions for an extended day supply, their OOP costs for the Medicare Prescription Payment Plan for those prescriptions must be attributed to the month the prescription was filled and not be pro-rated over the months covered by the prescription.

(6) *Mid-year plan switching.* When an individual opts into the Medicare Prescription Payment Plan after switching plans midyear, the new Part D sponsor must calculate the individual's monthly cap for the first month of participation under the new plan using the formula for the calculation of the maximum monthly cap in the first month.

(d) *Eligibility and election.* An individual is eligible for the Medicare Prescription Payment Plan if they are enrolled in a Part D plan and have not been precluded from participation due to failure to pay, as described in paragraphs (f)(2)(ii) and (f)(5) of this section. LIS-eligible Part D enrollees are eligible to participate in the program. The requirements described in this paragraph (d) are applicable beginning October 1, 2025, with respect to eligibility and election in the Medicare Prescription Payment Plan for 2026.

(1) *Election.* A Part D sponsor must allow any Part D enrollee, including those who are LIS-eligible, to opt into the program prior to the beginning of the plan year or at any point during the plan year. A Part D enrollee must also be allowed to opt into the program in advance of a new plan enrollment effective date, including during any of the following:

(i) The annual coordinated election period for the subsequent plan year.

(ii) The Part D initial enrollment period.

(iii) Part D special election periods.

(2) *Format of election requests.* A Part D sponsor must allow any Part D enrollee or a Part D enrollee's authorized legal representative acting on behalf of the enrollee to opt into the program using a paper or electronic election request form or through a telephone call. Part D sponsors must process any election request regardless of format.

(i) *Paper election requests.* Paper election requests are considered received on the date and time:

(A) The Part D sponsor initially stamps a document received by regular mail (that is, U.S. Postal Service); or

(B) A delivery service that has the ability to track when a shipment is delivered (for example, U.S. Postal Service, UPS, FedEx, or DHL) delivers the document.

(ii) *Telephonic election requests.* Telephonic election requests are considered received on the date and time that either of the following occurs:

(A) The verbal request is made by telephone with a customer service representative.

(B) A message is left on the Part D sponsor's voicemail system if the Part D sponsor utilizes a voicemail system to accept requests or supporting statements after normal business hours.

(iii) *Electronic election requests.* An electronic election request is considered received on the date and time a request is received through the Part D sponsor's website. This is true regardless of when a Part D sponsor ultimately retrieves or downloads the request.

(3) *Completion of election request.* For an election request to be considered complete, the Part D sponsor must receive all of the following:

(i) The name of the Part D enrollee.

(ii) The Medicare ID number of the Part D enrollee.

(iii) The Part D enrollee's or their authorized legal representative's agreement to the Part D sponsor's terms and conditions for the program (signature or, in the case of telephonic requests, verbal attestation).

(4) *Processing an election request*—(i) *Prior to plan year.* Part D sponsors must process election requests received prior to the plan year within the following timeframes:

(A) Within 10 calendar days of receipt, process a complete election request as specified in paragraph (d)(3) of this section.

(B) Within 10 calendar days of receipt of an incomplete election request, contact the Part D enrollee to request the necessary information to process the request as specified in paragraph (d)(3) of this section.

(C) If information necessary to consider the request complete, as required at paragraph (d)(3) of this section, is not received within 21 calendar days of the request for information, the Part D sponsor may deny the request.

(ii) *During a plan year.* Part D sponsors must process election requests received during a plan year within the following timeframes:

(A) Within 24 hours of receipt, process a complete election request, as specified in paragraph (d)(3) of this section.

(B) Within 24 hours of receipt of an incomplete election request, contact the Part D enrollee to request the necessary information to process the request, as required in paragraph (d)(3) of this section.

(C) If information necessary to consider the request complete, as required at paragraph (d)(3) of this section, is not received within 21 calendar days of the request for information, the Part D sponsor may deny the request.

(D) In the event a Part D sponsor fails to process the request within 24 hours due to no fault of the Part D enrollee, the Part D sponsor must—

(*1*) Process a retroactive election effective on the date on which the enrollee should have been admitted into the program; and

(*2*) Reimburse the enrollee for any cost-sharing paid on or after that date within 45 calendar days and include those amounts, as appropriate, in the program calculations.

(5) *Inclusion of all covered Part D drugs once in the program.* Once a participant has opted into the program, cost sharing for all covered Part D drugs must be included in the program.

(6) *Retroactive election.* (i) A Part D sponsor must have in place a process to effectuate a retroactive election into the Medicare Prescription Payment Plan if both of the following conditions are met:

(A) The Part D enrollee believes that any delay in filling the prescription(s) due to the 24-hour timeframe required to process their request to opt in may seriously jeopardize their life, health, or ability to regain maximum function.

(B) The Part D enrollee requests retroactive election within 72 hours of the date and time the claim(s) were adjudicated.

(ii) The Part D sponsor must process the reimbursement for all cost sharing paid by the enrollee for the prescription and any covered Part D prescription filled between the date of adjudication of the claim and the date that the enrollee's election is effectuated within 45 calendar days of the election date.

(iii) If the Part D sponsor determines that an enrollee failed to request retroactive election within the required timeframe, it must promptly notify the individual of its determination and provide instructions on how the individual may file a grievance, as required under paragraph (h)(2) of this section.

(7) *Retroactive LIS eligibility.* A Part D sponsor must develop standardized procedures for determining and processing reimbursements for excess Medicare Prescription Payment Plan payments made by program participants who become LIS eligible and that meet requirements specified at §§ 423.800(c) and (e) and 423.466(a).

(8) *Mid-year plan switching.* When a Part D enrollee switches Part D plans, whether offered by the same or a different Part D sponsor, during the plan year or is reassigned by CMS, the Part D sponsor of the new Part D plan is not permitted to automatically sign up the individual for the Medicare Prescription Payment Plan under the new plan but must allow the individual to opt into the program. Part D plan has the definition established at § 423.4.

(i) The Part D sponsor of the prior Part D plan must offer the participant the option to repay the full outstanding amount in a lump sum. If the individual chooses to continue paying monthly, the Part D sponsor must continue to bill the participant monthly based on the participant's accrued OOP costs for the Medicare Prescription

Payment Plan while in the program under that sponsor's Part D plan. The Part D sponsor cannot require full immediate repayment.

(ii) Part D enrollees may only be precluded from opting into the program under a new Part D plan if both of the following conditions are met:

(A) Both the former and new plans are offered by the same Part D sponsor.

(B) The enrollee was involuntarily terminated from the program under the former plan, as described in paragraph (f)(2)(ii) of this section, for failure to pay and still owes an overdue balance.

(9) *Automatic renewal.* A Part D sponsor is required to automatically renew a Part D enrollee's participation in the Medicare Prescription Payment Plan for subsequent plan years. The Part D sponsor must notify the enrollee of the renewal and remind enrollees that they may opt out of the program at any time, in accordance with paragraph (f)(2)(i) of this section.

(10) *Election communications*—(i) *Election request form.* A Part D sponsor must make available throughout the plan year and during the Part D plan enrollment periods described at paragraph (d)(4)(i)(A) of this section an election request form in the formats specified in paragraph (d)(2) of this section.

(A) *Timing.* A Part D sponsor must send a paper election request form within the same timeframe as the membership ID card mailing specified at §423.2267(e)(32)(i). The election form may be sent in the membership ID card mailing itself or in a separate mailing.

(B) *Contents.* The election request form must include or provide all of the following:

(*1*) Fields for all of the following Part D enrollee information:

(*i*) First and last name.

(*ii*) Medicare Number.

(*iii*) Birth date.

(*iv*) Phone number.

(*v*) Permanent residence street address, and mailing address, if different from permanent residence street address.

(*vi*) Signature field, allowing the enrollee to attest that they understand that form is a request to participate in the Medicare Prescription Payment Plan and the Part D sponsor will contact them if more information is needed to complete the request; their signature indicates they have read and understood the Part D sponsor's terms and conditions; and the Part D sponsor will inform the individual when their participation in the program is active, and, until the individual receives that notification, they are not a participant in the program.

(*2*) Instructions for how to submit the form to the Part D sponsor.

(*3*) Instructions for how the Part D enrollee can contact the Part D sponsor for questions or assistance.

(C) *Additional information.* Additional educational information about the Medicare Prescription Payment Plan must accompany the election request form when provided in hard copy or on the web. The additional information requirement may be fulfilled by including with the election request form the CMS-developed fact sheet about the program. If the Part D sponsor develops and uses alternative informational materials in lieu of the CMS-developed fact sheet to satisfy this paragraph (d)(10)(i)(C), they must ensure that these alternative materials accurately convey program information and are compliant with existing Part D requirements specified at subpart V of this part.

(D) *Terms and conditions.* A Part D sponsor may include their program terms and conditions on the election request form or may include them on a separate attachment.

(ii) *Notice of election approval.* Upon accepting an election request, the Part D sponsor must send a notice of election approval.

(A) *Timing.* (*1*) For requests received prior to the plan year, the notice of election approval must be sent within 10 calendar days of receipt of the election request.

(*2*) For requests received during the plan year, the notice of election approval must be sent within 24 hours of receipt of the election request.

(*3*) The initial notice must be delivered via telephone, to be followed by a written notice delivered to the participant within 3 calendar days of delivering the initial telephone notice. If a Part D plan sponsor is processing an

election request over the phone or electronically and at that same time provides the enrollee with the effective date of their program effectuation and other notice of election requirements as outlined at this paragraph (d)(10)(ii), then a second telephonic notification of election acceptance is not required.

(B) *Contents.* The notice of election approval must include all of the following:

(*1*) The effective date of the individual's participation.

(*2*) A description of how payments for covered Part D drugs under the program will work.

(*3*) An overview of how the monthly bill is calculated.

(*4*) Information about procedures for involuntary termination due to failure to pay and how to submit an inquiry or file a grievance.

(*5*) A statement that leaving the program will not affect the individual's Part D plan enrollment.

(*6*) A description of how individuals may still owe a program balance if they leave the program, and they can choose to pay their balance all at once or be billed monthly.

(*7*) An overview of other Medicare programs that can help lower costs and how to learn more about these programs. These programs include all of the following:

(*i*) Extra Help.

(*ii*) The Medicare Savings Program.

(*iii*) The State Pharmaceutical Assistance Program.

(*iv*) A manufacturer's Pharmaceutical Assistance Program.

(C) *Additional information.* Additional educational information about the Medicare Prescription Payment Plan must accompany the notice of election approval. The additional information requirement may be fulfilled by including with the notice the CMS-developed fact sheet about the program. If the Part D sponsor develops and uses alternative informational materials in lieu of the CMS-developed fact sheet to satisfy this paragraph (d)(10)(ii)(C), they must ensure that these alternative materials accurately convey program information and are compliant with existing Part D requirements specified at subpart V of this part.

(iii) *Notification of denial.* Upon denial of an election request, the Part D sponsor must send a notice of denial.

(A) *Timing.* (*1*) For requests received prior to the plan year, the notice of denial must be sent within 10 calendar days of receipt of the election request.

(*2*) For requests received during the plan year, the notice of denial must be sent within 24 hours of receipt of the election request.

(*3*) For incomplete election requests, within 10 calendar days of the expiration of the timeframe for submission of additional information.

(B) *Contents.* The notice of denial must explain the reason for denial and a description of the grievance process available to the individual.

(iv) *Renewal notice.* A Part D sponsor must send a notice alerting program participants that their participation in the program will automatically renew for the subsequent plan year.

(A) *Timing.* The notice must be sent after the end of the annual coordinated election period, as described at § 422.62(a)(2) of this chapter, but prior to the end of the plan year.

(B) *Contents.* The notice must include all of the following:

(*1*) Notification to the participant that their participation will automatically renew for the upcoming year.

(*2*) Reminder that the participant may opt out of the program at any time, including for the upcoming plan year.

(*3*) Terms and conditions. A Part D sponsor must include their program terms and conditions for the upcoming year as part of the renewal notice or as a separate attachment.

(e) *Part D enrollee targeted outreach.* A Part D sponsor must undertake targeted outreach to enrollees who are likely to benefit from making an election into the Medicare Prescription Payment Plan. The requirements described in this paragraph (e) are applicable beginning October 1, 2025, with respect to targeted outreach for the Medicare Prescription Payment Plan for 2026.

(1) *Identification criteria.* An enrollee deemed to be ''likely to benefit'' from the Medicare Prescription Payment Plan is identified by the Part D sponsor based on the following criteria.

(i) For 2026 and subsequent years, the targeted outreach criteria are as follows:

(A) A Part D enrollee is likely to benefit from participating in the program if the enrollee incurs $600 or more in out-of-pocket costs for a single covered Part D drug.

(B) A Part D enrollee is likely to benefit from participating in the program if the enrollee incurred $2,000 in out-of-pocket costs for covered Part D drugs in the first nine months of the year prior to the upcoming plan year.

(ii) A Part D sponsor may develop supplemental strategies for identification of additional Part D enrollees likely to benefit. If supplemental strategies are implemented, then the Part D sponsor must apply any additional identification criteria to every enrollee of each plan equally.

(2) *Point of sale notification.* (i) A Part D sponsor must have a mechanism to notify a pharmacy when a Part D enrollee incurs out-of-pocket costs with respect to covered Part D drugs that make it likely the enrollee may benefit from participating in the program using the identification criteria set forth in paragraphs (e)(1)(i)(A) and (e)(1)(ii) of this section.

(ii) A Part D sponsor must ensure that a pharmacy, after receiving such a notification from the Part D sponsor, informs the Part D enrollee that it is likely that the Part D enrollee may benefit from the Medicare Prescription Payment Plan.

(3) *Part D sponsor notification.* A Part D sponsor must directly outreach to enrollees identified as likely to benefit from the program during either of the following timeframes:

(i) *Prior to the plan year.* Prior to the plan year, a Part D sponsor must notify current enrollees that they are likely to benefit from the program during the fourth quarter of the year, and no later than the end of the annual coordinated election period, as described at § 422.62(a)(2) of this chapter, using the identification criteria set forth in paragraphs (e)(1)(i)(B) and (e)(1)(ii) of this section.

(ii) *On an ongoing basis during the plan year.* Part D sponsors must put in place reasonable guidelines for ongoing identification and notification of enrollees that are likely to benefit from the program on an ongoing basis during the plan year.

(4) *Targeted outreach notification requirements.* When an enrollee is identified as likely to benefit from the program, using the identification criteria set forth in paragraphs (e)(1)(i) and (ii) of this section or based on Part D sponsor-developed guidelines set forth at paragraph (e)(3)(ii) of this section, the Part D sponsor must provide to the enrollee the standardized ''Medicare Prescription Payment Plan Likely to Benefit Notice'' consistent with the requirements at § 423.2267(b).

(i) When the enrollee is identified as likely to benefit directly by the Part D sponsor, either prior to or during the plan year, the notification may be done via mail or electronically (based on the Part D enrollee's preferred and authorized communication methods).

(A) The outreach must include a program election request form and additional information about the Medicare Prescription Payment Plan. The additional information requirement may be fulfilled by including with the notice the CMS-developed fact sheet about the program. If the Part D sponsor develops and uses alternative informational materials in lieu of the CMS-developed fact sheet to satisfy this paragraph (e)(4)(i)(A), they must ensure that these alternative materials accurately convey program information and are compliant with existing Part D requirements specified at subpart V of this part.

(B) During the plan year, the initial notice may be provided via telephone, so long as the written ''Medicare Prescription Payment Plan Likely to Benefit Notice,'' election request form, and additional information are sent within 3 calendar days of the telephone notification.

(ii) When the enrollee is identified as likely to benefit during the plan year at the pharmacy point of sale, the notice must be provided as described in paragraph (i)(2) of this section.

(5) *Targeted outreach exclusions.* A Part D sponsor does not have to notify enrollees that they are likely to benefit from the program under any of the following circumstances:

(i) For the current year during the final month of the plan year (December).

(ii) When the enrollee is currently participating in the program, including—

(A) For the current year; and

(B) For the upcoming year.

(iii) When the enrollee is precluded from opting into the program.

(iv) When the PDP is non-renewing its contract or individual plan benefit package. This exclusion only applies to the requirements at paragraph (e)(3)(i) of this section related to prior to plan year targeted outreach.

(f) *Termination of election, reinstatement, and preclusion*—(1) *General rule.* Except as provided in paragraph (f)(2) of this section, a Part D sponsor may not do any of the following:

(i) Terminate an individual from the Medicare Prescription Payment Plan.

(ii) Orally or in writing, or by any action or inaction, request or encourage an individual to disenroll.

(2) *Basis for termination*—(i) *Voluntary terminations.* A Part D sponsor must have a process to allow participants who have opted into the Medicare Prescription Payment Plan to opt out during the plan year.

(A) When a participant opts out of the Medicare Prescription Payment Plan, a Part D sponsor must—

(*1*) Process the termination with an effective date within 3 calendar days of receipt of the request for termination.

(*2*) Provide the individual with a notice of termination after the individual notifies the Part D sponsor that they intend to opt out under the Part D sponsor's established process.

(*i*) *Timing.* The Part D sponsor must send the notice of termination within 10 calendar days of receipt of the request for termination.

(*ii*) *Contents.* The notice of voluntary termination must include all of the following. The date on which the individual's participation in the program ends. An explanation of why the individual is receiving the notice. A statement clarifying that the notice only applies to participation in the Medicare Prescription Payment Plan. A statement clarifying that the individual will continue to be billed monthly or can choose to pay the amount owed all at once, and that the individual will not pay interest or fees on the amount owed. A statement clarifying that the individual can join the Medicare Prescription Payment Plan again and instructions for how to do so. An overview of other Medicare programs that can help lower costs and how to learn more about these programs, including Extra Help, the Medicare Savings Program, the State Pharmaceutical Assistance Program, and a manufacturer's Pharmaceutical Assistance Program.

(*3*) Offer the participant the option to repay the full outstanding amount in a lump sum. A Part D sponsor is prohibited from requiring full immediate repayment from a participant who has been terminated from the Medicare Prescription Payment Plan.

(*4*) If the participant opts not to repay the full outstanding amount in a lump sum, continue to bill amounts owed under the program in monthly amounts not to exceed the maximum monthly cap according to the statutory formula for the duration of the plan year after an individual has been terminated.

(*5*) Maintain appropriate records of the termination once the termination is processed.

(B) [Reserved]

(ii) *Involuntary termination.* If a participant fails to pay their monthly billed amount under the program, a Part D sponsor is required to terminate that individual's Medicare Prescription Payment Plan participation.

(A) A participant will be considered to have failed to pay their monthly billed amount only after the conclusion of the required grace period as specified at paragraph (f)(4) of this section.

(B) When a Part D sponsor involuntarily terminates a participant, the sponsor must do all of the following:

(*1*) Provide the individual with a notice of termination consistent with the requirements of paragraphs (f)(2)(ii)(C) and (D) of this section.

(*2*) Offer the participant the option to repay the full outstanding amount in a lump sum. A Part D sponsor is prohibited from requiring full immediate repayment from a participant who has been terminated from the Medicare Prescription Payment Plan.

(*3*) If the participant opts not to repay the full outstanding amount in a lump sum, continue to bill amounts owed under the program in monthly amounts not to exceed the maximum monthly cap according to the statutory formula for the duration of the plan year after an individual has been terminated.

(C) If a Part D sponsor involuntarily terminates a participant under this paragraph (f)(2)(ii), the Part D sponsor must send the individual an initial notice explaining that the individual has failed to pay the billed amount.

(*1*) *Timing*. The notice of failure to pay must be sent within 15 calendar days of the payment due date.

(*2*) *Contents*. The notice of failure to pay must include all of the following:

(*i*) Pertinent dates, including the date the missed monthly payment was due, the amount the individual must pay to remain in the program, and the date by when payment must be received, which is the date of the end of the grace period.

(*ii*) A statement clarifying that the notice only applies to participation in the Medicare Prescription Payment Plan.

(*iii*) Instructions for how to submit payment.

(*iv*) Information about procedures for involuntary termination due to failure to pay, including the date on which the participant would be removed if payment is not received, and how to submit an inquiry or file a grievance.

(*v*) A statement describing how individuals should pay their Part D plan premium first if they cannot afford both their premium and their program balance.

(*vi*) An overview of other Medicare programs that can help lower costs and how to learn more about these programs, including Extra Help, the Medicare Savings Program, the State Pharmaceutical Assistance Program, and a manufacturer's Pharmaceutical Assistance Program.

(D) If the individual has failed to pay the amount due by the end of the grace period described at paragraph (f)(4) of this section, the Part D sponsor must send the individual a termination notice explaining that the individual has been terminated from the Medicare Prescription Payment Plan.

(*1*) *Timing*. The involuntary termination notice must be sent within 3 calendar days following the last day of the end of the grace period.

(*2*) *Contents*. The involuntary termination notice must include all of the following:

(*i*) Pertinent dates, including the date the individual was originally notified of the missed monthly payment and the due date for that payment, as well as the date on which the individual's participation in the program ends, which should be the same date as the notice.

(*ii*) A statement clarifying that the notice only applies to participation in the Medicare Prescription Payment Plan, and that the individual's Part D drug coverage will not be impacted.

(*iii*) Instructions for how to submit payment and the amount owed.

(*iv*) Instructions for how to submit an inquiry or file a grievance.

(*v*) A statement clarifying that the individual can join the Medicare Prescription Payment Plan again if they pay the amount owed.

(*vi*) An overview of other Medicare programs that can help lower costs and how to learn more about these programs, including Extra Help, the Medicare Savings Program, the State Pharmaceutical Assistance Program, and a manufacturer's Pharmaceutical Assistance Program.

(E) If either notice is returned to the Part D sponsor as undeliverable, the Part D sponsor must immediately implement its existing procedure for researching a potential change of address.

(3) *Required grace period and reinstatement*. When a program participant fails to pay a program bill, the Part D sponsor must provide individuals with a grace period of at least two months upon notifying the individual of the initial missed payment.

(i) The grace period must begin on the first day of the month following the date on which the initial notice described in this paragraph (f)(3) is sent.

(ii) A participant must be allowed to pay the overdue balance in full during the grace period to remain in the program.

(iii) If a participant fails to pay their monthly billed amount under the program with fewer than two full calendar months remaining in the calendar year, the grace period must carry over into the next calendar year.

(A) If the program participant is within their grace period from the prior year, the Part D sponsor must allow the participant to opt into the program for the next year.

(B) If that participant fails to pay the amount due from the prior year during the required grace period, the Part D sponsor may terminate the individual's participation in the program in the new year following the procedures outlined in paragraph (f)(2)(ii) of this section.

(iv) If an individual who has been terminated from the Medicare Prescription Payment Plan demonstrates good cause for failure to pay the program billed amount within the grace period and pays all overdue amounts billed, a Part D sponsor must reinstate that individual into the Medicare Prescription Payment Plan.

(A) A Part D sponsor is expected to reinstate an individual into the program within a reasonable timeframe after the individual has repaid their past due Medicare Prescription Payment Plan balance in full.

(B) To demonstrate good cause, the individual must establish by a credible statement that failure to pay the monthly amount billed within the grace period was due to circumstances for which the individual had no control, or which the individual could not reasonably have been expected to foresee.

(v) If an individual who has been terminated from the Medicare Prescription Payment Plan pays all overdue amounts billed in full, a Part D sponsor may also reinstate that individual, at the sponsor's discretion and within a reasonable timeframe, even if the individual does not demonstrate good cause.

(4) *Preclusion of election in a subsequent plan year.* If an individual fails to pay the amount billed for a month as required under the Medicare Prescription Payment Plan, a Part D sponsor may preclude that individual from opting into the Medicare Prescription Payment Plan in a subsequent year.

(i) A Part D sponsor may only preclude an individual from opting into the Medicare Prescription Payment Plan in a subsequent year if the individual owes an overdue balance to that Part D sponsor.

(ii) If an individual enrolls in a Part D plan offered by a different Part D sponsor than the Part D sponsor to which the individual owes an overdue balance, that individual cannot be precluded from opting into the Medicare Prescription Payment Plan in a subsequent year by that different Part D sponsor.

(iii) If a Part D enrollee remains in a plan offered by the same Part D sponsor and continues to owe an overdue balance, preclusion may extend beyond the immediately subsequent plan year.

(A) If an individual pays off the outstanding balance under the Medicare Prescription Payment Plan during a subsequent year, the Part D sponsor must promptly permit them to opt into the Medicare Prescription Payment Plan after the balance is paid.

(B) [Reserved]

(iv) A Part D sponsor that offers more than one Part D plan may have different preclusion policies for its different plans. However, the Part D sponsor must apply its preclusion policy consistently among all enrollees of the same Part D plan.

(5) *Prohibition on Part D enrollment penalties.* A Part D plan sponsor is prohibited from doing any of the following:

(i) Disenrolling a Part D enrollee from a Part D plan for failure to pay any amount billed under the Medicare Prescription Payment Plan.

(ii) Declining future enrollment into a Part D plan based on an individual's failure to pay a monthly amount billed under the Medicare Prescription Payment Plan.

(6) *Disenrollment.* (i) If a participant in the Medicare Prescription Payment Plan is disenrolled voluntarily or involuntarily from their Part D plan under the provisions in § 423.44(b), the participant is also terminated from the Medicare Prescription Payment Plan in that plan.

(ii) If the participant enrolls in a different plan, they may opt into the Medicare Prescription Payment Plan under their new plan.

(7) *Billing for amounts owed.* Nothing in this section prohibits a Part D sponsor from billing an individual for an outstanding Medicare Prescription Payment Plan amount owed.

(g) *Participant billing rights*—(1) *General rule.* For each billing period after an individual has opted into the program and incurred out-of-pocket costs, a Part D sponsor must calculate a monthly amount that takes into account the out-of-pocket costs in that month that were incurred on or after the date on which the individual opted into the program.

(i) A Part D sponsor must not bill a participant who is in the program but has not yet incurred any out-of-pocket costs during the plan year.

(ii) While past due balances from prior monthly bills may also be included in a billing statement, which could result in the total amount on the billing statement exceeding the maximum monthly cap, the amount billed for the month for which the maximum monthly cap is being calculated cannot be higher than the cap for that month.

(iii) A Part D sponsor must not charge late fees, interest payments, or other fees, such as for different payment mechanisms.

(A) A Part D sponsor must ensure that—

(*1*) Any third party it contracts with complies with such requirements.

(*2*) Participants do not incur any charges or fees as a result of overbilling or overpayment errors made by the Part D sponsor.

(B) [Reserved]

(iv) A Part D sponsor must send a bill for the Medicare Prescription Payment Plan that is separate from the bill for collection of premiums, if applicable.

(2) *Billing period.* Each billing period will be a calendar month.

(i) The billing period begins on either of the following:

(A) The effective date of a Part D enrollee's participation in the Medicare Prescription Payment Plan (for the first month a participant elects into the program during the plan year).

(B) The first day of the month (for each subsequent month or for the first month of a participant who elects into the program prior to the start of the plan year).

(ii) The billing period ends on the last date of that month.

(3) *Billing statement.* Billing statements must include all of the following information:

(i) A statement that the bill is for the Medicare Prescription Payment Plan.

(ii) A brief description of the program.

(iii) A reference to where additional information about the program can be found.

(iv) The effective date of program participation.

(v) The last payment received, showing the date, amount of the last payment, and the means of payment made by the participant.

(vi) Any balance carried over from the prior month, including any missed payments.

(vii) Itemized out-of-pocket costs by prescription for the month being billed.

(viii) The amount due from the participant for the month being billed (that is, the amount based on the application of the monthly cap calculation).

(ix) The remaining total out-of-pocket cost sharing balance.

(x) Information on the next steps if the participant fails to pay by the stated due date.

(xi) Information on how to voluntarily opt out of the program and balances due if participation is terminated.

(xii) Information on the dispute processes available if the individual disputes their bill.

(xiii) LIS program information, including the following:

(A) General information about how to enroll in the LIS program (as an additional or alternative avenue for addressing prescription drug costs).

(B) A statement that LIS enrollment, for those who qualify, is likely to be more advantageous than participation in the Medicare Prescription Payment Plan.

(xiv) Plan contact information for participant questions about the billing statement.

(4) *Treatment of unsettled balances.* Any unsettled balances with respect to amounts owed under the program will be treated as plan losses.

(i) The Secretary is not liable for any such balances outside of those assumed as losses estimated in a Part D sponsor's plan bid.

(ii) If a Part D sponsor is compensated by or on behalf of the participant for an unsettled balance or sells an unsettled balance as a debt, that Part D sponsor cannot treat the amount as a loss and cannot include it in its bid.

(5) *Prioritization of premium payments.* If a Part D enrollee has opted into the program and makes payments directly to the Part D sponsor, and it is unclear whether a payment should go towards the participant's outstanding Part D plan premium or Medicare Prescription Payment Plan balance, then the payment must be applied to the Part D premium.

(6) *Financial reconciliation.* A Part D sponsor must have a financial reconciliation process in place to correct inaccuracies in billing or payments or both.

(i) *Participant payment.* (A) A participant may pay more than the maximum monthly cap, up to the annual out-of-pocket threshold.

(B) The participant cannot pay more than their total OOP costs for the Medicare Prescription Payment Plan.

(C) If a participant does pay more than their total OOP costs for the Medicare Prescription Payment Plan, then the Part D sponsor must reimburse the participant the amount that is paid above the balance owed.

(ii) *Reimbursements for excess participant payments.* A Part D sponsor must develop standardized procedures for determining and processing reimbursements for excess Medicare Prescription Payment Plan payments made by program participants.

(iii) *Claims adjustments resulting in increased amounts owed.* When Part D claims adjustments result in increased amounts owed by the participant, and these amounts have not yet been billed to the participant, they must be included in the revised remaining OOP costs owed by the participant (as defined at paragraph (b)(1) of this section) and, thus, in the subsequent month maximum cap for the next billing period.

(h) *Participant disputes*—(1) *Coverage determination and appeals procedures.* A Part D sponsor must apply the Part D coverage determination and appeals procedures specified at § 423.566(a) to any disputes made by program participants concerning the cost sharing amount of a covered Part D drug.

(2) *Grievance procedures.* A Part D sponsor must apply the Part D grievance procedure specified at § 423.562 to any dispute made by a program participant related to any aspect of the Medicare Prescription Payment Plan.

(i) *Pharmacy point of sale notification process.* (1) When a Part D sponsor is notifying a pharmacy that a Part D enrollee has incurred out-of-pocket costs with respect to covered Part D drugs that make it likely the enrollee may benefit from participating in the program, as required at paragraph (e)(2) of this section, the Part D sponsor must use standard code values for notifying the pharmacy that an enrollee has been identified as likely to benefit, as outlined by the National Council for Prescription Drug Programs.

(2) A Part D sponsor must ensure that the ''Medicare Prescription Payment Plan Likely to Benefit Notice'' is provided to enrollees identified as likely to benefit (or the person acting on their behalf) through the pharmacy point of sale notification process.

(i) In pharmacy settings in which there is direct contact with enrollees (for example, community pharmacies where enrollees present in person to pick up prescriptions), the Part D sponsor must ensure that a hard copy of the ''Medicare Prescription Payment Plan Likely to Benefit Notice'' is provided to enrollees identified as likely to benefit (or the person acting on their behalf) at the time the prescription is picked up.

(ii) For non-retail pharmacy settings without in-person encounters (such as mail order pharmacies), a Part D sponsor must require the pharmacy to notify the Part D enrollee via a telephone call or their preferred contact method.

(iii) For long-term care pharmacy settings, the Part D plan sponsor should not require that the pharmacy

notify the Part D enrollee prior to dispensing the medication. Instead, the Part D plan sponsor should require the long-term care pharmacy to provide the notice to the Part D enrollee (or their authorized representative) at the time of its typical enrollee cost-sharing billing process.

(iv) If the pharmacy is in contact with a Part D enrollee identified as likely to benefit and the enrollee declines to complete the prescription filling process, the Part D sponsor must ensure that the pharmacy provides the ''Medicare Prescription Payment Plan Likely to Benefit Notice'' to the Part D enrollee.

(3) A Part D sponsor must ensure that any contract between the Part D sponsor and a pharmacy (or between a first tier, downstream, or related entity and a pharmacy on the Part D sponsor's behalf) for participation in one or more of the Part D sponsor's networks includes a provision requiring pharmacies to provide this notification to Part D enrollees.

(j) *Pharmacy claims processing*—(1) *Electronic claims processing methodology*. Part D sponsors must use, and must ensure pharmacies use, a bank identification number (BIN) or processor control number (PCN) electronic claims processing methodology for applicable Medicare Prescription Payment Plan transactions.

(i) Part D sponsors must utilize, and ensure pharmacies utilize, an additional BIN/PCN that is unique to the Medicare Prescription Payment Plan to facilitate electronic processing of supplemental coordination of benefits (COB) transactions for program participants.

(ii) A Part D sponsor must provide the unique Medicare Prescription Payment Plan BIN/PCN and any other pertinent billing information to the pharmacy on paid claim responses when the enrollee is also a Medicare Prescription Payment Plan participant.

(iii) A Part D sponsor must assign a program-specific PCN that starts with ''MPPP'' and report the new BIN/PCN to CMS.

(iv) The transaction processed through the Medicare Prescription Payment Plan BIN/PCN will be submitted after processing any applicable other payer transactions in order to capture the final patient responsibility amount after all other payers have paid.

(2) *Supplemental coverage that increases final patient pay amount*. When a Part D enrollee has supplemental coverage that modifies their final out-of-pocket responsibility for covered Part D drugs:

(i) When the final patient pay amount returned to the pharmacy by a supplemental payer for a covered Part D drug is higher than the original Part D patient pay amount, the Part D sponsor may only include in the Medicare Prescription Payment Plan the participant's original Part D cost sharing, as determined by their plan-specific benefit structure.

(ii) [Reserved]

(3) *Prescription drug event reporting*. A Part D sponsor must ensure that the claims processing methodology described in paragraph (j)(1) of this section has no impact on prescription drug event (PDE) cost/payment field reporting, meaning PDE records must reflect participant and plan liability amounts as if the Medicare Prescription Payment Plan did not apply.

(4) *Real-time benefit tools*. A Part D sponsor must ensure that participation in the Medicare Prescription Payment Plan or the associated claims processing methodology described in paragraph (j)(1) of this section or both has no impact on the cost-sharing information displayed in real-time benefit tools.

(5) *Inclusion of retroactive claims*. A Part D sponsor is not required to retroactively include under this program claims submitted to the Part D sponsor by a Medicare Prescription Payment Plan participant (whether the request is made via paper form, telephonically, or electronically) except as provided in paragraph (d)(6) of this section.

(6) *Re-adjudication of prescription drug claims for new program participants*. (i) When a Part D enrollee receives the ''Medicare Prescription Payment Plan Likely to Benefit Notice'' from the pharmacy, they may choose to take time to consider opting into the program and leave the pharmacy without the prescription that triggered the notification.

(ii) When the Part D enrollee returns to the pharmacy after their election into the Medicare Prescription Payment Plan has been effectuated, the plan sponsor must require the pharmacy to reverse and reprocess the high-cost claim that triggered the likely to benefit notification.

(A) Should a Part D enrollee have other unpaid claims at the same pharmacy for covered Part D drugs from prior dates of service, in addition to the prescription that may have triggered the likely to benefit notification, they may also request that those claims be readjudicated.

(B) [Reserved]

(iii) When the Part D claim date of service is the same as the date of program effectuation), the Part D sponsor is not required to ensure the pharmacy reverse and resubmit the Part D claim, provided that they otherwise obtain the necessary Medicare Prescription Payment Plan BIN/PCN for the program-specific transaction.

(k) *Pharmacy payment obligations.* A Part D sponsor must ensure that enrollee participation in the Medicare Prescription Payment Plan does not affect the amount paid to pharmacies or the timing of such payments, consistent with § 423.520. A Part D sponsor must not do either of the following:

(1) Impose any fees or costs related to program implementation on pharmacies.

(2) Hold pharmacies responsible for any unsettled balances of a participant or for collecting unpaid balances from the participant on the Part D sponsor's behalf.

(l) [Reserved]

(m) *General Part D sponsor outreach and education requirements.* The requirements described in this paragraph (m) are applicable beginning October 1, 2025, with respect to general outreach for the Medicare Prescription Payment Plan for 2026.

(1) *Mailing.* A Part D sponsor, except a dual eligible special needs plan (D–SNP), must provide a Medicare Prescription Payment Plan election request form, described at paragraph (d)(10)(i) of this section, and additional educational information on the program in a hard copy mailing.

(i) The mailing must be sent by the later of—

(A) Within 10 calendar days from receipt of CMS confirmation of enrollment in the Part D plan; or

(B) The last day of the month prior to the plan effective date.

(ii) The election request form and supplemental information may be sent—

(A) With the membership ID card mailing described at § 423.2267(e)(32); or

(B) In its own envelope.

(iii) The mailing may be sent only to a Part D enrollee who is receiving a new membership ID card or to all Part D enrollees.

(iv) The additional information requirement may be fulfilled by including in the mailing the CMS-developed fact sheet about the program. If the Part D sponsor develops and uses alternative informational materials in lieu of the CMS-developed fact sheet to satisfy this paragraph (m)(1)(iv), they must ensure that these alternative materials accurately convey program information and are compliant with existing Part D requirements specified at subpart V of this part.

(2) *Websites.* In addition to meeting requirements described at §§ 423.128(d)(2) and 423.2265(b), a Part D sponsor is required to include all of the following on its website:

(i) An election request mechanism, as described at paragraph (d)(2) of this section.

(ii) An overview of the Medicare Prescription Payment Plan.

(iii) Examples of the program calculation and explanations.

(iv) A description of Part D enrollees who may be likely to benefit from the program.

(v) The financial implications of participation.

(vi) The implications of not paying monthly bills.

(vii) Instructions for how to opt into and out of the program, including timing requirements around election effectuation.

(viii) A description of the standards for retroactive election in cases where an enrollee believes that a delay in filling a prescription may seriously jeopardize their life, health, or ability to regain maximum function.

(ix) A description of the dispute and grievance procedure, as required under § 423.137(h).

(x) Contact information Part D enrollees can use to obtain further information

(xi) General information about the LIS program, including an overview of how LIS enrollment, for those who qualify, is likely to be more advantageous than program participation.

[90 FR 15912, Apr. 15, 2025]

Subpart D—Cost Control and Quality Improvement Requirements

§ 423.150 Scope.

This subpart sets forth the requirements relating to the following:

(a) Drug utilization management programs, quality assurance measures and systems, and MTM programs for Part D sponsors.

(b) Appropriate dispensing of prescription drugs in long-term care facilities under PDPs and MA–PD plans.

(c) Consumer satisfaction surveys of Part D plans.

(d) Electronic prescription drug programs for prescribers, dispensers, and Part D sponsors.

(e) Quality improvement organization (QIO) activities.

(f) Compliance deemed on the basis of accreditation.

(g) Accreditation organizations.

(h) Procedures for the approval of accreditation organizations as a basis for deeming compliance.

[70 FR 4525, Jan. 28, 2005, as amended at 70 FR 67593, Nov. 7, 2005; 76 FR 21573, Apr. 15, 2011; 89 FR 30834, Apr. 23, 2024]

§ 423.153 Drug utilization management, quality assurance, medication therapy management (MTM) programs, drug management programs, and access to Medicare Parts A and B claims data extracts.

(a) *General rule.* Each Part D sponsor must have established, for covered Part D drugs furnished through a Part D plan, a drug utilization management program, quality assurance measures and systems, and an MTM program as described in paragraphs (b), (c), and (d) of this section. No later than January 1, 2022, a Part D plan sponsor must have established a drug management program for at-risk beneficiaries enrolled in their prescription drug benefit plans to address overutilization of frequently abused drugs, as described in paragraph (f) of this section.

(b) *Drug utilization management.* A Part D sponsor must have established a reasonable and appropriate drug utilization management program that address all of the following:

(1) Includes incentives to reduce costs when medically appropriate.

(2) Maintains policies and systems to assist in preventing over-utilization and under-utilization of prescribed medications.

(3) Provides CMS with information concerning the procedures and performance of its drug utilization management program, according to guidelines specified by CMS.

(4)(i) *Daily cost sharing rate.* Subject to paragraph (b)(4)(ii) of this section, establishes a daily cost-sharing rate (as defined in § 423.100) and applies it to a prescription presented to a network pharmacy for a covered Part D drug that is dispensed for a supply less than the approved month's supply, if the drug is in the form of a solid oral dose and may be dispensed for less than the approved month's supply under applicable law.

(ii) *Exceptions.* The requirements of paragraph (b)(4)(i) of this section do not apply to either of the following:

(A) Solid oral doses of antibiotics.

(B) Solid oral doses that are dispensed in their original container as indicated in the Food and Drug Administration Prescribing Information or are customarily dispensed in their original packaging to assist patients with compliance.

(iii) *Cost-sharing*—(A) *Copayments.* In the case of a drug that would incur a copayment, the Part D sponsor must apply cost-sharing as calculated by multiplying the applicable daily cost-sharing rate by the days' supply actually dispensed when the beneficiary receives less than the approved month's supply.

(B) *Coinsurance.* In the case of a drug that would incur a coinsurance percentage, the Part D sponsor must apply the coinsurance percentage for the

drug to the days' supply actually dispensed.

(c) *Quality assurance.* A Part D sponsor must have established quality assurance measures and systems to reduce medication errors and adverse drug interactions and improve medication use that include all of the following—

(1) Representation that network providers are required to comply with minimum standards for pharmacy practice as established by the States.

(2) Concurrent drug utilization review systems, policies, and procedures designed to ensure that a review of the prescribed drug therapy is performed before each prescription is dispensed to an enrollee in a sponsor's Part D plan, typically at the point-of-sale or point of distribution. The review must include, but not be limited to,

(i) Screening for potential drug therapy problems due to therapeutic duplication.

(ii) Age/gender-related contraindications.

(iii) Over-utilization and under-utilization.

(iv) Drug-drug interactions.

(v) Incorrect drug dosage or duration of drug therapy. (vi) Drug-allergy contraindications.

(vii) Clinical abuse/misuse.

(3) Retrospective drug utilization review systems, policies, and procedures designed to ensure ongoing periodic examination of claims data and other records, through computerized drug claims processing and information retrieval systems, in order to identify patterns of inappropriate or medically unnecessary care among enrollees in a sponsor's Part D plan, or associated with specific drugs or groups of drugs.

(4) Internal medication error identification and reduction systems.

(5) Provision of information to CMS regarding its quality assurance measures and systems, according to guidelines specified by CMS.

(d) *Medication therapy management (MTM) program*—(1) *General rule.* A Part D sponsor must have established a MTM program that—

(i) Is designed to ensure that covered Part D drugs prescribed to targeted beneficiaries described in paragraph (d)(2) of this section are appropriately used to optimize therapeutic outcomes through improved medication use;

(ii) Is designed to reduce the risk of adverse events, including adverse drug interactions, for targeted beneficiaries described in paragraph (d)(2) of this section;

(iii) May be furnished by a pharmacist or other qualified provider; and

(iv) May distinguish between services in ambulatory and institutional settings.

(v) Must enroll targeted beneficiaries using an opt-out method of enrollment only.

(vi) Must target beneficiaries for enrollment in the MTM program at least quarterly during each plan year.

(vii) Must offer a minimum level of medication therapy management services for each beneficiary enrolled in the MTM program that includes all of the following:

(A) Interventions for both beneficiaries and prescribers.

(B) *Annual comprehensive medication review with written summaries.* (*1*) The beneficiary's comprehensive medication review—

(*i*) Must include an interactive consultation, performed by a pharmacist or other qualified provider, that is either in person or performed via synchronous telehealth; and

(*ii*) May result in a recommended medication action plan.

(*2*) If a beneficiary is offered the annual comprehensive medication review and is unable to accept the offer to participate due to cognitive impairment, the pharmacist or other qualified provider may perform the comprehensive medication review with the beneficiary's prescriber, caregiver, or other authorized individual.

(C) Quarterly targeted medication reviews with follow-up interventions when necessary.

(D) Standardized action plans and summaries that comply with requirements as specified by CMS for the standardized format.

(E) Beginning January 1, 2022, for enrollees targeted in paragraph (d)(2) of this section, provide at least annually as part of the comprehensive medication review, a targeted medication review, or other MTM correspondence or

service, information about safe disposal of prescription drugs that are controlled substances, drug take back programs, in-home disposal and cost-effective means to safely dispose of such drugs.

(F) The information to be provided under paragraph (d)(1)(vii)(E) of this section must comply with all requirements of § 422.111(j) of this chapter.

(2) *Targeted beneficiaries.* Targeted beneficiaries for the MTM program described in paragraph (d)(1) of this section are enrollees in the sponsor's Part D plan who meet the characteristics of at least one of the following two groups:

(i)(A) Have multiple chronic diseases, with three chronic diseases being the maximum number a Part D plan sponsor may require for targeted enrollment;

(B) Are taking multiple Part D drugs, with eight Part D drugs being the maximum number of drugs a Part D plan sponsor may require for targeted enrollment; and

(C) Are likely to incur annual covered Part D drug costs greater than or equal to the MTM cost threshold determined by CMS, as specified in this paragraph (d)(2)(i)(C) of this section.

(*1*) For 2011, the MTM cost threshold is set at $3,000.

(*2*) For 2012 through 2024, the MTM cost threshold is set at $3,000 increased by the annual percentage specified in § 423.104(d)(5)(iv).

(*3*) For 2025, the MTM cost threshold is set at the average annual cost of eight generic drugs, as defined at § 423.4, as determined using the PDE data specified at § 423.104(d)(2)(iv)(C).

(ii) Beginning January 1, 2022, are at-risk beneficiaries as defined in § 423.100.

(iii) Beginning January 1, 2025, in identifying beneficiaries who have multiple chronic diseases under paragraph (d)(2)(i)(A) of this section, Part D plan sponsors must include all of the following diseases, and may include additional chronic diseases:

(A) Alzheimer's disease.

(B) Bone disease-arthritis (including osteoporosis, osteoarthritis, and rheumatoid arthritis).

(C) Chronic congestive heart failure (CHF).

(D) Diabetes.

(E) Dyslipidemia.

(F) End-stage renal disease (ESRD).

(G) Human immunodeficiency virus/acquired immunodeficiency syndrome (HIV/AIDS).

(H) Hypertension.

(I) Mental health (including depression, schizophrenia, bipolar disorder, and other chronic/disabling mental health conditions).

(J) Respiratory disease (including asthma, chronic obstructive pulmonary disease (COPD), and other chronic lung disorders).

(iv) Beginning January 1, 2025, in identifying the number of Part D drugs under paragraph (d)(2)(i)(B) of this section, Part D plan sponsors must include all Part D maintenance drugs, relying on information in a widely accepted, commercially or publicly available drug database to make such determinations, and may include all Part D drugs.

(3) *Use of experts.* The MTM program must be developed in cooperation with licensed and practicing pharmacists and physicians.

(4) *Coordination with care management plans.* The MTM program must be coordinated with any care management plan established for a targeted individual under a chronic care improvement program (CCIP) under section 1807 of the Act. A Part D sponsor must provide drug claims data to CCIPs for those beneficiaries that are enrolled in CCIPs in a manner specified by CMS.

(5) *Considerations in pharmacy fees.* An applicant to become a Part D sponsor must—

(i) Describe in its application how it takes into account the resources used and time required to implement the MTM program it chooses to adopt in establishing fees for pharmacists or others providing MTM services for covered Part D drugs under a Part D plan.

(ii) Disclose to CMS upon request the amount of the management and dispensing fees and the portion paid for MTM services to pharmacists and others upon request. Reports of these amounts are protected under the provisions of section 1927(b)(3)(D) of the Act.

(6) *MTM program reporting.* A Part D sponsor must provide CMS with information regarding the procedures and

performance of its MTM program, according to guidelines specified by CMS.

(e) *Exception for private fee-for-service MA plans offering qualified prescription drug coverage.* In the case of an MA plan described in §422.4(a)(3) of this chapter providing qualified prescription drug coverage, the requirements under paragraphs (b) and (d) of this section do not apply.

(f) *Drug management programs.* A drug management program must meet all the following requirements:

(1) *Written policies and procedures.* A sponsor must document its drug management program in written policies and procedures that are approved by the applicable P&T committee and reviewed and updated as appropriate. In the case of a Part D sponsor, including a PACE organization, without its own or a contracted P&T committee because it does not use a formulary, the written policies and procedures described in this section must be approved by the Part D sponsor's medical director as described at §423.562(a)(5) (or, for a PACE organization, at §460.60(b)) and applicable clinical and other staff or contractors as determined appropriate by the medical director. These policies and procedures must address all aspects of the sponsor's drug management program, including but not limited to the following:

(i) The appropriate credentials of the clinical staff conducting case management required under paragraph (f)(2) of this section, including that the staff must have a current and unrestricted license to practice within the scope of his or her profession in a State, Territory, Commonwealth of the United Stated (that is, Puerto Rico), or the District of Columbia.

(ii) The necessary and appropriate contents of files for case management required under paragraph (f)(2) of this section, which must include documentation of the substance of prescriber and beneficiary contacts.

(iii) Monitoring reports and notifications about incoming enrollees who meet the definition of an at-risk beneficiary or a potential at-risk beneficiary in §423.100 and responding to requests from other sponsors for information about at-risk beneficiaries and potential at-risk beneficiaries who recently disenrolled from the sponsor's prescription drug benefit plan.

(2) *Case management/clinical contact/prescriber verification*—(i) *General rule.* The sponsor's clinical staff must conduct case management for each potential at-risk beneficiary for the purpose of engaging in clinical contact with the prescribers of frequently abused drugs and verifying whether a potential at-risk beneficiary is an at-risk beneficiary. Except as provided in paragraph (f)(2)(ii) of this section, the sponsor must do all of the following:

(A) Send written information to the beneficiary's prescribers that the beneficiary met the clinical guidelines and is a potential at risk beneficiary.

(B) Elicit information from the prescribers about any factors in the beneficiary's treatment that are relevant to a determination that the beneficiary is an at-risk beneficiary, including whether prescribed medications are appropriate for the beneficiary's medical conditions or the beneficiary is an exempted beneficiary.

(C) In cases where prescribers have not responded to the inquiry described in paragraph (f)(2)(i)(B) of this section, make reasonable attempts to communicate with the prescribers telephonically and/or by another effective communication method designed to elicit a response from the prescribers within a reasonable period after sending the written information.

(ii) *Exception for identification by prior plan.* If a beneficiary was identified as a potential at-risk or an at-risk beneficiary by his or her most recent prior plan and such identification has not been terminated in accordance with paragraph (f)(14) of this section, the sponsor meets the requirements in paragraph (f)(2)(i) of this section, so long as the sponsor obtains case management information from the previous sponsor and such information is still clinically adequate and up to date.

(3) *Limitation on access to coverage for frequently abused drugs.* Subject to the requirements of paragraph (f)(4) of this section, a Part D plan sponsor may do any or all of the following:

(i) Implement a point-of-sale claim edit for frequently abused drugs that is specific to an at-risk beneficiary.

(ii) In accordance with paragraphs (f)(9) and (13) of this section, limit an at-risk beneficiary's access to coverage for frequently abused drugs to those that are—

(A) Prescribed for the beneficiary by one or more prescribers;

(B) Dispensed to the beneficiary by one or more network pharmacies; or

(C) Both.

(iii)(A) If the sponsor implements an edit as specified in paragraph (f)(3)(i) of this section, the sponsor must not cover frequently abused drugs for the beneficiary in excess of the edit, unless the edit is terminated or revised based on a subsequent determination, including a successful appeal.

(B) If the sponsor limits the at-risk beneficiary's access to coverage as specified in paragraph (f)(3)(ii) of this section, the sponsor must cover frequently abused drugs for the beneficiary only when they are obtained from the selected pharmacy(ies) or prescriber(s) or both, as applicable—

(*1*) In accordance with all other coverage requirements of the beneficiary's prescription drug benefit plan, unless the limit is terminated or revised based on a subsequent determination, including a successful appeal; and

(*2*) Except as necessary to provide reasonable access in accordance with paragraph (f)(12) of this section.

(4) *Requirements for limiting access to coverage for frequently abused drugs.* (i) A sponsor may not limit the access of an at-risk beneficiary to coverage for frequently abused drugs under paragraph (f)(3) of this section, unless the sponsor has done all of the following:

(A) Conducted case management as required by paragraph (f)(2) of this section and updated it, if necessary.

(B) Except in the case of a pharmacy limitation imposed pursuant to paragraph (f)(3)(ii)(B) of this section, obtained the agreement of at least one prescriber of frequently abused drugs for the beneficiary that the specific limitation is appropriate.

(C) Provided the notices to the beneficiary in compliance with paragraphs (f)(5) and (6) of this section.

(ii)(A) Except as provided in paragraph paragraph (f)(3)(ii)(A) of this sectionregarding a prescriber limitation, if the sponsor has complied with the requirement of paragraph paragraph (f)(2)(i)(B) of this section about attempts to reach prescribers, and the prescribers were not responsive after 3 attempts by the sponsor to contact them within 10 business days, then the sponsor has met the requirement of paragraph (f)(4)(i)(B) of this section for eliciting information from the prescribers.

(B) The sponsor may not implement a prescriber limitation pursuant to paragraph (f)(3)(ii)(A) of this section if no prescriber was responsive.

(5) *Initial notice to a beneficiary.* (i) After conducting the case management required by paragraph (f)(2) of this section, a Part D sponsor that intends to limit the access of a potential at-risk beneficiary, or subject to the exception in paragraph (f)(8)(ii) of this section, of an at-risk beneficiary (as defined in subparagraph (2) of the definition in §423.100), to coverage for frequently abused drugs under paragraph (f)(3) of this section must provide an initial written notice to the beneficiary.

(ii) The notice must do all of the following:

(A) Use language approved by the Secretary.

(B) Be in a readable and understandable form.

(C) Provide all of the following information:

(*1*) An explanation that the beneficiary's current or immediately prior Part D plan sponsor has identified the beneficiary as a potential at-risk beneficiary.

(*2*) A description, of all State and Federal public health resources that are designed to address prescription drug abuse to which the beneficiary has access, including mental health and other counseling services and information on how to access such services, including any such services covered by the plan under its Medicare benefits, supplemental benefits, or Medicaid benefits (if the plan integrates coverage of Medicare and Medicaid benefits).

(*3*) An explanation of the beneficiary's right to a redetermination if the sponsor issues a determination that the beneficiary is an at-risk beneficiary and the standard and expedited redetermination processes described at

§§ 423.582 and 423.584, including notice that if on redetermination the plan sponsor affirms its denial, in whole or in part, the case must be automatically forwarded to the independent review entity contracted with CMS for review and resolution.

(*4*) A request that the beneficiary submit to the sponsor within 30 days of the date of this initial notice any information that the beneficiary believes is relevant to the sponsor's determination, including which prescribers and pharmacies the beneficiary would prefer the sponsor to select if the sponsor implements a limitation under paragraph (f)(3)(ii) of this section.

(*5*) An explanation of the meaning and consequences of being identified as an at-risk beneficiary, including the following:

(*i*) An explanation of the sponsor's drug management program, the specific limitation the sponsor intends to place on the beneficiary's access to coverage for frequently abused drugs under the program.

(*ii*) The timeframe for the sponsor's decision.

(*iii*) If applicable, any limitation on the availability of the special enrollment period described in § 423.38.

(*6*) Clear instructions that explain how the beneficiary can contact the sponsor, including how the beneficiary may submit information to the sponsor in response to the request described in paragraph (f)(5)(ii)(C)(*4*) of this section.

(*7*) Contact information for other organizations that can provide the beneficiary with assistance regarding the sponsor's drug management program.

(*8*) Other content that CMS determines is necessary for the beneficiary to understand the information required in this notice.

(iii) The Part D plan sponsor must make reasonable efforts to provide the beneficiary's prescriber(s) of frequently abused drugs with a copy of the notice required under paragraph (f)(5)(i) of this section.

(iv) If the Part D plan sponsor subsequently intends to make a change to the terms of an ongoing limitation(s) established under paragraph (f)(3) of this section, including the intention to impose an additional limitation on the at-risk beneficiary, the sponsor must comply with the requirements of paragraph (f)(3) of this section, as well as all applicable requirements for beneficiary notices described in paragraphs (f)(5) through (8) of this section.

(6) *Second notice.* (i) Upon making a determination that a beneficiary is an at-risk beneficiary and to limit the beneficiary's access to coverage for frequently abused drugs under paragraph (f)(3) of this section, a Part D sponsor must provide a second written notice to the beneficiary.

(ii) The second notice must do all of the following:

(A) Use language approved by the Secretary.

(B) Be in a readable and understandable form.

(C) Provide all of the following information:

(*1*) An explanation that the beneficiary's current or immediately prior Part D plan sponsor has identified the beneficiary as an at-risk beneficiary.

(*2*) An explanation that the beneficiary is subject to the requirements of the sponsor's drug management program, including—

(*i*) The limitation the sponsor is placing on the beneficiary's access to coverage for frequently abused drugs and the effective and end date of the limitation; and

(*ii*) If applicable, any limitation on the availability of the special enrollment period described in § 423.38.

(*3*) The prescriber(s) or pharmacy(ies) or both, if and as applicable, from which the beneficiary must obtain frequently abused drugs in order for them to be covered by the sponsor.

(*4*) An explanation of the beneficiary's right to a redetermination under § 423.580, including all of the following:

(*i*) A description of both the standard and expedited redetermination processes.

(*ii*) The beneficiary's right to, and conditions for, obtaining an expedited redetermination.

(*iii*) Notice that if on redetermination the plan sponsor affirms its denial, in whole or in part, the case must be automatically forwarded to the independent review entity contracted with CMS for review and resolution.

(*5*) An explanation that the beneficiary may submit to the sponsor, if the beneficiary has not already done so, the prescriber(s) and pharmacy(ies), as applicable, from which the beneficiary would prefer to obtain frequently abused drugs.

(*6*) Clear instructions that explain how the beneficiary may contact the sponsor, including how the beneficiary may submit information to the sponsor in response to the request described in paragraph (f)(6)(ii)(C)(*5*) of this section.

(*7*) Other content that CMS determines is necessary for the beneficiary to understand the information required in this notice.

(iii) The Part D plan sponsor must make reasonable efforts to provide the beneficiary's prescriber(s) of frequently abused drugs with a copy of the notice required by paragraph (f)(6)(i) of this section.

(7) *Alternate second notice.* (i) If, after providing an initial notice to a potential at-risk beneficiary under paragraph (f)(4) of this section, a Part D sponsor determines that the potential at-risk beneficiary is not an at-risk beneficiary, the sponsor must provide an alternate second written notice to the beneficiary.

(ii) The alternate second notice must do all of the following:

(A) Use language approved by the Secretary.

(B) Be in a readable and understandable form.

(C) Provide all of the following information:

(*1*) The sponsor has determined that the beneficiary is not an at-risk beneficiary.

(*2*) The sponsor will not limit the beneficiary's access to coverage for frequently abused drugs.

(*3*) If applicable, the SEP limitation no longer applies.

(*4*) Clear instructions that explain how the beneficiary may contact the sponsor.

(*5*) Other content that CMS determines is necessary for the beneficiary to understand the information required in this notice.

(iii) The Part D sponsor must make reasonable efforts to provide the beneficiary's prescriber(s) of frequently abused drugs with a copy of the notice required in accordance with paragraph (f)(7)(i) of this section.

(8) *Notices: Timing and exceptions.* (i) Subject to paragraphs (f)(8)(ii) and (iii) of this section, a Part D sponsor must provide the second notice described in paragraph (f)(6) of this section or the alternate second notice described in paragraph (f)(7) of this section, as applicable, on a date that is not less than 30 days after the date of the initial notice described in paragraph (f)(5) of this section and not more than the earlier of the following two dates:

(A) Within 3 days of the date the sponsor makes the relevant determination.

(B) Sixty days after the date of the initial notice described in paragraph (f)(5) of this section.

(ii) In the case of a beneficiary who is determined by a Part D sponsor to be exempt, the sponsor must provide the alternate second notice within 3 days of the date the sponsor makes the relevant determination, even if such determination is made less than 30 days from the date of the initial notice described in paragraph (f)(5) of this section.

(iii) A gaining plan sponsor may forgo providing the initial notice and may immediately provide a second notice described in paragraph (f)(6) of this section to an at-risk beneficiary as defined in subparagraph (2) of the definition in § 423.100), if the sponsor is implementing either of the following:

(A) A beneficiary-specific point-of-sale claim edit as described in paragraph (f)(3)(i) of this section, if the edit is the same as the one that was implemented in the immediately prior plan.

(B) A limitation on access to coverage as described in paragraph (f)(3(ii) of this section, if such limitation would require the beneficiary to obtain frequently abused drugs from the same location of pharmacy and/or the same prescriber, as applicable, that was selected under the immediately prior plan under paragraph (f)(9) of this section.

(9) *Beneficiary preferences.* Except as described in paragraph (f)(10) of this section, if a beneficiary submits preferences for prescribers or pharmacies

or both from which the beneficiary prefers to obtain frequently abused drugs, the sponsor must do the following:

(i) Review such preferences.

(ii) If the beneficiary is—

(A) Enrolled in a stand-alone prescription drug benefit plan and specifies a prescriber(s) or network pharmacy(ies) or both, select or change the selection of prescriber(s) or network pharmacy(ies) or both for the beneficiary based on beneficiary's preference(s).

(B) Enrolled in a Medicare Advantage prescription drug benefit plan and specifies a network prescriber(s) or network pharmacy(ies) or both, select or change the selection of prescriber(s) or pharmacy(ies) or both for the beneficiary based on the beneficiary's preference(s).

(iii) The sponsor must inform the beneficiary of the selection or change in—

(A) The second notice; or

(B) If the second notice is not feasible due to the timing of the beneficiary's submission, in a subsequent written notice, issued no later than 14 days after receipt of the submission.

(10) *Exception to beneficiary preferences.* (i) If the Part D sponsor determines that the selection or change of a prescriber or pharmacy under paragraph (f)(9) of this section would contribute to prescription drug abuse or drug diversion by the at-risk beneficiary, the sponsor may change the selection without regard to the beneficiary's preferences if there is strong evidence of inappropriate action by the prescriber, pharmacy, or beneficiary.

(ii) If the sponsor changes the selection, the sponsor must provide the beneficiary with—

(A) At least 30 days advance written notice of the change; and

(B) A rationale for the change.

(11) *Reasonable access.* In making the selections under paragraph (f)(12) of this section, a Part D plan sponsor must ensure that the beneficiary continues to have reasonable access to frequently abused drugs, taking into account all relevant factors, including but not limited to—

(i) Geographic location;

(ii) Beneficiary preference;

(iii) The beneficiary's predominant usage of a prescriber or pharmacy or both;

(iv) The impact on cost-sharing;

(v) Reasonable travel time;

(vi) Whether the beneficiary has multiple residences;

(vii) Natural disasters and similar situations; and

(viii) The provision of emergency services.

(12) *Selection of prescribers and pharmacies.* (i) A Part D plan sponsor must select, as applicable—

(A) One, or, if the sponsor reasonably determines it necessary to provide the beneficiary with reasonable access, more than one, network prescriber who is authorized to prescribe frequently abused drugs for the beneficiary, unless the plan is a stand-alone PDP, or the selection of an out-of-network provider is necessary; and

(B) One, or, if the sponsor reasonably determines it necessary to provide the beneficiary with reasonable access, more than one, network pharmacy that may dispense such drugs to such beneficiary, unless the selection of an out-of-network pharmacy is necessary.

(ii)(A) For purposes of this paragraph (f)(12) of this section, in the case of a pharmacy that has multiple locations that share real-time electronic data, all such locations of the pharmacy must collectively be treated as one pharmacy.

(B) For purposes of this paragraph (f)(12) of this section, in the case of a group practice, all prescribers of the group practice must be treated as one prescriber.

(13) *Confirmation of selections(s).* (i) Before selecting a prescriber or pharmacy under this paragraph, a Part D plan sponsor must notify the prescriber or pharmacy, as applicable, that the beneficiary has been identified for inclusion in the drug management program for at-risk beneficiaries and that the prescriber or pharmacy or both is(are) being selected as the beneficiary's designated prescriber or pharmacy or both for frequently abused drugs. For prescribers, this notification occurs during case management as described in paragraph (f)(2) or when the

prescriber provides agreement pursuant to paragraph (f)(4)(i)(B) of this section.

(ii) The sponsor must receive confirmation from the prescriber(s) or pharmacy(ies) or both, as applicable, that the selection is accepted before conveying this information to the at-risk beneficiary, unless the pharmacy has agreed in advance in a network agreement with the sponsor to accept all such selections and the agreement specifies how the pharmacy will be notified by the sponsor of its selection.

(14) *Termination of identification as an at-risk beneficiary.* The identification of an at-risk beneficiary as such must terminate as of the earlier of the following:

(i) The date the beneficiary demonstrates through a subsequent determination, including but not limited to, a successful appeal, that the beneficiary is no longer likely, in the absence of the limitation under this paragraph, to be an at-risk beneficiary; or

(ii)(A) The end of a one year period calculated from the effective date of the limitation, as specified in the notice provided under paragraph (f)(6) of this section, unless the limitation was extended pursuant to paragraph (f)(14)(ii)(B) of this section.

(B) The end of a two year period calculated from the effective date of the limitation, as specified in a notice provided under paragraph (f)(6) of this section, subject to the following requirements:

(*1*) The plan sponsor determines at the end of the one year period that there is a clinical basis to extend the limitation;

(*2*) Except in the case of a pharmacy limitation imposed pursuant to paragraph (f)(3)(ii)(B) of this section, the plan sponsor has obtained the agreement of a prescriber of frequently abused drugs for the beneficiary that the limitation should be extended.

(*3*) The plan sponsor has provided another notice to the beneficiary in compliance with paragraph (f)(6) of this section.

(*4*) If the prescribers were not responsive after 3 attempts by the sponsor to contact them within 10 business days, then the sponsor has met the requirement of paragraph (f)(14)((ii)(B)(2) of this section.

(*5*) The sponsor may not extend a prescriber limitation implemented pursuant to paragraph (f)(3)(ii)(A) of this section if no prescriber was responsive.

(15) *Data disclosure.* (i) CMS identifies potential at-risk beneficiaries to the sponsor of the prescription drug plan in which the beneficiary is enrolled.

(ii) A Part D sponsor that operates a drug management program must disclose any data and information to CMS and other Part D sponsors that CMS deems necessary to oversee Part D drug management programs at a time, and in a form and manner specified by CMS. The data and information disclosures must do all of the following:

(A) Provide information to CMS within 30 days of receiving a report about a potential at-risk beneficiary from CMS.

(B) Provide information to CMS about any potential at-risk beneficiary that meets paragraph (1) of the definition in §423.100 that a sponsor identifies within 30 days from the date of the most recent CMS report identifying potential at-risk beneficiaries;

(C) Provide information to CMS about any potential at-risk beneficiary or at-risk beneficiary that meets paragraph (2) of the definitions in §423.100 that a sponsor identifies within 30 days from the date of the most recent CMS report identifying potential at-risk beneficiaries.

(D) Provide information to CMS as soon as possible but no later than 7 days from the date of the initial notice or second notice that the sponsor provided to a beneficiary, or as soon as possible but no later than 7 days of a termination date, as applicable, about a beneficiary-specific opioid claim edit or a limitation on access to coverage for frequently abused drugs.

(E) Transfer case management information upon request of a gaining sponsor as soon as possible but not later than 2 weeks from the gaining sponsor's request when—

(*1*) An at-risk beneficiary or potential at-risk beneficiary disenrolls from the sponsor's plan and enrolls in another prescription drug plan offered by the gaining sponsor; and

(*2*) The edit or limitation that the sponsor had implemented for the beneficiary had not terminated before disenrollment.

(16) *Clinical guidelines.* Potential at-risk beneficiaries and at-risk beneficiaries are identified by CMS or a Part D sponsor using clinical guidelines that—

(i) Are developed with stakeholder consultation;

(ii) Are based on:

(1) The acquisition of frequently abused drugs from multiple prescribers, multiple pharmacies, the level of frequently abused drugs used, or any combination of these factors; or

(2) Beginning January 1, 2022, a history of opioid-related overdose as determined by at least one recent claim that contains a principal diagnosis indicating opioid overdose, and at least one recent claim for an opioid medication other than an opioid used for medication assisted therapy (MAT).

(iii) Are derived from expert opinion and an analysis of Medicare data; and

(iv) Include a program size estimate.

(g) *Prescription drug plan sponsors' access to Medicare Parts A and B claims data extracts.* (1)(i) Beginning in plan year 2020, a PDP sponsor may submit a request to CMS for the data described in paragraph (g)(2) of this section about enrollees in its prescription drug plans.

(ii) CMS makes the data requested in paragraph (g)(1)(i) of this section available to eligible PDP sponsors, in accordance with all applicable laws. The data is provided at least quarterly on a specified release date, and in an electronic format to be determined by CMS.

(iii) If CMS determines or has a reasonable belief that the PDP sponsor has violated the requirements of this paragraph (g) or that unauthorized uses, reuses, or disclosures of the Medicare claims data have taken place, at CMS' sole discretion, the PDP sponsor may be denied further access to the data described in paragraph (g)(2) of this section.

(2) *Data described.* The data that may be requested under paragraph (g)(1) of this section are standardized extracts of claims data under Medicare parts A and B for items and services furnished under such parts to beneficiaries who are enrolled in a plan offered by the PDP sponsor at the time of the disclosure.

(3) *Purposes.* A PDP sponsor must comply with all laws that may be applicable to data received under this provision, including State and Federal privacy and security laws, and, furthermore subject to the limitations in paragraph (g)(4) of this section may only use or disclose the data provided by CMS under paragraph (g)(1) of this section for the following purposes:

(i) To optimize therapeutic outcomes through improved medication use, as such phrase is used in paragraph (d)(1)(i) of this section.

(ii) To improve care coordination so as to prevent adverse health outcomes, such as preventable emergency department visits and hospital readmissions.

(iii) For activities falling under paragraph (1) of the definition of ''health care operations'' under 45 CFR 164.501.

(iv) For activities falling under paragraph (2) of the definition of ''health care operations'' under 45 CFR 164.501.

(v) For ''fraud and abuse detection or compliance activities'' under 45 CFR 164.506(c)(4)(ii).

(vi) For disclosures that qualify as ''required by law'' disclosures at 45 CFR 164.103.

(4) *Limitations.* A PDP sponsor must comply with the following requirements regarding the data provided by CMS under this paragraph (g):

(i) The PDP sponsor will not use the data to inform coverage determinations under Part D.

(ii) The PDP sponsor will not use the data to conduct retroactive reviews of medically accepted indications determinations.

(iii) The PDP sponsor will not use the data to facilitate enrollment changes to a different prescription drug plan or an MA–PD plan offered by the same parent organization.

(iv) The PDP sponsor will not use the data to inform marketing of benefits.

(v) The PDP sponsor will contractually bind its contractors that have access to the Medicare claims data, and require their contractors to contractually bind any other potential downstream data recipients, to the terms and conditions imposed on the PDP sponsor under this paragraph (g).

(5) *Ensuring the privacy and security of data.* As a condition of receiving the requested data, the PDP sponsor must attest that it will adhere to the permitted uses and limitations on the use of the Medicare claims data listed in paragraphs (g)(3) and (4) of this section.

[70 FR 4525, Jan. 28, 2005, as amended at 75 FR 19818, Apr. 15, 2010; 75 FR 32860, June 10, 2010; 76 FR 21573, Apr. 15, 2011; 77 FR 22169, Apr. 12, 2012; 80 FR 7963, Feb. 12, 2015; 83 FR 16739, Apr. 16, 2018; 84 FR 15841, Apr. 16, 2019; 86 FR 6116, Jan. 19, 2021; 89 FR 30834, Apr. 23, 2024; 89 FR 79452, Sept. 30, 2024]

§ 423.154 Appropriate dispensing of prescription drugs in long-term care facilities under PDPs and MA–PD plans.

(a) *In general.* Except as provided in paragraph (b) of this section, when dispensing covered Part D drugs to enrollees who reside in long-term care facilities, a Part D sponsor must—

(1) Require all pharmacies servicing long-term care facilities, as defined in § 423.100 to—

(i) Dispense solid oral doses of brand-name drugs, as defined in § 423.4, to enrollees in such facilities in no greater than 14-day increments at a time;

(ii) Permit the use of uniform dispensing techniques for Part D drugs dispensed to enrollees in long-term care facilities under paragraph (a)(1)(i) of this section as defined by each of the long-term care facilities in which such enrollees reside; and

(2) Not penalize long-term care facilities' choice of more efficient uniform dispensing techniques described in paragraph (a)(1)(ii) of this section by prorating dispensing fees based on days' supply or quantity dispensed.

(3) Ensure that any difference in payment methodology among long-term care pharmacies incentivizes more efficient dispensing techniques.

(4) Collect and report information, in a form and manner specified by CMS, on the dispensing methodology used for each dispensing event described by paragraph (a)(1) of this section.

(b) *Exclusions.* CMS excludes from the requirements under paragraph (a) of this section—

(1) Solid oral doses of antibiotics; or

(2) Solid oral doses that are dispensed in their original container as indicated in the Food and Drug Administration Prescribing Information or are customarily dispensed in their original packaging to assist patients with compliance (for example, oral contraceptives).

(c) *Waivers.* CMS waives the requirements under paragraph (a) of this section, except paragraphs (a)(2) and (3) o this section, for pharmacies when they service intermediate care facilities for individuals with intellectual disabilities (ICFs/IID) and institutes for mental disease (IMDs) as defined in § 435.1010 and for I/T/U pharmacies (as defined in § 423.100).

(d) *Applicability date.* The applicability date for this section is January 1, 2013. Nothing precludes a Part D sponsor and pharmacy from mutually agreeing to an earlier implementation date.

(e) *Unused drugs returned to the pharmacy.* The terms and conditions that must be offered by a Part D sponsor under § 423.120(a)(5) must include provisions that address the disposal of drugs that have been dispensed to an enrollee in a long-term care facility but not used and which have been returned to the pharmacy, in accordance with Federal and State regulations, as well as whether return for credit and reuse is authorized where permitted under State law.

[76 FR 21573, Apr. 15, 2011, as amended at 80 FR 7963, Feb. 12, 2015; 88 FR 22337, Apr. 12, 2023]

§ 423.156 Consumer satisfaction surveys.

Part D contracts with 600 or more enrollees as of July of the prior year must contract with approved Medicare Consumer Assessment of Healthcare Providers and Systems (CAHPS) survey vendors to conduct the Medicare CAHPS satisfaction survey of Part D plan enrollees in accordance with CMS specifications and submit the survey data to CMS. Part D sponsors are not required to submit CAHPS data that would otherwise be required for the calculation of the 2021 Star Ratings.

[75 FR 19818, Apr. 15, 2010, as amended at 85 FR 19290, Apr. 6, 2020]

§ 423.159 Electronic prescription drug program.

(a) *Definitions.* For purposes of this section, the following definitions apply:

Dispenser means a person or other legal entity licensed, registered, or otherwise permitted by the jurisdiction in which the person practices or the entity is located to provide drug products for human use by prescription in the course of professional practice.

Electronic media has the same meaning given this term in 45 CFR 160.103.

E-prescribing means the transmission using electronic media, of prescription or prescription-related information between a prescriber, dispenser, pharmacy benefit manager, or health plan, either directly or through an intermediary, including an e-prescribing network. E-prescribing includes, but is not limited to, two-way transmissions between the point of care and the dispenser.

Electronic prescription drug program means a program that provides for e-prescribing for covered Part D drugs prescribed for Part D eligible individuals.

Prescriber means a physician, dentist, or other person licensed, registered, or otherwise permitted by the U.S. or the jurisdiction in which he or she practices, to issue prescriptions for drugs for human use.

Prescription-related information means information regarding eligibility for drug benefits, medication history, or related health or drug information for Part D eligible individuals.

(b) [Reserved]

(c) *Requirement.* Part D sponsors must support and comply with electronic prescription standards relating to covered Part D drugs for Part D enrollees developed by CMS once final standards are effective.

(d) *Promotion of electronic prescribing by MA-PD plans.* An MA organization offering an MA-PD plan may provide for a separate or differential payment to a participating physician that prescribes covered Part D drugs in accordance with electronic prescription standards, including initial standards and final standards established by CMS once final standards are effective. Any payments must be in compliance with applicable Federal and State laws related to fraud and abuse, including the physician self-referral prohibition (section 1877 of the Act) and the Federal anti kickback statute (section 1128B(b) of the Act).

[70 FR 4525, Jan. 28, 2005, as amended at 70 FR 67593, Nov. 7, 2005]

§ 423.160 Standards for electronic prescribing.

(a) *General rules.* (1) Part D sponsors must establish and maintain an electronic prescription drug program that complies with the applicable standards in paragraph (b) of this section when transmitting, directly or through an intermediary, prescriptions and prescription-related information using electronic media for covered Part D drugs for Part D eligible individuals.

(2) Except as provided in paragraph (a)(3) of this section, prescribers and dispensers that transmit, directly or through an intermediary, prescriptions and prescription-related information using electronic media (including entities transmitting prescriptions or prescription-related information where the prescriber is required by law to issue a prescription for a patient to a non-prescribing provider, such as a nursing facility, that in turn forwards the prescription to a dispenser), must comply with the applicable standards in paragraph (b) of this section when e-prescribing for covered Part D drugs for Part D eligible individuals.

(3)(i) Entities transmitting prescriptions or prescription-related information must utilize the NCPDP SCRIPT standard, consistent with paragraph (b)(1) of this section, in all instances other than temporary/transient network transmission failures.

(ii) Electronic transmission of prescriptions or prescription-related information by means of computer-generated facsimile is only permitted in instances of temporary/transient transmission failure and communication problems that would preclude the use of the NCPDP SCRIPT standard adopted by this section.

(iii) Entities may use either HL7 messages or the NCPDP SCRIPT standard to transmit prescriptions or prescription-related information internally when the sender and the recipient

are part of the same legal entity. If an entity sends prescriptions outside the entity (for example, from an HMO to a non-HMO pharmacy), it must use the adopted NCPDP SCRIPT standard or other applicable adopted standards. Any pharmacy within an entity must be able to receive electronic prescription transmittals for Medicare beneficiaries from outside the entity using the adopted NCPDP SCRIPT standard. This exemption does not supersede any HIPAA requirement that may require the use of a HIPAA transaction standard within an organization.

(4) In accordance with section 1860D–4(e)(5) of the Act, the standards under this paragraph (b) of this section supersede any State law or regulation that—

(i) Is contrary to the standards or restricts the ability to carry out Part D of Title XVIII of the Act; and

(ii) Pertains to the electronic transmission of medication history and of information on eligibility, benefits, and prescriptions with respect to covered Part D drugs under Part D of Title XVIII of the Act.

(5) Beginning on January 1, 2021, prescribers must, except in the circumstances described in paragraphs (a)(5)(i) through (iii) of this section, conduct prescribing for at least 70 percent of their Schedule II, III, IV, and V controlled substances that are Part D drugs electronically using the applicable standards in paragraph (b) of this section, subject to the exemption in paragraph (a)(3)(iii) of this section. Prescriptions written for a beneficiary in a long-term care facility will not be included in determining compliance until January 1, 2028. Compliance actions against prescribers who do not meet the compliance threshold based on prescriptions written for a beneficiary in a long-term care facility will commence on or after January 1, 2028. Compliance actions against prescribers who do not meet the compliance threshold based on other prescriptions will commence on or after January 1, 2023. Prescribers will be exempt from this requirement in the following situations:

(i) Prescriber issues 100 or fewer controlled substance prescriptions for Part D drugs per calendar year as determined using CMS claims data with dates of service as of December 31st of the current year.

(ii) Prescriber has an address in PECOS in the geographic area of an emergency or disaster declared by a Federal, State, or local government entity. If a prescriber does not have an address in PECOS, prescriber has an address in NPPES in the geographic area of an emergency or disaster declared by a Federal, State, or local government entity. Starting in the 2024 measurement year, CMS will identify which emergencies or disasters qualify for this exception.

(iii) Prescriber has received a CMS-approved waiver because the prescriber is unable to conduct electronic prescribing of controlled substances (EPCS) due to circumstances beyond the prescriber's control.

(b) *Standards*—(1) *Prescriptions, electronic prior authorization, and medication history.* The communication of a prescription or prescription-related information must comply with a standard in 45 CFR 170.205(b) (incorporated by reference, *see* paragraph (c) of this section) for the following transactions, as applicable to the version of the standard in use:

(i)(A) GetMessage.

(B) Status.

(C) Error.

(D) RxChangeRequest and RxChangeResponse.

(E) RxRenewalRequest and RxRenewalResponse.

(F) Resupply.

(G) Verify.

(H) CancelRx and CancelRxResponse.

(I) RxFill.

(J) DrugAdministration.

(K) NewRxRequest.

(L) NewRx.

(M) NewRxResponseDenied.

(N) RxTransferInitiationRequest.

(O) RxTransfer.

(P) RxTransferConfirm.

(Q) RxFillIndicatorChange.

(R) Recertification.

(S) REMSInitiationRequest and REMSInitiationResponse.

(T) REMSRequest and REMSResponse.

(U) RxHistoryRequest and RxHistoryResponse.

(V) PAInitiationRequest and PAInitiationResponse.

(W) PARequest and PAResponse.
(X) PAAppealRequest and PAAppealResponse.
(Y) PACancelRequest and PACancelResponse.
(Z) PANotification.
(ii) [Reserved]

(2) *Eligibility*. Eligibility inquiries and responses between the Part D sponsor and prescribers and between the Part D sponsor and dispensers must comply with 45 CFR 162.1202.

(3) *Formulary and benefits*. The National Council for Prescription Drug Programs Formulary and Benefits Standard, Implementation Guide, Version 3, Release 0 (Version 3.0), (incorporated by reference, *see* paragraph (c)) of this section) or comply with a standard in 45 CFR 170.205(u) (incorporated by reference, *see* paragraph (c) of this section) for transmitting formulary and benefits information between prescribers and Part D sponsors. Beginning January 1, 2027, transmission of formulary and benefit information between prescribers and Part D sponsors must comply with a standard in 45 CFR 170.205(u) (incorporated by reference, *see* paragraph (c) of this section).

(4) *Provider identifier*. The National Provider Identifier (NPI), as defined at 45 CFR 162.406, to identify an individual health care provider to Medicare Part D sponsors, prescribers and dispensers, in electronically transmitted prescriptions or prescription-related materials for Medicare Part D covered drugs for Medicare Part D eligible individuals.

(5) *Real-time benefit tools*. Part D sponsors must implement one or more electronic real-time benefit tools (RTBT) that are capable of integrating with at least one prescriber's e-Prescribing (eRx) system or electronic health record (EHR) to provide complete, accurate, timely, clinically appropriate, patient-specific formulary and benefit information to the prescriber in real time for assessing coverage under the Part D plan. Such information must include enrollee cost-sharing information, clinically appropriate formulary alternatives, when available, and the formulary status of each drug presented including any utilization management requirements applicable to each alternative drug. Beginning January 1, 2027, Part D sponsors' RTBT must comply with a standard in 45 CFR 170.205(c) (incorporated by reference, *see* paragraph (c) of this section).

(c) *Incorporation by reference*. The material listed in this paragraph (c) is incorporated by reference into this section with the approval of the Director of the Federal Register under 5 U.S.C. 552(a) and 1 CFR part 51. All approved incorporation by reference (IBR) material is available for inspection at the Centers for Medicare & Medicaid Services (CMS) and at the National Archives and Records Administration (NARA). Contact CMS at: CMS 7500 Security Boulevard, Baltimore, Maryland 21244; phone: (410) 786–4132 or (877) 267–2323; email: *PartDPolicy@cms.hhs.gov*. For information on the availability of this material at NARA, visit *www.archives.gov/federal-register/cfr/ibr-locations* or email *fr.inspection@nara.gov*. The material may be obtained from National Council for Prescription Drug Programs (NCPDP), Incorporated, 9240 E Raintree Drive, Scottsdale, AZ 85260–7518; phone: (480) 477–1000; email: *info@ncpdp.org;* website: *www.ncpdp.org*.

(1) NCPDP Formulary and Benefit Standard, Implementation Guide, Version 3, Release 0 (Version 3.0), ANSI-approved January 28, 2011.

(2) NCPDP SCRIPT Standard, Implementation Guide Version 2017071, ANSI-approved July 28, 2017.

(3) NCPDP SCRIPT Standard, Implementation Guide Version 2023011, ANSI-approved January 17, 2023.

(4) NCPDP Real-Time Prescription Benefit Standard, Implementation Guide Version 13, ANSI-approved May 19, 2022.

(5) NCPDP Formulary and Benefit Standard, Implementation Guide Version 60, ANSI-approved April 12, 2023.

[89 FR 51263, June 17, 2024, as amended by 89 FR 98565, Dec. 9, 2024]

§ 423.162 Quality improvement organization activities.

(a) *General rule*. Quality improvement organizations (QIOs) are required to offer providers, practitioners, and Part D sponsors quality improvement assistance pertaining to health care services, including those related to prescription

drug therapy, in accordance with contracts established with the Secretary.

(b) *Collection of information.* Information collected, acquired, or generated by a QIO in the performance of its responsibilities under this section is subject to the confidentiality provisions of part 480 of this chapter. Part D sponsors are required to provide specified information to CMS for distribution to the QIOs as well as directly to QIOs.

(c) *Applicability of QIO confidentiality provisions.* The provisions of part 480 of this chapter apply to Part D sponsors in the same manner as such provisions apply to institutions under part 480 of this chapter.

§ 423.165 Compliance deemed on the basis of accreditation.

(a) *General rule.* A Part D sponsor is deemed to meet all of the requirements of any of the areas described in paragraph (b) of this section if—

(1) The Part D sponsor is fully accredited (and periodically reaccredited) for the standards related to the applicable area under paragraph (b) of this section by a private, national accreditation organization approved by CMS; and

(2) The accreditation organization uses the standards approved by CMS for the purposes of assessing the Part D sponsor's compliance with Medicare requirements.

(b) Deemable requirements. The requirements relating to the following areas are deemable:

(1) Access to covered drugs, as provided under §§ 423.120 and 423.124.

(2) Drug utilization management programs, quality assurance measures and systems, and MTM programs as provided under § 423.153.

(3) Privacy, confidentiality, and accuracy of enrollee records, as provided under § 423.136.

(c) *Effective date of deemed status.* The date the Part D sponsor is deemed to meet the applicable requirements is the later of the following:

(1) The date the accreditation organization is approved by CMS.

(2) The date the Part D sponsor is accredited by the accreditation organization.

(d) *Obligations of deemed Part D sponsors.* A Part D sponsor deemed to meet Medicare requirements must—

(1) Submit to surveys by CMS to validate its accreditation organization's accreditation process; and

(2) Authorize its accreditation organization to release to CMS a copy of its most recent accreditation survey, together with any survey-related information that CMS may require (including corrective action plans and summaries of unmet CMS requirements).

(e) *Removal of deemed status.* CMS removes part or all of a Part D sponsor's deemed status for any of the following reasons—

(1) CMS determines, on the basis of its own investigation, that the Part D sponsor does not meet the Medicare requirements for which deemed status was granted.

(2) CMS withdraws its approval of the accreditation organization that accredited the Part D sponsor.

(3) The Part D sponsor fails to meet the requirements of paragraph (d) of this section.

(f) *Authority.* Nothing in this section limits CMS' authority under subparts K and O of this part, including, but not limited to the ability to impose intermediate sanctions, civil money penalties, and terminate a contract with a Part D plan sponsor.

[70 FR 4525, Jan. 28, 2005, as amended at 75 FR 19818, Apr. 15, 2010; 89 FR 30835, Apr. 23, 2024]

§ 423.168 Accreditation organizations.

(a) *Conditions for approval.* CMS may approve an accreditation organization for a given standard under this part if the organization meets the following conditions:

(1) In accrediting Part D sponsors and Part D plans, it applies and enforces standards that are at least as stringent as Medicare requirements for the standard or standards in question.

(2) It complies with the application and reapplication procedures set forth in § 423.171.

(3) It ensures that—

(i) Any individual associated with it, who is also associated with an entity it accredits, does not influence the accreditation decision concerning that entity;

(ii) The majority of the membership of its governing body is not comprised of managed care organizations, Part D sponsors or their representatives; and

(iii) Its governing body has a broad and balanced representation of interests and acts without bias.

(b) *Notice and comment*—(1) *Proposed notice.* CMS publishes a notice in the FEDERAL REGISTER whenever it is considering granting an accreditation organization's application for approval. The notice-

(i) Announces CMS's receipt of the accreditation organization's application for approval;

(ii) Describes the criteria CMS uses in evaluating the application; and

(iii) Provides at least a 30-day comment period.

(2) *Final notice.* (i) After reviewing public comments, CMS publishes a final notice in the FEDERAL REGISTER indicating whether it has granted the accreditation organization's request for approval.

(ii) If CMS grants the request, the final notice specifies the effective date and the term of the approval that may not exceed 6 years.

(c) *Ongoing responsibilities of an approved accreditation organization.* An accreditation organization approved by CMS must undertake the following activities on an ongoing basis:

(1) Provide to CMS in written form and on a monthly basis all of the following:

(i) Copies of all accreditation surveys, together with any survey-related information that CMS may require including corrective action plans and summaries of unmet CMS requirements).

(ii) Notice of all accreditation decisions.

(iii) Notice of all complaints related to deemed Part D sponsors.

(iv) Information about any Part D sponsor against which the accrediting organization has taken remedial or adverse action, including revocation, withdrawal, or revision of the Part D sponsor's accreditation. (The accreditation organization must provide this information within 30 days of taking the remedial or adverse action.)

(v) Notice of any proposed changes in its accreditation standards or requirements or survey process. If the organization implements the changes before or without CMS approval, CMS may withdraw its approval of the accreditation organization.

(2) Within 30 days of a change in CMS requirements, submit the following to CMS—

(i) An acknowledgment of CMS's notification of the change.

(ii) A revised crosswalk reflecting the new requirements.

(iii) An explanation of how the accreditation organization plans to alter its standards to conform to CMS's new requirements, within the timeframes specified in the notification of change it receives from CMS.

(3) Permit its surveyors to serve as witnesses if CMS takes an adverse action based on accreditation findings.

(4) Within 3 days of identifying, in an accredited Part D sponsor, a deficiency that as determined by the accrediting organization poses immediate jeopardy to the plan's enrollees or to the general public, give CMS written notice of the deficiency.

(5) Within 10 days of CMS's notice of withdrawal of approval, give written notice of the withdrawal to all accredited Part D sponsors.

(6) On an annual basis, provide summary data specified by CMS that relate to the past year's accreditation activities and trends.

(d) *Continuing Federal oversight of approved accreditation organizations.* Specific criteria and procedures for continuing oversight and for withdrawing approval of an accreditation organization include the following:

(1) *Equivalency review.* CMS compares the accreditation organization's standards and its application and enforcement of those standards to the comparable CMS requirements and processes when—

(i) CMS imposes new requirements or changes its survey process;

(ii) An accreditation organization proposes to adopt new standards or changes in its survey process; or

(iii) The term of an accreditation organization's approval expires.

(2) *Validation review.* CMS or its agent may conduct a survey of an accredited organization, examine the results of the accreditation organization's own

survey, or attend the accreditation organization's survey to validate the organization's accreditation process. At the conclusion of the review, CMS identifies any accreditation programs for which validation survey results indicate—

(i) A 20 percent rate of disparity between certification by the accreditation organization and certification by CMS or its agent on standards that do not constitute immediate jeopardy to patient health and safety if unmet;

(ii) Any disparity between certification by the accreditation organization and certification by CMS or its agent on standards that constitute immediate jeopardy to patient health and safety if unmet; or

(iii) That, regardless of the rate of disparity, there are widespread or systematic problems in an organization's accreditation process that accreditation no longer provides assurance that the Medicare requirements are met or exceeded.

(3) *Onsite observation.* CMS may conduct an onsite inspection of the accreditation organization's operations and offices to verify the organization's representations and assess the organization's compliance with its own policies and procedures. The onsite inspection may include, but is not limited to the following:

(i) Reviewing documents.

(ii) Auditing meetings concerning the accreditation process.

(iii) Evaluating survey results or the accreditation status decision-making process.

(iv) Interviewing the organization's staff.

(4) *Notice of intent to withdraw approval.* If an equivalency review, validation review, onsite observation, or CMS's daily experience with the accreditation organization suggests that the accreditation organization is not meeting the requirements of this subpart, CMS gives the organization written notice of its intent to withdraw approval.

(5) *Withdrawal of approval.* CMS may withdraw its approval of an accreditation organization at any time if CMS determines that—

(i) Deeming, based on accreditation, no longer guarantees that the Part D sponsor meets the requirements for offering qualified prescription drug coverage, and failure to meet those requirements may jeopardize the health or safety of Medicare enrollees and constitute a significant hazard to the public health; or

(ii) The accreditation organization has failed to meet its obligations under this section or under § 423.165 or § 423.171.

(6) *Reconsideration of withdrawal of approval.* An accreditation organization dissatisfied with a determination to withdraw CMS approval may request a reconsideration of that determination in accordance with subpart D of part 488 of this chapter.

§ 423.171 Procedures for approval of accreditation as a basis for deeming compliance.

(a) *Required information and materials.* A private, national accreditation organization applying for approval must furnish to CMS all of the following information and materials (when reapplying for approval, the organization need furnish only the particular information and materials requested by CMS):

(1) The types of Part D plans and sponsors that it reviews as part of its accreditation process.

(2) A detailed comparison of the organization's accreditation requirements and standards with the Medicare requirements (for example, a crosswalk).

(3) Detailed information about the organization's survey process, including the following:

(i) Frequency of surveys and whether surveys are announced or unannounced.

(ii) Copies of survey forms, and guidelines and instructions to surveyors.

(iii) Descriptions of—

(A) The survey review process and the accreditation status decision making process;

(B) The procedures used to notify accredited Part D sponsors of deficiencies and to monitor the correction of those deficiencies; and

(C) The procedures used to enforce compliance with accreditation requirements.

(4) Detailed information about the individuals who perform surveys for the

accreditation organization, including the—

(i) Size and composition of accreditation survey teams for each type of plan reviewed as part of the accreditation process;

(ii) Education and experience requirements surveyors must meet;

(iii) Content and frequency of the in-service training provided to survey personnel;

(iv) Evaluation systems used to monitor the performance of individual surveyors and survey teams; and

(v) Organization's policies and practice for the participation, in surveys or in the accreditation decision process by an individual who is professionally or financially affiliated with the entity being surveyed.

(5) A description of the organization's data management and analysis system for its surveys and accreditation decisions, including the kinds of reports, tables, and other displays generated by that system.

(6) A description of the organization's procedures for responding to and investigating complaints against accredited organizations, including policies and procedures regarding coordination of these activities with appropriate licensing bodies and ombudsmen programs.

(7) A description of the organization's policies and procedures for the withholding or removal of accreditation for failure to meet the accreditation organization's standards or requirements, and other actions the organization takes in response to noncompliance with its standards and requirements.

(8) A description of all types (for example, full or partial) and categories (for example, provisional, conditional, or temporary) of accreditation offered by the organization, the duration of each type and category of accreditation, and a statement identifying the types and categories that serve as a basis for accreditation if CMS approves the accreditation organization.

(9) A list of all currently accredited Part D sponsors and MA organizations and the type, category, and expiration date of the accreditation held by each of them.

(10) A list of all full and partial accreditation surveys scheduled to be performed by the accreditation organization as requested by CMS.

(11) The name and address of each person with an ownership or control interest in the accreditation organization.

(b) *Required supporting documentation.* A private, national accreditation organization applying or reapplying for approval also must submit the following supporting documentation—

(1) A written presentation that demonstrates its ability to furnish CMS with electronic data in CMS compatible format.

(2) A resource analysis that demonstrates that it's staffing, funding, and other resources are adequate to perform the required surveys and related activities.

(3) A statement acknowledging that, as a condition for approval, it agrees to comply with the ongoing responsibility requirements of § 423.168(c).

(c) *Additional information.* If CMS determines that it needs additional information for a determination to grant or deny the accreditation organization's request for approval, it notifies the organization and allows time for the organization to provide the additional information.

(d) *Onsite visit.* CMS may visit the accreditation organization's offices to verify representations made by the organization in its application, including, but not limited to, review of documents and interviews with the organization's staff.

(e) *Notice of determination.* CMS gives the accreditation organization, within 210 days of receipt of its completed application, a formal notice that—

(1) States whether the request for approval is granted or denied;

(2) Gives the rationale for any denial; and

(3) Describes the reconsideration and reapplication procedures.

(f) *Withdrawal.* An accreditation organization may withdraw its application for approval at any time before it receives the formal notice specified in paragraph (e) of this section.

(g) *Reconsideration of adverse determination.* An accreditation organization that has received a notice of denial of its request for approval may request a reconsideration in accordance

with subpart D of part 488 of this chapter.

(h) *Request for approval following denial.* (1) Except as provided in paragraph (h)(2) of this section, an accreditation organization that has received notice of denial of its request for approval may submit a new request if it—

(i) Has revised its accreditation program to correct the deficiencies on which the denial was based.

(ii) Can demonstrate that the Part D sponsors that it has accredited meet or exceed applicable Medicare requirements; and

(iii) Resubmits the application in its entirety.

(2) An accreditation organization that has requested reconsideration of CMS' denial of its request for approval may not submit a new request until the reconsideration is administratively final.

§ 423.180 Basis and scope of the Part D Prescription Drug Plan Quality Rating System.

(a) *Basis.* This subpart is based on sections 1851(d), 1852(e), 1853(o) and 1854(b)(3)(iii), (v), and (vi) of the Act and the general authority under section 1856(b) of the Act requiring the establishment of standards consistent with and to carry out Part D.

(b) *Purpose.* Ratings calculated and assigned under this subpart will be used by CMS for the following purposes:

(1) To provide comparative information on plan quality and performance to beneficiaries for their use in making knowledgeable enrollment and coverage decisions in the Medicare program.

(2) To provide quality ratings on a 5-star rating system.

(3) To provide a means to evaluate and oversee overall and specific compliance with certain regulatory and contract requirements by Part D plans, where appropriate and possible to use data of the type described in § 423.182(c).

(c) *Applicability.* Except for § 423.182(b)(3), the regulations in this subpart will be applicable beginning with the 2019 measurement period and the associated 2021 Star Ratings that are released prior to the annual coordinated election period for the 2021 contract year.

[83 FR 16743, Apr. 16, 2018]

§ 423.182 Part D Prescription Drug Plan Quality Rating System.

(a) *Definitions.* In this subpart the following terms have the meanings:

Absolute percentage cap is a cap applied to non-CAHPS measures that are on a 0 to 100 scale that restricts movement of the current year's measure-threshold-specific cut point to no more than the stated percentage as compared to the prior year's cut point.

CAHPS refers to a comprehensive and evolving family of surveys that ask consumers and patients to evaluate the interpersonal aspects of health care. CAHPS surveys probe those aspects of care for which consumers and patients are the best or only source of information, as well as those that consumers and patients have identified as being important. CAHPS initially stood for the Consumer Assessment of Health Plans Study, but as the products have evolved beyond health plans the acronym now stands for Consumer Assessment of Healthcare Providers and Systems.

Case-mix adjustment means an adjustment to the measure score made prior to the score being converted into a Star Rating to take into account certain enrollee characteristics that are not under the control of the plan. For example age, education, chronic medical conditions, and functional health status that may be related to the enrollee's survey responses.

Categorical Adjustment Index (CAI) means the factor that is added to or subtracted from an overall or summary Star Rating (or both) to adjust for the average within-contract (or within-plan as applicable) disparity in performance associated with the percentages of beneficiaries who are dually eligible for Medicare and enrolled in Medicaid, beneficiaries who receive a Low Income Subsidy, or have disability status in that contract (or plan as applicable).

Clustering refers to a variety of techniques used to partition data into distinct groups such that the observations within a group are as similar as possible to each other, and as dissimilar as

possible to observations in any other group. Clustering of the measure-specific scores means that gaps that exist within the distribution of the scores are identified to create groups (clusters) that are then used to identify the four cut points resulting in the creation of five levels (one for each Star Rating), such that the scores in the same Star Rating level are as similar as possible and the scores in different Star Rating levels are as different as possible. Technically, the variance in measure scores is separated into within-cluster and between-cluster sum of squares components. The clusters reflect the groupings of numeric value scores that minimize the variance of scores within the clusters. The Star Ratings levels are assigned to the clusters that minimize the within-cluster sum of squares. The cut points for star assignments are derived from the range of measure scores per cluster, and the star levels associated with each cluster are determined by ordering the means of the clusters.

Consolidation means when an MA organization that has at least two contracts for health and/or drug services of the same plan type under the same parent organization in a year combines multiple contracts into a single contract for the start of the subsequent contract year.

Consumed contract means a contract that will no longer exist after a contract year's end as a result of a consolidation.

Cut point cap is a restriction on the change in the amount of movement a measure-threshold-specific cut point can make as compared to the prior year's measure-threshold-specific cut point. A cut point cap can restrict upward movement, downward movement, or both.

Display page means the CMS website on which certain measures and scores are publicly available for informational purposes; the measures that are presented on the display page are not used in assigning Part C and D Star Ratings.

Domain rating means the rating that groups measures together by dimensions of care.

Dual-eligible (DE) means a beneficiary who is enrolled in both Medicare and Medicaid.

Guardrail is a bidirectional cap that restricts both upward and downward movement of a measure-threshold-specific cut point for the current year's measure-level Star Ratings as compared to the prior year's measure-threshold-specific cut point.

Health equity index means an index that summarizes contract performance among those with specified social risk factors (SRFs) across multiple measures into a single score.

Highest rating means the overall rating for MA–PDs, the Part C summary rating for MA-only contracts, and the Part D summary rating for PDPs.

Highly-rated contract means a contract that has 4 or more stars for its highest rating when calculated without the improvement measures and with all applicable adjustments in § 423.186(f).

Low-income subsidy (LIS) means the subsidy that a beneficiary receives to help pay for prescription drug coverage (see § 423.34 for definition of a low-income subsidy eligible individual).

Mean resampling refers to a technique where measure-specific scores for the current year's Star Ratings are randomly separated into 10 equal-sized groups. The hierarchal clustering algorithm is done 10 times, each time leaving one of the 10 groups out. By leaving out one of the 10 groups for each run, 9 of the 10 groups, which is 90 percent of the applicable measure scores, are used for each run of the clustering algorithm. The method results in 10 sets of measure-specific cut points. The mean cut point for each threshold per measure is calculated using the 10 values.

Measurement period means the period for which data are collected for a measure or the performance period that a measures covers.

Measure score means the numeric value of the measure or an assigned 'missing data' message.

Measure star means the measure's numeric value is converted to a Star Rating. It is displayed to the nearest whole star, using a 1–5 star scale.

Overall rating means a global rating that summarizes the quality and performance for the types of services offered across all unique Part C and Part D measures.

Part C summary rating means a global rating that summarizes the health plan quality and performance on Part C measures.

Part D summary rating means a global rating that summarizes prescription drug plan quality and performance on Part D measures.

Plan benefit package (PBP) means a set of benefits for a defined MA or PDP service area. The PBP is submitted by Part D plan sponsors and MA organizations to CMS for benefit analysis, bidding, marketing, and beneficiary communication purposes.

Reliability means a measure of the fraction of the variation among the observed measure values that is due to real differences in quality (''signal'') rather than random variation (''noise''); it is reflected on a scale from 0 (all differences in plan performance measure scores are due to measurement error) to 1 (the difference in plan performance scores is attributable to real differences in performance).

Restricted range is the difference between the maximum and minimum measure score values using the prior year measure scores excluding outer fence outliers (first quartile −3*Interquartile Range (IQR) and third quartile + 3*IQR).

Restricted range cap is a cap applied to non-CAHPS measures that restricts movement of the current year's measure-threshold-specific cut point to no more than the stated percentage of the restricted range of a measure calculated using the prior year's measure score distribution.

Reward factor means a rating-specific factor added to the contract's summary or overall ratings (or both) if a contract has both high and stable relative performance.

Statistical significance assesses how likely differences observed in performance are due to random chance alone under the assumption that plans are actually performing the same.

Surviving contract means the contact that will still exist under a consolidation, and all of the beneficiaries enrolled in the consumed contract(s) are moved to the surviving contracts.

Traditional rounding rules mean that the last digit in a value will be rounded. If rounding to a whole number, look at the digit in the first decimal place. If the digit in the first decimal place is 0, 1, 2, 3 or 4, then the value should be rounded down by deleting the digit in the first decimal place. If the digit in the first decimal place is 5 or greater, then the value should be rounded up by 1 and the digit in the first decimal place deleted.

Tukey outer fence outliers are measure scores that are below a certain point (first quartile − 3.0 × (third quartile − first quartile)) or above a certain point (third quartile + 3.0 × (third quartile − first quartile)).

(b) *Contract ratings*—(1) *General.* CMS calculates an overall Star Rating, Part C summary rating, and Part D summary rating for each MA–PD contract and a Part D summary rating for each PDP contract using the 5-star rating system described in this subpart. For PDP contracts, the Part D summary rating is the highest rating. Measures are assigned stars at the contract level and weighted in accordance with § 423.186(a). Domain ratings are the unweighted mean of the individual measure ratings under the topic area in accordance with § 423.186(b). Summary ratings are the weighted mean of the individual measure ratings for Part C or Part D in accordance with § 423.186(c), with the applicable adjustments provided in paragraph (f) of this section. Overall Star Ratings are calculated by using the weighted mean of the individual measure ratings in accordance with § 423.186(d), with the applicable adjustments provided in paragraph (f) of this section. CMS includes the Star Ratings measures in the overall and summary ratings that are associated with the contract type for the Star Ratings year.

(2) *Plan benefit packages.* All plan benefit packages (PBPs) offered under an MA contract or PDP plan sponsor have the same overall and/or summary Star Ratings as the contract under which the PBP is offered by the MA organization or PDP plan sponsor. Data from all the PBPs offered under a contract

are used to calculate the measure and domain ratings for the contract.

(3) *Contract consolidations.* (i) In the case of contract consolidations involving two or more contracts for health and/or drug services of the same plan type under the same parent organization, CMS assigns Star Ratings for the first and second years following the consolidation based on the enrollment-weighted mean of the measure scores of the surviving and consumed contract(s) as provided in paragraph (b)(3)(ii) of this section.

(ii) The Star Ratings posted on Medicare Plan Finder for contracts that consolidate are as follows:

(A)(*1*) For the first year after consolidation, CMS uses enrollment-weighted measure scores using the July enrollment of the measurement period of the consumed and surviving contracts for all measures, except survey-based measures, call center measures, and improvement measures. The survey-based measures will use enrollment of the surviving and consumed contracts at the time the sample is pulled for the rating year. The call center measures will use average enrollment during the study period. The Part C and D improvement measures are not calculated for first year consolidations.

(*2*) For contract consolidations approved on or after January 1, 2022, if a measure score for a consumed or surviving contract is missing due to a data integrity issue as described in § 423.184(g)(1)(i) and (ii), CMS assigns a score of zero for the missing measure score in the calculation of the enrollment-weighted measure score.

(B)(*1*) For the second year after consolidation, CMS uses the enrollment-weighted measure scores using the July enrollment of the measurement year of the consumed and surviving contracts for all measures except for CAHPS. CMS ensures that the CAHPS survey sample includes enrollees in the sample frame from both the surviving and consumed contracts.

(*2*) For contract consolidations approved on or after January 1, 2022, for all measures except CAHPS if a measure score for a consumed or surviving contract is missing due to a data integrity issue as described in § 423.184(g)(1)(i) and (ii), CMS assigns a score of zero for the missing measure score in the calculation of the enrollment-weighted measure score.

(iii) This provision governing the Star Ratings of surviving contracts is applicable to contract consolidations that are approved on or after January 1, 2019.

(c) *Data sources.* (1) Part D Star Ratings measures reflect structure, process, and outcome indices of quality. This includes information of the following types: Beneficiary experiences, benefit administration information, clinical data, and CMS administrative data. Data underlying Star Ratings measures may include survey data, data separately collected and used in oversight of Part D plans' compliance with contract requirements, data submitted by plans, and CMS administrative data.

(2) Part D sponsors are required to collect, analyze, and report data that permit measurements of health outcomes and other indices of quality. Part D sponsors must provide unbiased, accurate, and complete quality data described in paragraph (c)(1) of this section to CMS on a timely basis as requested by CMS.

(3) For 2021 Star Ratings only, Part D sponsors are not required to submit CAHPS data that would otherwise be required for the calculation of the 2021 Star Ratings.

[83 FR 16743, Apr. 16, 2018; 84 FR 15841, Apr. 16, 2019, as amended at 85 FR 19290, Apr. 6, 2020; 85 FR 33911, June 2, 2020; 86 FR 6118, Jan. 19, 2021; 88 FR 22337, Apr. 12, 2023]

§ 423.184 Adding, updating, and removing measures.

(a) *General.* CMS adds, updates, and removes measures used to calculate the Star Ratings as provided in this section. CMS lists the measures used for a particular Star Rating each year in the Technical Notes or similar guidance document with publication of the Star Ratings.

(b) *Review of data quality.* CMS reviews the quality of the data on which performance, scoring and rating of a measure is based before using the data to score and rate performance or in calculating a Star Rating. This includes review of variation in scores among MA organizations and Part D plan

sponsors, and the accuracy, reliability, and validity of measures and performance data before making a final determination about inclusion of measures in each year's Star Ratings.

(c) *Adding measures.* (1) CMS will continue to review measures that are nationally endorsed and in alignment with the private sector, such as measures developed by National Committee for Quality Assurance (NCQA) and the Pharmacy Quality Alliance (PQA) or endorsed by the National Quality Forum for adoption and use in the Part D Quality Ratings System. CMS may develop its own measures as well when appropriate to measure and reflect performance specific to the Medicare program.

(2) In advance of the measurement period, CMS will announce potential new measures and solicit feedback through the process described for changes in and adoption of payment and risk adjustment policies in section 1853(b) of the Act and then subsequently will propose and finalize new measures through rulemaking.

(3) New measures added to the Part D Star Ratings program will be on the display page on *www.cms.gov* for a minimum of 2 years prior to becoming a Star Ratings measure.

(4) A measure will remain on the display page for longer than 2 years if CMS finds reliability or validity issues with the measure specification.

(d) *Updating measures*—(1) *Non-substantive updates.* For measures that are already used for Star Ratings, CMS will update measures so long as the changes in a measure are not substantive. CMS will announce non-substantive updates to measures that occur (or are announced by the measure steward) during or in advance of the measurement period through the process described for changes in and adoption of payment and risk adjustment policies in section 1853(b) of the Act. Non-substantive measure specification updates include those that—

(i) Narrow the denominator or population covered by the measure;

(ii) Do not meaningfully impact the numerator or denominator of the measure;

(iii) Update the clinical codes with no change in the target population or the intent of the measure;

(iv) Provide additional clarifications:

(A) Adding additional qualifiers that would meet the numerator requirements;

(B) Clarifying documentation requirements;

(C) Adding additional instructions; or

(v) Add alternative data sources or expand modes of data collection.

(2) *Substantive updates.* For measures that are already used for Star Ratings, in the case of measure specification updates that are substantive updates not subject to paragraph (d)(1) of this section, CMS will propose and finalize these measures through rulemaking similar to the process for adding new measures. CMS will initially solicit feedback on whether to make substantive measure updates through the process described for changes in and adoption of payment and risk adjustment policies in section 1853(b) of the Act. Once the update has been made to the measure specification by the measure steward, CMS may continue collection of the performance data for the legacy measure and include it in Star Ratings until the updated measure has been on display for 2 years. CMS will place the updated measure on the display page for at least 2 years prior to using the updated measure to calculate and assign Star Ratings as specified in paragraph (c) of this section.

(e) *Removing measures.* (1) CMS will remove a measure from the Star Ratings program as follows:

(i) When the clinical guidelines associated with the specifications of the measure change such that the specifications are no longer believed to align with positive health outcomes, or

(ii) A measure shows low statistical reliability.

(iii) The measure steward other than CMS retires a measure.

(2) CMS will announce in advance of the measurement period the removal of a measure based upon its application of this paragraph (e) through the process described for changes in and adoption of payment and risk adjustment policies in section 1853(b) of the Act in advance of the measurement period.

(f) *Improvement measure.* CMS will calculate improvement measure scores based on a comparison of the measure scores for the current year to the immediately preceding year as provided in this paragraph (f); the improvement measure score would be calculated for Parts C and D separately by taking a weighted sum of net improvement divided by the weighted sum of the number of eligible measures.

(1) *Identifying eligible measures.* Annually, the subset of measures to be included in the Part D improvement measure will be announced through the process described for changes in and adoption of payment and risk adjustment policies in section 1853(b) of the Act. CMS identifies measures to be used in the improvement measure if the measures meet all the following:

(i) CMS will include only measures available for the current and previous year in the improvement measures and that have numeric value scores in both the current and prior year.

(ii) CMS will exclude any measure for which there was a substantive specification change from the previous year.

(iii) The Part D improvement measure will include only Part D measure scores.

(iv) CMS excludes any measure that receives a measure-level Star Rating reduction for data integrity concerns for either the current or prior year from the improvement measure(s).

(2) *Determining eligible contracts.* CMS will calculate an improvement score only for contracts that have numeric measure scores for both years in at least half of the measures identified for use applying the standards in paragraphs (f)(1)(i) through (iii) of this section.

(3) *Special rules for calculation of the improvement score.* For any measure used for the improvement measure for which a contract received 5 stars in each of the years examined, but for which the measure score demonstrates a statistically significant decline based on the results of the significance testing (at a level of significance of 0.05) on the change score, the measure will be categorized as having no significant change and included in the count of measures used to determine eligibility for the measure (that is, for the denominator of the improvement measure score).

(4) *Calculation of the improvement score.* The improvement measure will be calculated as follows:

(i) The improvement change score (the difference in the measure scores in the 2-year period) will be determined for each measure that has been designated an improvement measure and for which a contract has a numeric score for each of the 2 years examined.

(ii) Each contract's improvement change score per measure will be categorized as a significant change or not a significant change by employing a two-tailed t-test with a level of significance of 0.05.

(iii) The net improvement per measure category (outcome, access, patient experience, process) would be calculated by finding the difference between the weighted number of significantly improved measures and significantly declined measures, using the measure weights associated with each measure category.

(iv) The improvement measure score will then be determined by calculating the weighted sum of the net improvement per measure category divided by the weighted sum of the number of eligible measures.

(v) The improvement measure scores will be converted to measure-level Star Ratings by determining the cut points using hierarchical clustering algorithms in accordance with § 423.186(a)(2)(i) through (iii).

(vi) The Part D improvement measure cut points for MA–PDs and PDPs will be determined using separate clustering algorithms in accordance with §§ 422.166(a)(2)(iii) and 423.186(a)(2)(iii).

(g) *Data integrity.* (1) CMS will reduce a contract's measure rating when CMS determines that a contract's measure data are inaccurate, incomplete, or biased; such determinations may be based on a number of reasons, including mishandling of data, inappropriate processing, or implementation of incorrect practices that have an impact on the accuracy, impartiality, or completeness of the data used for one or more specific measure(s).

(i) CMS will reduce measures based on data that a Part D organization must submit to CMS under § 423.514 to 1

star when a contract did not score at least 95 percent on data validation for the applicable reporting section or was not compliant with CMS data validation standards/sub-standards for data directly used to calculate the associated measure.

(ii) [Reserved]

(2) CMS will reduce a measure rating to 1 star for additional concerns that data inaccuracy, incompleteness, or bias have an impact on measure scores and are not specified in paragraphs (g)(1)(i) and (ii) of this section, including a contract's failure to adhere to CAHPS reporting requirements.

(h) *Review of sponsors' data.* (1) A Part D plan sponsor may request that CMS or the IRE review its' contract's appeals data provided that the request is received by the annual deadline set by CMS for the applicable Star Ratings year.

(2) A Part D plan sponsor may request that CMS review its' contract's Complaints Tracking Module (CTM) data provided that the request is received by the annual deadline set by CMS for the applicable Star Ratings year.

(i) [Reserved]

(3) Beginning with the 2025 measurement year (2027 Star Ratings), Part D sponsor may request that CMS review its contract's administrative data for Patient Safety measures provided that the request is received by the annual deadline set by CMS for the applicable Star Ratings year.

[83 FR 16743, Apr. 16, 2018, as amended at 84 FR 15842, Apr. 16, 2019; 85 FR 19291, Apr. 6, 2020; 86 FR 6118, Jan. 19, 2021; 87 FR 27899, May 9, 2022; 88 FR 22338, Apr. 12, 2023; 89 FR 30835, Apr. 23, 2024]

§ 423.186 Calculation of Star Ratings.

(a) *Measure Star Ratings*—(1) *Cut points.* CMS will determine cut points for the assignment of a Star Rating for each numeric measure score by applying either a clustering or a relative distribution and significance testing methodology. For the Part D measures, CMS will determine MA–PD and PDP cut points separately.

(2) Clustering algorithm for all measures except CAHPS measures.

(i) The method maximizes differences across the star categories and minimizes the differences within star categories using mean resampling with the hierarchal clustering of the current year's data. Effective for the Star Ratings issued in October 2023 and subsequent years, prior to applying mean resampling with hierarchal clustering, Tukey outer fence outliers are removed. Effective for the Star Ratings issued in October 2022 and subsequent years, CMS will add a guardrail so that the measure-threshold-specific cut points for non-CAHPS measures do not increase or decrease more than the value of the cap from 1 year to the next. The cap is equal to 5 percentage points for measures having a 0 to 100 scale (absolute percentage cap) or 5 percent of the restricted range for measures not having a 0 to 100 scale (restricted range cap). New measures that have been in the Part C and D Star Rating program for 3 years or less use the hierarchal clustering methodology with mean resampling with no guardrail for the first 3 years in the program.

(ii) In cases where multiple clusters have the same measure score value range, those clusters would be combined, leading to fewer than 5 clusters.

(iii) The clustering algorithm for the improvement measure scores is done in two steps to determine the cut points for the measure-level Star Ratings. Clustering is conducted separately for improvement measure scores greater than or equal to zero and those with improvement measure scores less than zero.

(A) Improvement scores of zero or greater would be assigned at least 3 stars for the improvement Star Rating.

(B) Improvement scores less than zero would be assigned either 1 or 2 stars for the improvement Star Rating.

(3) *Relative distribution and significance testing for CAHPS measures.* The method combines evaluating the relative percentile distribution with significance testing and accounts for the reliability of scores produced from survey data; no measure Star Rating is produced if the reliability of a CAHPS measure is less than 0.60. Low reliability scores are defined as those with at least 11 respondents, reliability greater than or equal to 0.60 but less

than 0.75, and also in the lowest 12 percent of contracts ordered by reliability. The following rules apply:

(i) A contract is assigned 1 star if both of the criteria in paragraphs (a)(3)(i)(A) and (B) of this section are met plus at least one of the criteria in paragraphs (a)(3)(i)(C) or (D) of this section is met:

(A) Its average CAHPS measure score is lower than the 15th percentile; and

(B) Its average CAHPS measure score is statistically significantly lower than the national average CAHPS measure score;

(C) The reliability is not low; or

(D) Its average CAHPS measure score is more than one standard error below the 15th percentile.

(ii) A contract is assigned 2 stars if it does not meet the 1-star criteria and meets at least one of these three criteria:

(A) Its average CAHPS measure score is lower than the 30th percentile and the measure does not have low reliability; or

(B) Its average CAHPS measure score is lower than the 15th percentile and the measure has low reliability; or

(C) Its average CAHPS measure score is statistically significantly lower than the national average CAHPS measure score and below the 60th percentile.

(iii) A contract is assigned 3 stars if it meets at least one of these three criteria:

(A) Its average CAHPS measure score is at or above the 30th percentile and lower than the 60th percentile, and it is not statistically significantly different from the national average CAHPS measure score; or

(B) Its average CAHPS measure score is at or above the 15th percentile and lower than the 30th percentile, the reliability is low, and the score is not statistically significantly lower than the national average CAHPS measure score; or

(C) Its average CAHPS measure score is at or above the 60th percentile and lower than the 80th percentile, the reliability is low, and the score is not statistically significantly higher than the national average CAHPS measure score.

(iv) A contract is assigned 4 stars if it does not meet the 5-star criteria and meets at least one of these three criteria:

(A) Its average CAHPS measure score is at or above the 60th percentile and the measure does not have low reliability; or

(B) Its average CAHPS measure score is at or above the 80th percentile and the measure has low reliability; or

(C) Its average CAHPS measure score is statistically significantly higher than the national average CAHPS measure score and above the 30th percentile.

(v) A contract is assigned 5 stars if both of the following criteria in paragraphs (a)(3)(v)(A) and (B) of this section are met plus at least one of the criteria in paragraphs (a)(3)(v)(C) or (D) of this section is met:

(A) Its average CAHPS measure score is at or above the 80th percentile; and

(B) Its average CAHPS measure score is statistically significantly higher than the national average CAHPS measure score;

(C) The reliability is not low; or

(D) Its average CAHPS measure score is more than one standard error above the 80th percentile.

(4) *5-Star Scale.* Measure scores are converted to a 5-star scale ranging from 1 (worst rating) to 5 (best rating), with whole star increments for the cut points.

(b) *Domain Star Ratings.* (1)(i) CMS groups measures by domains solely for purposes of public reporting the data on Medicare Plan Finder. They are not used in the calculation of the summary or overall ratings. Domains are used to group measures by dimensions of care that together represent a unique and important aspect of quality and performance.

(ii) The 4 domains for the Part D Star Ratings are: Drug Plan Customer Service; Member Complaints and Changes in the Drug Plan's Performance; Member Experience with the Drug Plan; and Drug Safety and Accuracy of Drug Pricing.

(2) CMS calculates the domain ratings as the unweighted mean of the Star Ratings of the included measures.

(i) A contract must have scores for at least 50 percent of the measures required to be reported for that contract

type for that domain to have a domain rating calculated.

(ii) The domain ratings are on a 1 to 5 star scale ranging from 1 (worst rating) to 5 (best rating) in whole star increments using traditional rounding rules.

(c) *Part D summary ratings.* (1) CMS will calculate the Part D summary ratings using the weighted mean of the measure-level Star Ratings for Part D, weighted in accordance with paragraph (e) of this section and with the applicable adjustments provided in paragraph (f) of this section.

(2)(i) A contract must have scores for at least 50 percent of the measures required to be reported for the contract type to have a summary rating calculated.

(ii) The Part D improvement measure is not included in the count of the minimum number of rated measures.

(3) The summary ratings are on a 1 to 5 star scale ranging from 1 (worst rating) to 5 (best rating) in half-star increments using traditional rounding rules.

(d) *Overall MA–PD rating.* (1) The overall rating for a MA–PD contract will be calculated using a weighted mean of the Part C and Part D measure-level Star Ratings, weighted in accordance with paragraph (e) of this section and with the applicable adjustments provided in paragraph (f) of this section.

(2)(i) An MA–PD must have both Part C and Part D summary ratings and scores for at least 50 percent of the measures required to be reported for the contract type to have the overall rating calculated.

(ii) The Part C and D improvement measures are not included in the count of measures needed for the overall rating.

(iii) Any measures that share the same data and are included in both the Part C and Part D summary ratings will be included only once in the calculation for the overall rating.

(iv) The overall rating is on a 1 to 5 star scale ranging from 1 (worst rating) to 5 (best rating) in half-increments using traditional rounding rules.

(e) *Measure weights*—(1) *General rules.* Subject to paragraphs (e)(2) and (3) of this section, CMS will assign weights to measures based on their categorization as follows.

(i) Improvement measures receive the highest weight of 5.

(ii) Outcome and Intermediate outcome measures receive a weight of 3.

(iii) Through the 2025 Star Ratings, patient experience and complaint measures receive a weight of 4. Starting with the 2026 Star Ratings and subsequent Star Ratings years, patient experience and complaint measures receive a weight of 2.

(iv) Through the 2025 Star Ratings, access measures receive a weight of 4. Starting with the 2026 Star Ratings and subsequent Star Ratings years, access measures receive a weight of 2.

(v) Process measures receive a weight of 1.

(2) *Rules for new and substantively updated measures.* New measures to the Star Ratings program will receive a weight of 1 for their first year in the Star Ratings program. Substantively updated measures will receive a weight of 1 in their first year returning to the Star Ratings after being on the display page. In subsequent years, a new or substantively updated measure will be assigned the weight associated with its category.

(3) *Special rule for Puerto Rico.* Contracts that have service areas that are wholly located in Puerto Rico will receive a weight of zero for the Part D adherence measures for the summary and overall rating calculations and will have a weight of 3 for the adherence measures for the improvement measure calculations.

(f) *Completing the Part D summary and overall rating calculations.* CMS will adjust the summary and overall rating calculations to take into account the reward factor (if applicable) and the categorical adjustment index (CAI) as provided in this paragraph (f).

(1) *Reward factor.* Through the 2026 Star Ratings, this rating-specific reward factor is added to both the summary and overall ratings of contracts that qualify for this reward factor based on both high and stable relative performance for the rating level.

(i) The contract's performance will be assessed using its weighted mean and its ranking relative to all rated contracts in the rating level (overall

for MA–PDs and Part D summary for MA–PDs and PDPs) for the same Star Ratings year. The contract's stability of performance will be assessed using the weighted variance and its ranking relative to all rated contracts in the rating type (overall for MA–PDs and Part D summary for MA–PDs and PDPs). The weighted mean and weighted variance are compared separately for MA–PD and standalone Part D contracts (PDPs). The measure weights are specified in paragraph (e) of this section. Since highly-rated contracts may have the improvement measure(s) excluded in the determination of their final highest rating, each contract's weighted variance and weighted mean will be calculated both with and without the improvement measures. For an MA–PD's Part C and D summary ratings, its ranking is relative to all other contracts' weighted variance and weighted mean for the rating type (Part C summary, Part D summary) with the improvement measure. For the 2022 Star Ratings only, since all contracts may have the improvement measure(s) excluded in the determination of their highest rating and summary rating(s), each contract's weighted variance and weighted mean are calculated both with and without the improvement measures.

(ii) Relative performance of the weighted variance (or weighted variance ranking) will be categorized as being high (at or above 70th percentile), medium (between the 30th and 69th percentile) or low (below the 30th percentile). Relative performance of the weighted mean (or weighted mean ranking) will be categorized as being high (at or above the 85th percentile), relatively high (between the 65th and 84th percentiles), or other (below the 65th percentile).

(iii) The combination of the relative variance and relative mean is used to determine the reward factor to be added to the contract's summary and overall ratings as follows:

(A) A contract with low variance and a high mean will have a reward factor equal to 0.4.

(B) A contract with medium variance and a high mean will have a reward factor equal to 0.3.

(C) A contract with low variance and a relatively high mean will have a reward factor equal to 0.2.

(D) A contract with medium variance and a relatively high mean will have a reward factor equal to 0.1.

(E) A contract with all other combinations of variance and relative mean will have a reward factor equal to 0.0.

(iv) The reward factor is determined and applied before application of the CAI adjustment under paragraph (f)(2) of this section; the reward factor is based on unadjusted scores.

(2) *Categorical adjustment index.* CMS applies the categorical adjustment index (CAI) as provided in this paragraph(f)(2) to adjust for the average within-contract disparity in performance associated with the percentages of beneficiaries who receive a low income subsidy or are dual eligible (LIS/DE) or have disability status. The factor is calculated as the mean difference in the adjusted and unadjusted ratings (overall, Part D for MA–PDs, Part D for PDPs) of the contracts that lie within each final adjustment category for each rating type.

(i) The CAI is added to or subtracted from the contract's overall and summary ratings and is applied after the reward factor adjustment described in paragraph (f)(1) of this section (if applicable).

(A) The adjustment factor is monotonic (that is, as the proportion of LIS/DE and disabled increases in a contract, the adjustment factor increases in at least one of the dimensions) and varies by a contract's categorization into a final adjustment category that is determined by a contract's proportion of LIS/DE and disabled beneficiaries.

(B) To determine a contract's final adjustment category, contract enrollment is determined using enrollment data for the month of December for the measurement period of the Star Ratings year.

(*1*) For the first 2 years following a consolidation, for the surviving contract of a contract consolidation involving two or more contracts for health or drug services of the same plan type under the same parent organization, the enrollment data for the

month of December for the measurement period of the Star Ratings year are combined across the surviving and consumed contracts in the consolidation.

(*2*) The count of beneficiaries for a contract is restricted to beneficiaries that are alive for part or all of the month of December of the applicable measurement year.

(*3*) A beneficiary is categorized as LIS/DE if the beneficiary was designated as full or partially dually eligible or receiving a LIS at any time during the applicable measurement period.

(*4*) Disability status is determined using the variable original reason for entitlement (OREC) for Medicare using the information from the Social Security Administration and Railroad Retirement Board record systems.

(C) A MA–PD contract may be adjusted up to three times with the CAI: One for the overall Star Rating and one for each of the summary ratings (Part C and Part D).

(D) A PDP contract may be adjusted only once for the CAI for the Part D summary rating.

(E) The CAI values are rounded and displayed with 6 decimal places.

(ii) In determining the CAI values, a measure will be excluded from adjustment if the measure meets any of the following:

(A) The measure is already case-mix adjusted for socioeconomic status.

(B) The focus of the measurement is not a beneficiary-level issue but rather a plan or provider-level issue.

(C) The measure is scheduled to be retired or revised.

(D) The measure is applicable only to SNPs.

(iii) The Star Ratings measures that remain after the exclusion criteria, paragraph (f)(2)(ii) of this section, have been applied will be adjusted for the determination of the CAI. CMS will announce the measures identified for adjustment in the calculations of the CAI under this paragraph (f)(2) through the process described for changes in and adoption of payment and risk adjustment policies in section 1853(b) of the Act.

(iv) The adjusted measures scores for the selected measures are determined using the results from regression models of beneficiary level measure scores that adjust for the average within-contract difference in measure scores for MA or PDP contracts.

(A) A logistic regression model with contract fixed effects and beneficiary level indicators of LIS/DE and disability status is used for the adjustment.

(B) The adjusted measure scores are converted to a measure-level Star Rating using the measure thresholds for the Star Ratings year that corresponds to the measurement period of the data employed for the CAI determination.

(v) The rating-specific CAI values will be determined using the mean differences between the adjusted and unadjusted Star Ratings (overall, Part D summary for MA–PDs and Part D summary for PDPs) in each final adjustment category.

(A) For the annual development of the CAI, the distribution of the percentages for LIS/DE and disabled (using the enrollment data that parallels the previous Star Ratings year's data) would be examined to determine the number of equal-sized initial groups for each attribute (LIS/DE and disabled).

(B) The initial categories are created using all groups formed by the initial LIS/DE and disabled groups.

(C) The mean difference between the adjusted and unadjusted summary or overall ratings per initial category would be calculated and examined. The initial categories would then be collapsed to form the final adjustment categories. The collapsing of the initial categories to form the final adjustment categories would be done to enforce monotonicity in at least one dimension (LIS/DE or disabled).

(D) The mean difference within each final adjustment category by rating-type (overall, Part D for MA–PD, and Part D for PDPs) would be the CAI values for the next Star Ratings year.

(vi) CMS develops the model for the modified contract-level LIS/DE percentage for Puerto Rico using the following sources of information:

(A) The most recent data available at the time of the development of the model of both 1-year American Community Survey (ACS) estimates for the percentage of people living below the

Federal Poverty Level (FPL) and the ACS 5-year estimates for the percentage of people living below 150 percent of the FPL. The data to develop the model will be limited to the 10 states, drawn from the 50 states plus the District of Columbia with the highest proportion of people living below the FPL, as identified by the 1-year ACS estimates.

(B) The Medicare enrollment data from the same measurement period as the Star Rating's year. The Medicare enrollment data would be aggregated from MA contracts that had at least 90 percent of their enrolled beneficiaries with mailing addresses in the 10 highest poverty states.

(vii) A linear regression model is developed to estimate the percentage of LIS/DE for a contacts that solely serve the population of beneficiaries in Puerto Rico.

(A) The maximum value for the modified LIS/DE indicator value per contract would be capped at 100 percent.

(B) All estimated modified LIS/DE values for Puerto Rico would be rounded to 6 decimal places when expressed as a percentage.

(C) The model's coefficient and intercept are updated annually and published in the Technical Notes.

(3) *Health equity index.* Starting with the 2027 Star Ratings year and subsequent Star Ratings years, CMS applies a health equity index rating-specific factor to both the summary and overall ratings of contracts that qualify based on an assessment of contract performance on quality measures among enrollees with certain social risk factors (SRFs).

(i) The health equity index (HEI) is calculated separately for the overall rating for MA–PDs and cost contracts including the applicable Part C and D measures; Part C summary rating for MA-only, MA–PD, and cost contracts including the applicable Part C measures; Part D summary rating for MA–PDs and cost contracts including the applicable Part D measures; and Part D summary rating for PDPs including the applicable Part D measures.

(A) The SRFs included in the HEI are receipt of the low-income subsidy or being dually eligible for Medicare and Medicaid (LIS/DE), or having a disability. Enrollees will be identified as LIS/DE or as having a disability as specified in paragraph (f)(2)(i)(B) of this section. If a person meets the LIS/DE criteria for only one of the two measurement years included in the HEI, the data for that person for just that year are used. Measures that are case-mix adjusted in the Star Ratings are adjusted using all standard case-mix adjustors for the measure except for those adjusters that are the SRFs of interest in the index, are strongly correlated with the SRFs of interest, or are conceptually similar to the SRFs of interest.

(B) The HEI is calculated by combining measure-level scores for the subset of enrollees with SRFs of interest included in the HEI across the two most recent measurement years using a modeling approach that includes year as an adjustor to account for potential differences in performance across years and to adjust the data to reflect performance in the second of the 2 years of data used. Measure-level scores are used for contracts that have data for only the most recent of the 2 years, but measure-level scores are not used for contracts that have data for only the first of the 2 years.

(ii) In determining the HEI scores, a measure will be excluded from the calculation of the index if the measure meets any of the following:

(A) The focus of the measurement is not the enrollee but rather the plan or provider.

(B) The measure is retired, moved to display, or has a substantive specification change in either year of data used to construct the HEI.

(C) The measure is applicable only to SNPs.

(D) At least 25 percent of contracts are unable to meet the criteria specified in paragraph (f)(3)(iv) of this section. For Part D measures, this criterion is assessed separately for MA–PDs and cost contracts, and for PDPs.

(iii) The Star Ratings measures that remain after the exclusion criteria in paragraph (f)(3)(ii) of this section have been applied will be included in the calculation of the HEI. CMS will announce the measures being evaluated for inclusion in the calculation of the

HEI under this paragraph (f)(3) of this section through the process described for changes in and adoption of payment and risk adjustment policies in section 1853(b) of the Act.

(iv) For a measure to be included in the calculation of a contract's HEI score, the measure must meet both of the following criteria:

(A) The measure must have a reliability of at least 0.7 for the contract when calculated for the combined subset of enrollees with the SRF(s) specified in paragraph (f)(3)(i)(A) of this section across 2 years of data.

(B) The measure-specific denominator criteria must be met for the contract using only the combined subset of enrollees with the SRF(s) specified in paragraph (f)(3)(i)(A) of this section across 2 years of data.

(v) To calculate the rating-specific HEI score, the distribution of contract performance on each eligible measure for the subset of enrollees that have one or more of the specified SRFs will be assessed and separated into thirds, with the top third of contracts receiving 1 point, the middle third of contracts receiving 0 points, and the bottom third of contracts receiving −1 point. The rating-specific HEI will then be calculated as the weighted sum of points across all measures included in the index using the Star Ratings measure weight for each measure divided by the weighted sum of the number of eligible measures for the given contract. The measure weight for each measure is the weight used for the measure in the current Star Ratings year as specified in paragraph (e) of this section.

(vi) To have the HEI calculated, contracts must have at least 500 enrollees in the most recent measurement year used in the HEI and have at least half of the measures included in the HEI meet the criteria specified under paragraph (f)(3)(iv) of this section.

(vii) In order to qualify for the full HEI reward, contracts must have percentages of enrollees with the specified SRFs combined greater than or equal to the contract-level median in the most recent year of data used to calculate the HEI and a rating-specific minimum index score of greater than zero. In order to qualify for one-half of the HEI reward, contracts must have percentages of enrollees with SRFs greater than or equal to one-half of the contract-level median up to, but not including, the contract-level median percentage of enrollees with SRFs in the most recent year of data used to calculate the HEI and a rating-specific minimum index score of greater than zero. One-half of the contract-level median and the contract-level median enrollment percentages are assessed separately for contracts that offer Part C and stand-alone Part D contracts.

(A) For contracts with service areas wholly located in Puerto Rico, the percentage of enrollees that are LIS/DE or disabled is calculated by adding the number of DE/disabled enrollees to the estimated LIS percentage calculated by taking the percentage LIS/DE as calculated at §§422.166(f)(2)(vi) and (vii) and 423.186(f)(2)(vi) and (vii) and subtracting the percentage of DE enrollees.

(B) Contracts with service areas wholly located in Puerto Rico are excluded from the calculation of one-half of the contract-level median and the contract-level median.

(viii) For contracts that have percentages of enrollees with SRFs greater than or equal to the contract-level median enrollment percentage, the HEI reward added to the contract's summary and overall ratings will vary from 0 to 0.4 on a linear scale with a contract receiving 0 if the contract receives a score of 0 or less on the HEI and 0.4 if the contract receives a score of 1 on the HEI. For contracts that have percentages of enrollees with SRFs greater than or equal to one-half the median percentage of enrollees with SRFs up to, but not including, the contract-level median percentage of enrollees with SRFs, the HEI reward added to the contract's summary and overall ratings will vary from 0 to 0.2 on a linear scale, with a contract receiving 0 if the contract receives a score of 0 or less on the HEI and 0.2 if the contract receives a score of 1 on the HEI. The HEI reward is rounded and displayed with 6 decimal places. Contracts that cannot have a HEI score calculated (that is, contracts that are not scored on at least half of the measures included in the index) will not receive an HEI reward.

(A) In the case of contract consolidations involving two or more contracts for health or drug services of the same plan type under the same parent organization, CMS calculates the HEI reward for the surviving contract accounting for both the surviving and consumed contract(s). For the first year following a consolidation, the HEI reward for the surviving contract is calculated as the enrollment-weighted mean of the HEI reward of the consumed and surviving contracts using total contract enrollment from July of the most recent measurement year used in calculating the HEI reward. A reward value of zero is used in calculating the enrollment-weighted mean for contracts that do not meet the minimum percentage of enrollees with the SRF thresholds or the minimum performance threshold specified at paragraph (f)(3)(vii) of this section.

(B) For the second year following a consolidation when calculating the HEI score for the surviving contract, the patient-level data used in calculating the HEI score will be combined from the consumed and surviving contracts and used in calculating the HEI score.

(ix) The HEI reward is calculated separately for, and then added to, the overall rating, Part C rating for MA–PDs and MA-only contracts (and cost contracts), Part D rating for MA–PDs (and cost contracts), and Part D rating for PDPs after the addition of the CAI as specified in paragraph (f)(2) of this section and application of the improvement measures as specified in paragraph (g) of this section and before the final overall and Part C and D summary ratings are calculated by rounding to the nearest half star.

(g) *Applying the improvement measure scores.* (1) CMS runs the calculations twice for the highest level rating for each contract-type (overall rating for MA–PD contracts and Part D summary rating for PDPs), with the reward factor adjustment if applicable and the CAI adjustment, once including the improvement measure(s) and once without including the improvement measure(s). In deciding whether to include the improvement measures in a contract's final highest rating, CMS applies the following rules:

(i) If the highest rating for each contract-type is 4 stars or more without the use of the improvement measure(s) and with all applicable adjustments (CAI and the reward factor), a comparison of the highest rating with and without the improvement measure(s) is done. The higher rating is used for the rating.

(ii) If the highest rating is less than 4 stars without the use of the improvement measure(s) and with all applicable adjustments (CAI and the reward factor), the rating will be calculated with the improvement measure(s).

(2) The Part D summary rating for MA–PDs will include the Part D improvement measure.

(3) For 2022 Star Ratings only, CMS runs the calculations twice for the highest rating for each contract-type (overall rating for MA–PD contracts and Part D summary rating for PDPs) and Part D summary rating for MA–PDs with all applicable adjustments (CAI and the reward factor), once including the improvement measure(s) and once without including the improvement measure(s). In deciding whether to include the improvement measures in a contract's highest and summary rating(s), CMS applies the following rules:

(i) For MA–PDs and PDPs, a comparison of the highest rating with and without the improvement measure is done. The higher rating is used for the highest rating.

(ii) For MA–PDs, a comparison of the Part D summary rating with and without the improvement measure is done. The higher rating is used for the summary rating.

(h) *Posting and display of ratings.* For all ratings at the measure, domain, summary and overall level, posting and display of the ratings is based on there being sufficient data to calculate and assign ratings. If a contract does not have sufficient data to calculate a rating, the posting and display would be the flag ''Not enough data available.'' If the measurement period is prior to one year past the contract's effective date, the posting and display would be the flag ''Plan too new to be measured''.

(1) *Medicare Plan Finder performance icons.* Icons are displayed on Medicare

Plan Finder to note performance as provided in this paragraph (h)(1):

(i) *High-performing icon.* The high performing icon is assigned to a Part D plan sponsor for achieving a 5-star Part D summary rating and an MA–PD contract for a 5-star overall rating.

(ii) *Low-performing icon.* (A) A contract receives a low performing icon as a result of its performance on the Part C or Part D summary ratings. The low performing icon is calculated by evaluating the Part C and Part D summary ratings for the current year and the past 2 years. If the contract had any combination of Part C or Part D summary ratings of 2.5 or lower in all 3 years of data, it is marked with a low performing icon. A contract must have a rating in either Part C or Part D for all 3 years to be considered for this icon.

(B) CMS may disable the Medicare Plan Finder online enrollment function (in Medicare Plan Finder) for Medicare health and prescription drug plans with the low performing icon; beneficiaries will be directed to contact the plan directly to enroll in the low-performing plan.

(2) *Plan preview of the Star Ratings.* CMS will have plan preview periods before each Star Ratings release during which Part D plan sponsors can preview their Star Ratings data in HPMS prior to display on the Medicare Plan Finder.

(i) *Extreme and uncontrollable circumstances.* In the event of extreme and uncontrollable circumstances that may negatively impact operational and clinical systems and contracts' abilities to conduct surveys needed for accurate performance measurement, CMS calculates the Star Ratings as specified in paragraphs (i)(2) through (8) of this section for each contract that is an affected contract during the performance period for the applicable measures. We use the start date of the incident period to determine which year of Star Ratings could be affected, regardless of whether the incident period lasts until another calendar year.

(1) *Identification of affected contracts.* A contract that meets all of the following criteria is an affected contract:

(i) The contract's service area is within an ''emergency area'' during an ''emergency period'' as defined in section 1135(g) of the Act.

(ii) The contract's service area is within a county, parish, U.S. territory or tribal area designated in a major disaster declaration under the Stafford Act and the Secretary exercised authority under section 1135 of the Act based on the same triggering event(s).

(iii) As specified in paragraphs (i)(2) through (8) of this section, a certain minimum percentage (25 percent or 60 percent) of the enrollees under the contract must reside in a Federal Emergency Management Agency (FEMA)-designated Individual Assistance area at the time of the extreme and uncontrollable circumstance.

(2) *CAHPS adjustments.* (i) A contract, even if an affected contract, must administer the CAHPS survey unless exempt under paragraph (i)(2)(ii) of this section.

(ii) An affected contract with at least 25 percent of enrollees in FEMA-designated Individual Assistance areas at the time of the extreme and uncontrollable circumstance is exempt from administering the CAHPS survey if the contract completes both of the following:

(A) Demonstrates to CMS that the required sample for the survey cannot be contacted because a substantial number of the contract's enrollees are displaced due to the FEMA-designated disaster identified in paragraph (i)(1)(iii) of this section in the prior calendar year.

(B) Requests and receives a CMS approved exemption.

(iii) An affected contract with an exemption described in paragraph (i)(2)(ii) of this section receives the contract's CAHPS measure stars and corresponding measure scores from the prior year.

(iv) For an affected contract with at least 25 percent of enrollees in FEMA-designated Individual Assistance areas at the time of the extreme and uncontrollable circumstance, the contract receives the higher of the previous year's Star Rating or the current year's Star Rating (and corresponding measure score) for each CAHPS measure.

(v) When a contract is an affected contract with at least 25 percent of enrollees in FEMA-designated Individual Assistance areas at the time of the extreme and uncontrollable circumstance with regard to separate extreme and uncontrollable circumstances that begin in successive years, it is a multiple year-affected contract. A multiple year-affected contract receives the higher of the current year's Star Rating or what the previous year's Star Rating would have been in the absence of any adjustments that took into account the effects of the previous year's disaster for each measure (using the corresponding measure score for the Star Ratings year selected).

(3) *New measure adjustments.* For affected contracts with at least 25 percent of enrollees in a FEMA-designated Individual Assistance area at the time of the extreme and uncontrollable circumstance, CMS holds the affected contract harmless by using the higher of the contract's summary or overall rating or both with and without including all of the applicable new measures.

(4) *Other Star Ratings measure adjustments.* (i) For all other Part D measures except those measures identified in this paragraph (i)(4)(ii) of this section, affected contracts with at least 25 percent of enrollees in a FEMA-designated Individual Assistance area at the time of the extreme and uncontrollable circumstance receive the higher of the previous or current year's measure Star Rating (and corresponding measure score).

(ii) CMS does not adjust the scores of the Star Ratings for the Part D Call Center—Foreign Language Interpreter and TTY Availability measure, unless the exemption listed in paragraph (i)(4)(iii) of this section applies.

(iii) CMS adjusts the measure listed in paragraph (i)(4)(ii) of this section using the adjustments listed in paragraph (i)(4)(i) of this section for contracts affected by extreme and uncontrollable circumstances where there are continuing communications issues related to loss of electricity and damage to infrastructure during the call center study.

(iv) When a contract is an affected contract with at least 25 percent of enrollees in FEMA-designated Individual Assistance areas at the time of the extreme and uncontrollable circumstance with regard to separate extreme and uncontrollable circumstances that begin in successive years, it is a multiple year-affected contract. A multiple year-affected contract receives the higher of the current year's Star Rating or what the previous year's Star Rating would have been in the absence of any adjustments that took into account the effects of the previous year's disaster for each measure (using the corresponding measure score for the Star Ratings year selected).

(5) *Exclusion from improvement measures.* Any measure that reverts back to the data underlying the previous year's Star Rating due to the adjustments made in paragraph (i) of this section is excluded from both the count of measures and the applicable improvement measures for the current and next year's Star Ratings for the affected contract. Contracts affected by extreme and uncontrollable circumstances do not have the option of reverting to the prior year's improvement rating.

(6) *Missing data.* For an affected contract that has missing data in the current or previous year, the final measure rating comes from the current year unless an exemption described in paragraph (i)(2)(ii) of this section applies. Missing data includes data where there is a data integrity issue as defined at § 423.184(g)(1).

(7) *Cut points for non-CAHPS measures.* (i) Through the 2025 Star Ratings, CMS excludes the numeric values for affected contracts with 60 percent or more of their enrollees in the FEMA-designated Individual Assistance area at the time of the extreme and uncontrollable circumstance from the clustering algorithms described in paragraph (a)(2) of this section.

(ii) The cut points calculated as described in paragraph (i)(7)(i) of this section are used to assess all affected contracts' measure Star Ratings.

(8) *Reward factor.* (i) Through the 2025 Star Ratings, CMS excludes the numeric values for affected contracts with 60 percent or more of their enrollees in the FEMA-designated Individual Assistance area at the time of the extreme and uncontrollable circumstance

from the determination of the performance summary and variance thresholds for the reward factor described in paragraph (f)(1) of this section.

(ii) All affected contracts are eligible for the Reward Factor based on the calculations described in paragraph (i)(8)(i) of this section.

(9) *Special rules for the 2022 Star Ratings only.* For the 2022 Star Ratings only, CMS will not apply the provisions in paragraph (i)(7) or (8) of this section and CMS will not exclude the numeric values for affected contracts with 60 percent or more of their enrollees in the FEMA-designated Individual Assistance area at the time of the extreme and uncontrollable circumstance from the clustering algorithms or from the determination of the performance summary and variance thresholds for the Reward Factor.

(j) *Special rules for 2021 Star Ratings only.* (1) For the 2021 Star Ratings:

(i) The measures calculated based on CAHPS data are calculated based on survey data collected from March through May 2019.

(ii) The measure-level change score calculation described at § 423.184(f)(4)(i) is not applied for CAHPS measures and the measure-level change score used for the 2020 Star Ratings is applied in its place for all CAHPS-based measures.

(iii) The provisions of § 423.184(g)(2) are not applied for failure to submit CAHPS-based measures.

(iv) [Reserved]

(2) [Reserved]

[83 FR 16743, Apr. 16, 2018, as amended at 84 FR 15842, Apr. 16, 2019; 85 FR 19291, Apr. 6, 2020; 85 FR 33911, June 2, 2020; 85 FR 54872, Sept. 2, 2020; 86 FR 6118, Jan. 19, 2021; 87 FR 27899, May 9, 2022; 88 FR 22338, Apr. 12, 2023; 89 FR 30835, Apr. 23, 2024]

Subpart E [Reserved]

Subpart F—Submission of Bids and Monthly Beneficiary Premiums; Plan Approval

§ 423.251 Scope.

This section sets forth the requirements and limitations on submission, review, negotiation and approval of competitive bids for prescription drug plans and MA-PD plans; the calculation of the national average bid amount; and the determination of enrollee premiums.

§ 423.258 Definitions.

For the purposes of this subpart, the following definitions apply:

Full risk plan means a prescription drug plan that is not a limited risk plan or a fallback prescription drug plan.

Limited risk plan means a prescription drug plan that provides basic prescription drug coverage and for which the PDP sponsor includes a modification of risk level described in § 423.265(d) in its bid submitted for the plan. This term does not include a fallback prescription drug plan.

Standardized bid amount means, for a prescription drug plan that provides basic prescription drug coverage, the PDP approved bid; for a prescription drug plan that provides supplemental prescription drug coverage, the portion of the PDP approved bid that is attributable to basic prescription drug coverage; for a MA-PD plan, the portion of the accepted bid amount that is attributable to basic prescription drug coverage.

§ 423.265 Submission of bids and related information.

(a) *Eligibility for bidding.* An applicant may submit a bid to become a Part D plan sponsor.

(b) *Bid submission*—(1) *General.* Not later than the first Monday in June, each potential Part D sponsor must submit bids and supplemental information described in this section for each Part D plan it intends to offer in the subsequent calendar year.

(2) *Substantial differences between bids*—(i) *General rule.* Except as provided in paragraph (b)(2)(ii) of this section, potential Part D sponsors' bid submissions must reflect differences in benefit packages or plan costs that CMS determines to represent substantial differences relative to a sponsor's other bid submissions. In order to be considered ''substantially different,'' each bid must be significantly different from the sponsor's other bids with respect to beneficiary out-of-pocket costs or formulary structures.

(ii) *Exception.* A potential Part D sponsor's enhanced bid submission does not have to reflect the substantial differences as required in paragraph (b)(2)(i) of this section relative to any of its other enhanced bid submissions.

(3) *Limit on number of plan offerings.* Potential Part D sponsors' bid submissions may include no more than three stand-alone prescription drug plan offerings in a service area and must include only one basic prescription drug plan offering.

(4) *Bid acceptance.* CMS may decline to accept any or every bid submitted by a Part D sponsor or potential Part D sponsor.

(5) *Limitations on changes.* After a Part D sponsor is permitted to begin marketing prospective plan year offerings for the following contract year (consistent with § 423.2263(a)), the Part D sponsor must not change, and must provide the benefits described in its CMS-approved plan benefit package (PBP) (as defined at § 423.182) for the contract year without modification, except where a modification in benefits is required by law.

(c) *Basic rule for bid.* Each potential Part D sponsor must submit a bid and supplemental information in a format to be specified by CMS for each Part D plan it offers. Each bid must reflect a uniform benefit package, including premium (except as provided for the late enrollment penalty described in § 423.286(d)(3)) and all applicable cost sharing, for all individuals enrolled in the plan. Each bid must reflect the applicant's estimate of its average monthly revenue requirements to provide qualified prescription drug coverage (including any supplemental coverage) for a Part D eligible individual with a national average risk profile for the factors described in § 423.329(b)(1).

(1) *Included costs.* The bid includes costs (including administrative costs and return on investment/profit) for which the plan is responsible in providing basic and supplemental benefits.

(2) *Excluded costs.* The bid does not include costs associated with payments by the enrollee for deductible, co-payments, coinsurance, and liability above the plan allowance in the case of out-of-network claims, payments projected to be made by CMS for reinsurance, or any other costs for which the sponsor is not responsible.

(3) *Actuarial valuation.* The bid must be prepared in accordance with CMS actuarial guidelines based on generally accepted actuarial principles. A qualified actuary must certify the plan's actuarial valuation (which may be prepared by others under his or her direction or review), and must be a member of the American Academy of Actuaries to be deemed qualified. Applicants may use qualified outside actuaries to prepare their bids.

(d) *Specific requirements for bids.* The bid and supplemental information submission must include the following information:

(1) *Coverage.* A description of the coverage to be provided under the plan, including any supplemental coverage and the deductible and other cost sharing.

(2) *Actuarial value of bid components.* The applicant must provide the following information on bid components, as well as actuarial certification that the values are calculated according to CMS guidelines on actuarial valuation, including adjustment for the effect that providing alternative prescription drug coverage (rather than defined standard prescription drug coverage) has on drug utilization, if applicable.

(i) The actuarial value of the qualified prescription drug coverage to be offered under each plan for a Part D eligible individual with a national average risk profile for the factors described in § 423.329(b)(1) and the basis for the estimate.

(ii) The portion of the bid attributable to basic prescription drug coverage and the portion (if any) attributable to supplemental benefits.

(iii) The assumptions regarding reinsurance amounts payable under § 423.329(c) used in calculating the bid.

(iv) The assumptions regarding low-income cost-sharing payable under § 423.329(d) used in calculating the bid.

(v) The amount of administrative costs and return on investment or profit included in the bid.

(3) *Service area.* A description of the service area of the plan.

(4) *Level of risk assumed.* For a potential Part D sponsor, the level of risk assumed in the bid specified in paragraph (e) of this section.

(5) *Plan Average Risk Score.* An estimate of the plan's average prescription drug risk score (as established under § 423.329(b)) for all projected enrollees for purposes of risk adjusting any supplemental premium.

(6) *Additional information.* Additional information CMS requests to support bid amounts and facilitate negotiation.

(e) *Special rule for PDP sponsors.* Bids for all plans offered by a potential PDP sponsor in a region, but not those of potential MA organizations offering MA-PD plans, PACE organizations offering PACE plans including qualified prescription drug coverage, and cost-based HMOs or CMPs offering section 1876 cost plans including qualified prescription drug coverage, may include a uniform modification of the amount of risk assumed (based on a process to be specified) as described in one or more of the following paragraphs. Any such modification applies to all plans offered by the PDP sponsor in a PDP region.

(1) *Increase in Federal percentage assumed in initial risk corridor.* An equal percentage point increase in the percents applied for costs between the first and second threshold limits under § 423.336(b)(2)(i) and (b)(2)(ii)(A) and § 423.336 (b)(3)(i) and (b)(3)(ii)(A). This provision does not affect the application of a higher percentage for plans in 2006 or 2007 under § 423.336(b)(2)(iii).

(2) *Increase in Federal percentage assumed in second risk corridor.* An equal percentage point increase in the percents applied for costs above the second threshold upper limit or below the second threshold upper limit under paragraphs § 423.336(b)(2)(ii)(B) and (b)(3)(ii)(B).

(3) *Decrease in size of risk corridors.* A decrease in the size of the risk corridors by means of reductions in the threshold risk percentages specified in § 423.336(a)(2)(ii)(A) and/or (a)(2)(ii)(B).

(f) *Special rule for fallback prescription drug plans.* Fallback prescription drug plan bids are not subject to the rules in this section. They must follow requirements specified in § 423.863.

[70 FR 4525, Jan. 28, 2005, as amended at 75 FR 19818, Apr. 15, 2010; 76 FR 21573, Apr. 15, 2011; 83 FR 16749, Apr. 16, 2018; 86 FR 6118, Jan. 19, 2021; 88 FR 22339, Apr. 12, 2023; 89 FR 30836, Apr. 23, 2024]

§ 423.272 Review and negotiation of bid and approval of plans submitted by potential Part D sponsors.

(a) *Review and negotiation regarding information, terms and conditions.* CMS reviews the information filed under § 423.265(c) in order to conduct negotiations regarding the terms and conditions of the proposed bid and benefit plan. In addition to its general negotiating authority under section 1860D–11(d)(2)(A) of the Act, CMS has authority similar to that of the Director of the Office of Personnel Management for health benefit plans under Chapter 89 of title 5, U.S.C.

(b) *Approval of proposed plans.* CMS approves the Part D plan only if the plan and the Part D sponsor offering the plan comply with all applicable CMS Part D requirements, including those related to the provision of qualified prescription drug coverage and actuarial determinations.

(1) *Application of revenue requirements standard.* CMS approves a bid submitted under § 423.265 only if it determines that the portions of the bid attributable to basic and supplemental prescription drug coverage are supported by the actuarial bases provided and reasonably and equitably reflect the revenue requirements (as used for purposes of section 1302(8)(C) of the Public Health Service Act) for benefits provided under that plan, less the sum (determined on a monthly per capita basis) of the actuarial value of the reinsurance payments under § 423.329(c).

(2) *Plan design.* (i) CMS does not approve a bid if it finds that the design of the plan and its benefits (including any formulary and tiered formulary structure) or its utilization management program are likely to substantially discourage enrollment by certain Part D eligible individuals under the plan.

(ii) If the design of the categories and classes within a formulary is consistent with the model guidelines (if any) established by the United States Pharmacopeia, the formulary categories and classes alone will not be found to discourage enrollment.

(iii) A plan that adopts the categories and classes discussed in paragraph (b)(2)(ii) of this section may nevertheless be found to discourage enrollment

because it excludes specific drugs from the formulary.

(3) *Substantial differences between bids*—(i) *General.* CMS approves a bid only if it finds that the benefit package or plan costs represented by that bid are substantially different as provided under § 423.265(b)(2) of this subpart from the benefit package or plan costs represented by another bid submitted by the same Part D sponsor.

(ii) *Transition period for PDP sponsors with new acquisitions.* After a 2-year transition period, as determined by CMS, CMS approves a bid offered by a PDP sponsor (or by a parent organization to that PDP sponsor) that recently purchased (or otherwise acquired or merged with) another Part D sponsor if it finds that the benefit package or plan costs represented by that bid are substantially different from benefit packages or plan costs represented by another bid submitted by the same Part D sponsor (or parent organization to that Part D sponsor), as provided under § 423.265(b)(2).

(4) CMS may decline to approve a bid if the Part D sponsor proposes significant increases in cost sharing or decreases in benefits offered under the plan.

(c) *Limited risk plans.* (1) Application of limited risk plans. There is no limit on the number of full risk plans that CMS approves under paragraph (b) of this section. CMS approves a limited risk plan in accordance with paragraphs (c)(2) and (c)(3) of this section only if the access requirements under § 423.859 are not otherwise met for a PDP region.

(2) *Maximizing assumption of risk.* CMS gives priority in approval for those limited risk plans bearing the highest level of risk, but may take into account the level of the bids submitted by the plans and is not required to accept the limited risk plan with the highest assumption of risk. In no case does CMS approve a limited risk plan under which the modification of risk level provides for no (or a minimal) level of financial risk.

(3) *Limited exercise of authority.* CMS approves only the minimum number of limited risk plans needed to meet the access requirements.

(d) *Special rules for private fee-for-service (PFFS) plans that offer prescription drug coverage.* PFFS plans (as defined at § 422.4(a)(3)) choosing to offer prescription drug coverage are subject to all MA-PD bid submission and approval requirements applicable to MA-PD plans with the following exceptions:

(1) *Exemption from negotiations.* These plans are exempt from the review and negotiation process in paragraph (a) of this section, and are not held to the revenue requirements standard in paragraph (b)(1) of this section.

(2) *Requirements regarding negotiated prices.* These plans are not required to provide access to negotiated prices. However, if they do, they must meet the applicable requirements of § 423.104(h).

(3) *Modification of pharmacy access standard and disclosure requirement.* If the plan provides coverage for drugs purchased from all pharmacies, without charging additional cost sharing and without regard to whether they are network pharmacies, §§ 423.120(a) and 423.132 requiring certain network access standards and the disclosure of the availability of lower cost bioequivalent generic drugs does not apply to the plan.

(e) *Special rule for plans with standardized bids sufficiently below the national average monthly bid to result in a negative premium.* In the event of a negative premium, as described in § 423.286(d)(1), CMS negotiates the incorporation of the negative premium amount into the bid as either a reduction in the supplemental premium if the Part D plan already submitted a bid with an enhanced alternative benefit, or CMS requires the addition of new enhanced alternative benefit of no less value than the amount of the negative premium.

[70 FR 4525, Jan. 28, 2005, as amended at 75 FR 19819, Apr. 15, 2010; 76 FR 21574, Apr. 15, 2011; 83 FR 16749, Apr. 16, 2018]

§ 423.279 National average monthly bid amount.

(a) *Bids included.* For each year (beginning with 2006) CMS computes a national average monthly bid amount from approved bids submitted under § 423.265 in order to calculate the base beneficiary premium, as provided in § 423.286(c). The national average

monthly bid amount is equal to a weighted average of the standardized bid amounts for each prescription drug plan (not including fallbacks) and for each MA-PD plan described in section 1851(a)(2)(A)(i) of the Act. The calculation does not include bids submitted by MSA plans, MA private fee-for-service plans, specialized MA plans for special needs individuals, PACE programs under section 1894, and contracts under reasonable cost reimbursement contracts under section 1876(h) of the Act.

(b) *Calculation of weighted average.* (1) The national average monthly bid amount is a weighted average, with the weight for each plan equal to a percentage with the numerator equal to the number of Part D eligible individuals enrolled in the plan in the reference month (as defined in § 422.258(c)(1) of this chapter) and the denominator equal to the total number of Part D eligible individuals enrolled in a reference month in all Part D plans except MSA plans, fallbacks, MA private fee-for-service plans, specialized MA plans for special needs individuals, PACE programs under section 1894, and contracts under reasonable cost reimbursement contracts under section 1876(h) of the Act.

(2) For purposes of calculating the monthly national average monthly bid amount for 2006, CMS assigns equal weighting to PDP sponsors (other than fallback entities) and assigns MA-PD plans included in the national average bid a weight based on prior enrollment (new MA-PD plans are assigned zero weight).

(c) *Geographic adjustment.* (1) Upon the development of an appropriate methodology, the national average monthly bid amount for Part D plans will be adjusted to take into account differences in prices for Part D drugs among PDP regions.

(2) CMS does not apply any geographic adjustments if CMS determines that price variations among PDP regions are negligible.

(3) CMS applies any geographic adjustment in a budget neutral manner so as to not result in a change in the aggregate payments that may have been made if CMS had not applied an adjustment.

(4) CMS does not apply any geographic adjustment until an appropriate methodology is developed.

§ 423.286 Rules regarding premiums.

(a) *General rule.* Except as provided in paragraphs (d)(3), (d)(4), and (e) of this section, and with regard to employer group waivers, the monthly beneficiary premium for a Part D plan in a PDP region is the same for all Part D eligible individuals enrolled in the plan. The monthly beneficiary premium for a Part D plan is the base beneficiary premium, as determined in paragraph (c) of this section, adjusted as described in paragraph (d) of this section for the difference between the bid and the national average monthly bid amount, any supplemental benefits and for any late enrollment penalties.

(b) *Beneficiary premium percentage.* The beneficiary premium percentage for any year is a fraction, the—

(1) Numerator of which is 25.5 percent; and

(2) Denominator of which is as follows:

(i) 100 percent minus the percentage established in paragraph (b)(2)(ii) of this section.

(ii) The percentage established in this paragraph equals:

(A) The total reinsurance payments that CMS estimates will be paid under § 423.329(c) for the coverage year; divided by—

(B) The amount estimated under paragraph (b)(2)(ii)(A) of this section for the year plus total payments that CMS estimates will be paid to Part D plans that are attributable to the standardized bid amount during the year, taking into account amounts paid by both CMS and enrollees.

(c) *Base beneficiary premium.* The base beneficiary premium for a Part D plan for a month is equal to the product of the—

(1) Beneficiary premium percentage as specified in paragraph (b) of this section; and

(2) National average monthly bid amount (computed under § 423.279) for the month.

(d) *Adjustments to base beneficiary premium.* The base beneficiary premium may be adjusted to reflect any of the following scenarios, if applicable.

(1) *Adjustment to reflect difference between bid and national average bid.* If the amount of the standardized bid amount exceeds the adjusted national average monthly bid amount, the monthly base beneficiary premium is increased by the amount of the excess. If the amount of the adjusted national average monthly bid amount exceeds the standardized bid amount, the monthly base beneficiary premium is decreased by the amount of the excess. If the amount of the adjusted national average monthly bid amount exceeds the standardized bid amount by an amount greater than the base beneficiary premium and results in a negative premium, then the beneficiary premium is zero, and the excess amount is applied to supplemental Part D benefits as described in § 423.272(e).

(2) *Increase for supplemental prescription drug benefits.* The portion of the Part D plan approved bid that is attributable to supplemental prescription drug benefits increases the beneficiary premium. This supplemental portion of the bid may be adjusted to reflect the average risk of enrollees in the plan as determined based on negotiations between CMS and the Part D sponsor offering the plan.

(3) *Increase for late enrollment penalty.* The base beneficiary premium for a Part D enrollee subject to the late enrollment penalty is increased by the amount of any late enrollment penalty.

(i) *Late enrollment penalty amount.* The penalty amount for a Part D eligible individual for a continuous period of eligibility (as provided in § 423.46(a)) is the greater of—

(A) An amount that CMS determines is actuarially sound for each uncovered month in the same continuous period of eligibility; or

(B) 1 percent of the base beneficiary premium (computed under paragraph (c) of this section) for each uncovered month in the period.

(ii) *Special rule for 2006 and 2007.* In 2006 and 2007 the penalty amount discussed in paragraph (d)(3) of this chapter equals the amount referenced in paragraph (d)(3)(i)(B) of this section unless another amount is specified in a separate issuance based on available analysis or other information as determined by the Secretary.

(4) *Increase for income-related monthly adjustment amount (Part D—IRMAA).* Beginning January 1, 2011, Medicare beneficiaries enrolled in a Medicare Part D plan must pay an income-related monthly adjustment amount in addition to the Part D premium as determined under paragraph (c) of this section and adjusted under paragraph (d) of this section, if the enrollee's modified adjusted gross income exceeds the threshold amounts specified in 20 CFR 418.2115.

(i) *Social Security Administration determination.* (A) SSA determines which Part D enrollees are subject to the Part D—IRMAA and the amount each enrollee will have to pay.

(B) If an individual disagrees with SSA's determination that such individual is subject to the Part D—IRMAA, or about the amount the individual must pay, an individual may file an appeal or request a new initial determination consistent with 20 CFR part 418.

(ii) *Calculating the income-related monthly adjustment amount.* The income-related monthly adjustment is equal to the product of the standard base beneficiary premium, as determined under paragraph (c) of this section, and the ratio of the applicable premium percentage specified in 20 CFR 418.2120, reduced by 25.5 percent; divided by 25.5 percent (that is, premium percentage − 25.5 percent)/25.5 percent).

(e) *Decrease in monthly beneficiary premium for low-income assistance.* The monthly beneficiary premium may be eliminated or decreased in the case of a subsidy-eligible individual under § 423.780.

(f) *Special rules for fallback prescription drug plans.* The monthly beneficiary premium charged under a fallback prescription drug plan is calculated under § 423.867(a) and not under this section, except that enrollees in fallback prescription drug plans are subject to late enrollment penalties under paragraph (d)(3) of this section and fallback prescription drug plan premiums are reduced or eliminated in the case of a

subsidy-eligible individual, as described in paragraph (e) of this section.

[70 FR 4525, Jan. 28, 2005, as amended at 76 FR 21574, Apr. 15, 2011; 86 FR 6118, Jan. 19, 2021]

§ 423.293 Collection of monthly beneficiary premium.

(a) *General rules.* Part D sponsors must—

(1) Charge enrollees a consolidated monthly Part D premium equal to the sum of the Part D monthly premium for basic prescription drug coverage (if any) and the premium for supplemental coverage (if any and if the beneficiary has enrolled in such supplemental coverage).

(2) Permit payment of monthly Part D premiums (if any) under the timing of payments established in § 422.262(e) of this chapter; and

(3) Permit each enrollee, at the enrollee's option, to make payment of premiums (if any) under this part to the sponsor using any of the methods listed in § 422.262(f) of this chapter.

(4) *Retroactive collection of premiums.* In circumstances where retroactive collection of premium amounts is necessary and the enrollee is without fault in creating the premium arrearage, the Part D sponsor shall offer the enrollee the option of payment by lump sum, by equal monthly installment spread out over at least the same period for which the premiums were due, or through other arrangements mutually acceptable to the enrollee and the Part D sponsor. For monthly installments, for example, if 7 months of premiums are due, the member would have at least 7 months to repay.

(b) *Crediting of late enrollment penalty.* CMS estimates and specifies the portion of the late enrollment penalty imposed under § 423.286(d)(3) attributable to increased actuarial costs assumed by the Part D sponsor and not taken into account through risk adjustment provided under § 423.329(b)(1) or through reinsurance payments under § 423.329(c)) as a result of the late enrollment.

(c) *Collection of late enrollment penalty*—(1) *Collection through withholding.* In the case of a late enrollment penalty that is collected by the government from a Part D eligible individual in the manner described in § 422.262(f)(1) of this chapter, CMS pays only the portion of the late enrollment penalty described in paragraph (b) of this section to the Part D sponsor offering the Part D plan in which the individual is enrolled.

(2) *Collection by plan.* In the case of a late enrollment penalty collected from a Part D eligible individual in a manner other than the manner described in § 422.262(f)(1) of this chapter, CMS reduces payments otherwise made to the Part D plan by an amount equal to the portion of the late enrollment penalty.

(d) *Collection of the income-related monthly adjustment amount (Part D—IRMAA).* (1) *Collection through withholding.* Where the Social Security Administration has determined the income-related monthly adjustment amount for an individual whose income exceeds the income threshold amounts specified at 20 CFR 418.2115, the Part D—IRMAA must be paid through withholding from the enrollee's Social Security benefit payments, or benefit payments by the Railroad Retirement Board (RRB) or the Office of Personnel Management (OPM) in the manner that the Part B premium is withheld.

(2) *Collection through direct billing.* In cases where an enrollee's benefit payment check is not sufficient to have the Part D—IRMAA withheld, or if an enrollee is not receiving such benefits, the beneficiary must be billed directly for the Part D—IRMAA. The beneficiary will have the option of paying the amount through an electronic funds transfer mechanism (such as automatic charges of an account at a financial institution or a credit or debit card account) or according to other means that CMS may specify.

(3) *Failure to pay the income-related monthly adjustment amount: General rule.* CMS will terminate Part D coverage for any individual who fails to pay the Part D—IRMAA as determined by the Social Security Administration. CMS will terminate an enrollee's Part D coverage as specified in § 423.44(e).

(e) *Special rule for fallback plans.* This section does not apply to fallback prescription drug plans. The fallback plans follow the requirements set forth in § 423.867(b).

(f) *Prohibition on improper billing of premiums.* Part D plan sponsors shall not bill an enrollee for a premium payment period if the enrollee has had the premium for that period withheld from his or her Social Security, Railroad Retirement Board or Office of Personnel Management check.

[70 FR 4525, Jan. 28, 2005, as amended at 73 FR 20506, Apr. 15, 2008; 74 FR 1544, Jan. 12, 2009; 76 FR 21574, Apr. 15, 2011; 89 FR 30836, Apr. 23, 2024]

§ 423.294 Failure to collect and incorrect collections of premiums and cost sharing.

(a) *Requirement to collect premiums and cost sharing.* A Part D sponsor violates the uniform benefit provisions at § 423.104(b) if it fails to collect or incorrectly collects applicable cost sharing, or fails to collect or incorrectly collects premiums as required by § 422.262(e) of this chapter—

(1) In accordance with the timing of premium payments;

(2) At the time a drug is dispensed; or

(3) By billing the enrollee or another appropriate party after the fact.

(b) Refunds of incorrect collections—(1) *Definitions.* As used in this section the following definitions are applicable:

Amounts incorrectly collected. (A) Means amounts that exceed the monthly Part D enrollee premium limits under § 423.286 or exceed permissible cost-sharing or copayment amounts as specified in § 423.104(d) through (f), whether paid by or on behalf of the enrollee;

(B) Includes amounts collected with respect to an enrollee who was believed to be entitled to Medicare benefits but was later found not to be entitled; and

(C) Excludes de minimis amounts, as calculated per PDE transaction or per monthly premium billing.

De minimis amounts means an amount per PDE transaction for claims adjustments and per month for premium adjustments that does not exceed the de minimis amount determined for purposes of § 423.34(c)(2).

Other amounts due means amounts due to affected enrollees or others on their behalf (other than de minimis amounts) for covered Part D drugs that were—

(A) Accessed at an out-of-network pharmacy in accordance with the requirements at § 423.124; or

(B) Initially denied but, upon appeal, found to be covered Part D drugs the enrollee was entitled to have provided by the Part D plan.

(2) *General rule.* A Part D sponsor must make a reasonable effort to identify all amounts incorrectly collected and to pay any other amounts due during the timeframe for coordination of benefits as established at § 423.466(b). A Part D sponsor must issue a refund for an identified enrollee overpayment within the timeframe specified at § 423.466(a).

(3) *Refund methods*—(i) *Lump-sum payment.* The Part D sponsor must use lump-sum payments for the following:

(A) Amounts incorrectly collected as cost-sharing.

(B) Other amounts due.

(C) All amounts due if the Part D plan is going out of business or terminating its Part D contract for a prescription drug plan(s).

(ii) *Premium adjustment, lump-sum payment, or both.* If the amounts incorrectly collected were in the form of premiums, or included premiums as well as other charges, the Part D sponsor may refund by adjustment of future premiums or by a combination of premium adjustment and lump-sum payments.

(iii) *Refund when enrollee has died or cannot be located.* If an enrollee has died or cannot be located after reasonable effort, the Part D sponsor must make the refund in accordance with State law.

(4) *Premium reduction and compliance.* (i) If the Part D sponsor does not issue the refund as required under this section within the timeframe specified at § 423.466(a), CMS reduces the premium the Part D sponsor is allowed to charge a Part D enrollee by the amounts incorrectly collected or otherwise due.

(ii) The Part D plan may receive compliance notices from CMS or, depending on the extent of the non-compliance, be the subject of an intermediate sanction (for example, suspension of marketing and enrollment activities) in accordance with subpart O of this part.

(c) *Collections of cost-sharing and premium amounts*—(1) *General rule.* A Part D sponsor must make a reasonable effort to attempt to collect cost sharing from a beneficiary or to bill cost sharing or premiums to another appropriate party for all amounts other than de minimis amounts.

(2) *Timeframe.* Recovery notices must be processed and issued in accordance with the timeframe specified at § 423.466(a). A Part D sponsor must make a reasonable effort to attempt to collect these amounts during the timeframe for coordination of benefits as established at § 423.466(b).

(3) *Retroactive collection of premiums.* Nothing in this section alters the requirements of § 423.293(a)(4) of this part with respect to retroactive collection of premiums.

[89 FR 30836, Apr. 23, 2024]

Subpart G—Payments to Part D Plan Sponsors For Qualified Prescription Drug Coverage

§ 423.301 Scope.

This subpart sets forth rules for the calculation and payment of CMS direct and reinsurance subsidies for Part D plans; the application of risk corridors and risk-sharing adjustments to payments; and retroactive adjustments and reconciliations to actual enrollment and interim payments. This subpart does not apply to fallback entities or fallback prescription drug plans.

§ 423.308 Definitions and terminology.

For the purposes of this subpart, the following definitions apply—

Actually paid means that the costs must be actually incurred by the Part D sponsor and must be net of any direct or indirect remuneration (including discounts, charge backs or rebates, cash discounts, free goods contingent on a purchase agreement, up-front payments, coupons, goods in kind, free or reduced-price services, grants, or other price concessions or similar benefits offered to some or all purchasers) from any source (including manufacturers, pharmacies, enrollees, or any other person) that would serve to decrease the costs incurred under the Part D plan. Direct and indirect remuneration includes discounts, chargebacks or rebates, cash discounts, free goods contingent on a purchase agreement, upfront payments, coupons, goods in kind, free or reduced-price services, grants, or other price concessions or similar benefits from manufacturers, pharmacies or similar entities obtained by an intermediary contracting organization with which the Part D plan sponsor has contracted, regardless of whether the intermediary contracting organization retains all or a portion of the direct and indirect remuneration or passes the entire direct and indirect remuneration to the Part D plan sponsor and regardless of the terms of the contract between the plan sponsor and the intermediary contracting organization.

Administrative costs means costs incurred by a Part D sponsor in complying with the requirements of this Part for a coverage year and that are not drug costs incurred to purchase or reimburse the purchase of Part D drugs. Administrative costs include amounts paid by the Part D sponsor to an intermediary contracting organization for covered Part D drugs dispensed to enrollees in the sponsor's Part D plan that differ from the amount paid by the intermediary contracting organization to a pharmacy or other entity that is the final dispenser of the covered Part D drugs. For example, any profit or loss retained by an intermediary contracting organization (through discounts, rebates, or other direct or indirect price concessions) when negotiating prices with dispensing entities is considered an administrative cost.

Allowable reinsurance costs means the subset of gross covered prescription drug costs actually paid that are attributable to basic prescription drug coverage for covered Part D drugs only and that are actually paid by the Part D sponsor or by (or on behalf of) an enrollee under the Part D plan. The costs for any Part D plan offering enhanced alternative coverage must be adjusted not only to exclude any costs attributable to benefits beyond basic prescription drug coverage, but also to exclude any costs determined to be attributable to increased utilization over

the standard prescription drug coverage as the result of the insurance effect of enhanced alternative coverage in accordance with CMS guidelines on actuarial valuation.

Allowable risk corridor costs means—

(1) The subset of costs incurred under a Part D plan (not including administrative costs, but including dispensing fees) that are attributable to basic prescription drug coverage only and that are incurred and actually paid by the Part D sponsor to—

(i) A dispensing pharmacy or other dispensing provider (whether directly or through an intermediary contracting organization) under the Part D plan;

(ii) The parties listed in § 423.464(f)(1) of this part with which the Part D sponsor must coordinate benefits, including other Part D plans, as the result of any reconciliation process developed by CMS under § 423.464 of this part; or

(iii) An enrollee (or third party paying on behalf of the enrollee) to indemnify the enrollee when the reimbursement is associated with obtaining drugs under the Part D plan; and

(2) These costs must be based upon imposition of the maximum amount of copayments permitted under § 423.782 of this part. The costs for any Part D plan offering enhanced alternative coverage must be adjusted not only to exclude any costs attributable to benefits beyond basic prescription drug coverage, but also to exclude any prescription drug coverage costs determined to be attributable to increased utilization over standard prescription drug coverage as the result of the insurance effect of enhanced alternative coverage in accordance with CMS guidelines on actuarial valuation.

Coverage year means a calendar year in which covered Part D drugs are dispensed if the claim for those drugs (and payment on the claim) is made not later than 3 months after the end of the year

Gross covered prescription drug costs means those costs incurred under a Part D plan, excluding administrative costs, but including dispensing fees, during the coverage year. They equal the sum of the following:

(1) The share of actual costs (as defined by § 423.100 of this part) paid by the Part D plan that is received as reimbursement by the pharmacy, or other dispensing entity, reimbursement paid to indemnify an enrollee when the reimbursement is associated with an enrollee obtaining covered Part D drugs under the Part D plan, or payments made by the Part D sponsor to other parties listed in § 423.464(f)(1) of this part with which the Part D sponsor must coordinate benefits, including other Part D plans, or as the result of any reconciliation process developed by CMS under § 423.464 of this part.

(2) Nominal cost-sharing paid by or on behalf of an enrollee which is associated with drugs that would otherwise be covered Part D drugs, as defined in § 423.100 of this part, but are instead paid for, with the exception of said nominal cost-sharing, by a patient assistance program providing assistance outside the Part D benefit, provided that documentation of such nominal cost-sharing has been submitted to the Part D plan consistent with the plan processes and instructions for the submission of such information.

(3) All amounts paid under the Part D plan by or on behalf of an enrollee (such as the deductible, coinsurance, cost sharing, or amounts between the initial coverage limit and the out-of-pocket threshold) in order to obtain Part D drugs that are covered under the Part D plan. If an enrollee who is paying 100 percent cost sharing (as a result of paying a deductible or because the enrollee is between the initial coverage limit and the out-of-pocket threshold) obtains a covered Part D drug at a lower cost than is available under the Part D plan, such cost-sharing will be considered an amount paid under the plan by or on behalf of an enrollee under the previous sentence of this definition, if the enrollee's costs are incurred costs as defined under § 423.100 of this part and documentation of the incurred costs has been submitted to the Part D plan consistent with plan processes and instructions for the submission of such information. These costs are determined regardless of whether the coverage under the plan

exceeds basic prescription drug coverage.

Reopening—(1) *Global reopening* means a reopening under § 423.346 in which CMS includes all Part D sponsor contracts that meet the inclusion criteria at § 423.346(g).

(2) *Targeted reopening* means a reopening under § 423.346 in which CMS includes one or more (but not all) Part D sponsor contracts that meet the inclusion criteria at § 423.346(g).

Target amount means the total amount of payments (from both CMS and by or on behalf of enrollees) to a Part D plan for the coverage year for all standardized bid amounts as risk adjusted under § 423.329(b)(1) of this part, less the administrative expenses (including return on investment) assumed in the standardized bids.

[70 FR 4525, Jan. 28, 2005, as amended at 74 FR 1544, Jan. 12, 2009; 75 FR 19819, Apr. 15, 2010; 88 FR 22340, Apr. 12, 2023; 89 FR 30837, Apr. 23, 2024]

§ 423.315 General payment provisions.

(a) *Source of payments.* CMS payments under this section are made from the Medicare Prescription Drug Account.

(b) *Monthly payments.* CMS provides a direct subsidy in the form of advance monthly payments equal to the Part D plan's standardized bid, risk adjusted for health status as provided in § 423.329(b), minus the monthly beneficiary premium as determined in § 423.286.

(c) *Reinsurance subsidies.* CMS provides reinsurance subsidy payments described in § 423.329(c) on a monthly basis during a year based on either estimated or incurred allowable reinsurance costs as provided under § 423.329(c)(2)(i), and final reconciliation to actual allowable reinsurance costs as provided in § 423.343(c).

(d) *Low-income subsidies.* CMS makes payments for premium and cost sharing subsidies, including additional coverage above the initial coverage limit, on behalf of certain subsidy-eligible individuals as provided in §§ 423.780 and 423.782. CMS provides low-income cost-sharing subsidy payments described in § 423.782 through interim payments of amounts as provided under § 423.329(d)(2)(i) and reconciliation to actual allowable reinsurance costs as provided in § 423.343(d).

(e) *Risk-sharing arrangements.* CMS may issue lump-sum payments or adjust monthly payments in the following payment year based on the relationship of the Part D plan's adjusted allowable risk corridor costs to predetermined risk corridor thresholds in the coverage year as provided in § 423.336.

(f) *Retroactive adjustments and reconciliations.* CMS reconciles payment year disbursements with updated enrollment and health status data, actual low-income cost-sharing costs and actual allowable reinsurance costs as provided in § 423.343.

(g) *Special rules for private fee-for-service plans*—(1) *Application of reinsurance.* For private fee-for-service plans (as defined by § 422.4(a)(3) of this chapter) offering qualified prescription drug coverage, CMS determines the amount of reinsurance payments as provided under § 423.329(c)(3).

(2) *Exemption from risk corridor provisions.* The provisions of § 423.336 regarding risk sharing do not apply.

§ 423.322 Requirement for disclosure of information.

(a) *Payment conditional upon provision of information.* Payments to a Part D sponsor are conditioned upon provision of information to CMS that is necessary to carry out this subpart, or as required by law.

(b) *Restrictions on use of information.* (1) Officers, employees, and contractors of the Department of Health and Human Services may use the information disclosed or obtained in accordance with the provisions of this subpart for the purposes of, and to the extent necessary—

(i) In carrying out this subpart, including, but not limited to, determination of payments, and payment-related oversight and program integrity activities.

(ii) In conducting oversight, evaluation, and enforcement under Title XVIII of the Act.

(2) The United States Attorney General and the Comptroller General of the United States may use the information disclosed or obtained in accordance with the provisions of this subpart for

purposes of, and to the extent necessary in, carrying out health oversight activities.

(3) The restrictions described in paragraphs (b)(1) and (2) of this section do not limit either of the following:

(i) OIG's authority to fulfill the Inspector General's responsibilities in accordance with applicable Federal law.

(ii) CMS' ability to use data regarding drug claims in accordance with section 1848(m) of the Act.

[70 FR 4525, Jan. 28, 2005, as amended at 73 FR 54251, Sept. 18, 2008; 80 FR 7963, Feb. 12, 2015]

§ 423.325 PDE submission timeliness requirements.

(a) *General PDE submission timeliness requirements.* Unless paragraph (b) of this section applies, a Part D sponsor must submit PDE records to CMS as follows:

(1) Initial PDE records within 30 calendar days from the date the Part D sponsor (or its contracted first tier, downstream, or related entity) receives the claim.

(2) Adjustment or deletion PDE records within 90 calendar days of the Part D sponsor (or its contracted first tier, downstream, or related entity) discovering or receiving notification of an issue that requires a change to the previously submitted PDE record.

(3) Revised PDE records to resolve CMS rejected records within 90 calendar days of the rejection.

(b) *Selected Drugs PDE submission timeliness requirement.* A Part D sponsor must submit initial PDE records for selected drugs (as described at section 1192(c) of the Act) within 7 calendar days from the date the Part D sponsor (or its contracted first tier, downstream, or related entity) receives the claim.

[90 FR 15919, Apr. 15, 2025]

§ 423.329 Determination of payments.

(a) *Subsidy payments*—(1) *Direct subsidy.* CMS makes a direct subsidy payment for each Part D eligible beneficiary enrolled in a Part D plan for a month equal to the amount of the plan's approved standardized bid, adjusted for health status (as determined under § 423.329(b)(1)), and reduced by the base beneficiary premium for the plan (as determined under § 423.286(c) and adjusted in § 423.286(d)(1)). The direct subsidy payment may be increased by the excess amount of a negative premium as described in § 423.286(d)(1), if applicable.

(2) *Subsidy through reinsurance.* CMS makes reinsurance subsidy payments as provided under paragraph (c) of this section.

(3) *Low-income cost-sharing subsidy.* CMS makes low-income cost-sharing subsidy payments as provided under paragraph (d) of this section.

(b) *Health status risk adjustment*—(1) *Establishment of risk factors.* CMS establishes an appropriate methodology for adjusting the standardized bid amount to take into account variation in costs for basic prescription drug coverage among Part D plans based on the differences in actuarial risk of different enrollees being served. Any risk adjustment is designed in a manner so as to be budget neutral in the aggregate to the risk of the Part D eligible individuals who enroll in Part D plans.

(2) *Considerations.* In establishing the methodology under paragraph (b)(1) of this section, CMS takes into account the similar methodologies used under § 422.308(c) of this chapter to adjust payments to MA organizations for benefits under the original Medicare fee-for-service program option.

(3) *Data collection.* In order to carry out this paragraph, CMS requires—

(i) PDP sponsors to submit data regarding drug claims that can be linked at the individual level to Part A and Part B data in a form and manner similar to the process provided under § 422.310 of this chapter and other information as CMS determines necessary; and

(ii) MA organizations that offer MA-PD plans to submit data regarding drug claims that can be linked at the individual level to other data that the organizations are required to submit to CMS in a form and manner similar to the process provided under § 422.310 of this chapter and other information as CMS determines necessary.

(4) *Publication.* CMS publishes the risk adjustment factors established under paragraph (b)(1) of this section for the upcoming calendar year in the

Advance Notice and Rate Announcement publications specified under § 422.312 of this chapter.

(c) *Reinsurance payment amount*—(1) *General rule.* The reinsurance payment amount for a Part D eligible individual enrolled in a Part D plan for a coverage year is an amount equal to 80 percent of the allowable reinsurance costs attributable to that portion of gross covered prescription drug costs incurred in the coverage year after the individual has incurred true out-of-pocket costs that exceed the annual out-of-pocket threshold specified in § 423.104(d)(5)(iii).

(2) *Payment method.* Payments under this section are based on a method that CMS determines.

(i) Payments during the coverage year. CMS establishes a payment method by which payments of amounts under this section are made on a monthly basis during a year based on either estimated or incurred allowable reinsurance costs.

(ii) *Final payments.* CMS reconciles the payments made during the coverage year to final actual allowable reinsurance costs as provided in § 423.343(c).

(3) *Special rules for private fee-for-service Plans offering prescription drug coverage.* CMS determines the amount of reinsurance payments for private fee-for-service plans as defined by § 422.4(a)(3) of this chapter offering qualified prescription drug coverage using a methodology that—

(i) Bases the amount on CMS' estimate of the amount of the payments that are payable if the plan were an MA-PD plan described in section 1851(a)(2)(A)(i) of the Act; and

(ii) Takes into account the average reinsurance payments made under § 423.329(c) for populations of similar risk under MA-PD plans described in section 1851(a)(2)(A)(i) of the Act.

(d) *Low-income cost sharing subsidy payment amount*—(1) *General rule.* The low-income cost-sharing subsidy payment amount on behalf of a low-income subsidy eligible individual enrolled in a Part D plan for a coverage year is the difference between the cost sharing for a non-low-income subsidy eligible beneficiary under the Part D plan and the statutory cost sharing for a low-income subsidy eligible beneficiary.

(2) *Payment method.* Payments under this section are based on a method that CMS determines.

(i) *Interim payments.* CMS establishes a payment method by which interim payments of amounts under this section are made during a year based on the low-income cost-sharing assumptions submitted with plan bids under § 423.265(d)(2)(iv) of this part and negotiated and approved under § 423.272 of this part, or by an alternative method that CMS determines.

(ii) *Final payments.* CMS reconciles the interim payments to actual incurred low-income cost-sharing costs as provided in § 423.343(d).

[70 FR 4525, Jan. 28, 2005, as amended at 74 FR 1545, Jan. 12, 2009; 80 FR 7964, Feb. 12, 2015; 85 FR 33911, June 2, 2020]

§ 423.336 Risk-sharing arrangements.

(a) *Portion of total payments to a Part D sponsor subject to risk*—(1) *Adjusted allowable risk corridor costs.* For purposes of this paragraph, the term adjusted allowable risk corridor costs means—

(i) The allowable risk corridor costs for the Part D plan for the coverage year, reduced by—

(ii) The sum of—

(A) The total reinsurance payments made under § 423.329(c) to the Part D sponsor of the Part D plan for the year; and

(B) The total non-premium subsidy payments made under § 423.782 to the Part D sponsor of the Part D plan for the coverage year.

(2) *Establishment of risk corridors.* (i) *Risk corridors.* For each year, CMS establishes a risk corridor for each Part D plan. The risk corridor for a plan for a coverage year is equal to a range as follows:

(A) *First threshold lower limit.* The first threshold lower limit of the corridor is equal to—

(*1*) The target amount for the plan; minus

(*2*) An amount equal to the first threshold risk percentage for the plan (as determined under paragraph (a)(2)(ii)(A) of this section) of the target amount.

(B) *Second threshold lower limit.* The second threshold lower limit of the corridor is equal to—

(*1*) The target amount for the plan; minus

(*2*) An amount equal to the second threshold risk percentage for the plan (as determined under paragraph (a)(2)(ii)(B) of this section) of the target amount.

(C) *First threshold upper limit.* The first threshold upper limit of the corridor is equal to the sum of—

(*1*) The target amount; and

(*2*) An amount equal to the first threshold risk percentage for the plan (as determined under paragraph (a)(2)(ii)(A) of this section) of the target amount.

(D) *Second threshold upper limit.* The second threshold upper limit of the corridor is equal to the sum of—

(*1*) The target amount; and

(*2*) An amount equal to the second threshold risk percentage for the plan (as determined under paragraph (a)(2)(ii)(B) of this section) of the target amount.

(ii) *First and second threshold risk percentage defined.* (A) *First threshold risk percentage.* Subject to paragraph (a)(2)(iii) of this section, the first threshold risk percentage is for—

(*1*) 2006 and 2007, 2.5 percent;

(*2*) 2008 through 2011, 5 percent; and

(*3*) 2012 and subsequent years, a percentage CMS establishes, but in no case less than 5 percent.

(B) *Second threshold risk percentage.* Subject to paragraph (a)(2)(iii) of this section, the second threshold risk percentage is for—

(1) 2006 and 2007, 5.0 percent;

(2) 2008 through 2011, 10 percent

(3) 2012 and subsequent years, a percentage CMS establishes that is greater than the percent established for the year under paragraph (a)(2)(ii)(A)(3) of this section, but in no case less than 10 percent.

(iii) *Reduction of risk percentage to ensure two Plans in an area.* In accordance with § 423.265(e), a PDP sponsor may submit a bid that requests a decrease in the applicable first or second threshold risk percentages or an increase in the percents applied under paragraph (b) of this section. Only a PDP sponsor may request a reduction of risk under this paragraph. An MA organization offering an MA-PD plan, a PACE program offering qualified prescription drug coverage, and a cost-based HMO or CMP offering qualified prescription drug coverage may not request a reduction of risk under this paragraph.

(3) *Plans at risk for entire amount of supplemental prescription drug coverage.* A Part D sponsor that offers a Part D plan that provides supplemental prescription drug benefits is at full financial risk for the provision of the supplemental benefits.

(b) *Payment adjustments*—(1) *No adjustment if adjusted allowable risk corridor costs within risk corridor.* If the adjusted allowable risk corridor costs for the Part D plan for the coverage year are at least equal to the first threshold lower limit of the risk corridor (specified in paragraph (a)(2)(i)(A) of this section) but not greater than the first threshold upper limit of the risk corridor (specified in paragraph (a)(2)(i)(C) of this section) for the Part D plan for the coverage year, CMS makes no payment adjustment.

(2) *Increase in payment if adjusted allowable risk corridor costs above upper limit of risk corridor*—(i) *Costs between first and second threshold upper limits.* If the adjusted allowable risk corridor costs for the Part D plan for the year are greater than the first threshold upper limit, but not greater than the second threshold upper limit, of the risk corridor for the Part D plan for the year, CMS increases the total of the payments made to the Part D sponsor offering the Part D plan for the year under this section by an amount equal to 50 percent (or, for 2006 and 2007, 75 percent or 90 percent if the conditions described in paragraph (b)(2)(iii) of this section are met for the year) of the difference between the adjusted allowable risk corridor costs and the first threshold upper limit of the risk corridor.

(ii) *Costs above second threshold upper limits.* If the adjusted allowable risk corridor costs for the Part D plan for the year are greater than the second threshold upper limit of the risk corridor for the Part D plan for the year, CMS increases the total of the payments made to the Part D sponsor offering the Part D plan for the year under this section by an amount equal to the sum of—

(A) 50 percent (or, for 2006 and 2007, 75 percent or 90 percent if the conditions specified in paragraph (b)(2)(iii) of this section are met for the year) of the difference between the second threshold upper limit and the first threshold upper limit; and

(B) 80 percent of the difference between the adjusted allowable risk corridor costs and the second threshold upper limit of the risk corridor.

(iii) *Conditions for application of higher percentage for 2006 and 2007.* The conditions specified in this paragraph are met for 2006 or 2007 if CMS determines for the year that—

(A) At least 60 percent of Part D plans to which this paragraph applies have adjusted allowable risk corridor costs for the Part D plan for the year that are more than the first threshold upper limit of the risk corridor for the Part D plan for the year; and

(B) Such plans represent at least 60 percent of Part D eligible individuals enrolled in any Part D plan.

(3) *Reduction in payment if adjusted allowable risk corridor costs below lower limit of risk corridor*—(i) *Costs between first and second threshold lower limits.* If the adjusted allowable risk corridor costs for the Part D plan for the coverage year are less than the first threshold lower limit, but not less than the second threshold lower limit, of the risk corridor for the Part D plan for the coverage year, CMS reduces the total of the payments made to the Part D plan for the coverage year under this section by an amount (or otherwise recovers from the Part D sponsor an amount) equal to 50 percent (or, for 2006 and 2007, 75 percent) of the difference between the first threshold lower limit of the risk corridor and the adjusted allowable risk corridor costs.

(ii) *Costs below second threshold lower limit.* If the adjusted allowable risk corridor costs for the Part D plan for the coverage year are less the second threshold lower limit of the risk corridor for the Part D plan for the coverage year, CMS reduces the total of the payments made to the Part D sponsor for the coverage year under this section by an amount (or otherwise recovers from the Part D sponsor an amount) equal to the sum of—

(A) 50 percent (or, for 2006 and 2007, 75 percent) of the difference between the first threshold lower limit and the second threshold lower limit; and

(B) 80 percent of the difference between the second threshold upper limit of the risk corridor and the adjusted allowable risk corridor costs.

(c) *Payment methods.* CMS makes payments after a coverage year after obtaining all of the cost data information in paragraph (c)(1) of this section necessary to determine the amount of payment. CMS will not make payments under this section if the Part D sponsor fails to provide the cost data information in paragraph (c)(1) of this section.

(1) *Submission of cost data.* Within 6 months of the end of a coverage year, the Part D sponsor must provide the information that CMS requires.

(2) *Lump sum and adjusted monthly payments.* CMS at its discretion makes either lump-sum payments or adjusts monthly payments in the following payment year based on the relationship of the plan's adjusted allowable risk corridor costs to the predetermined risk corridor thresholds in the coverage year, as determined under this section.

(d) *No effect on monthly premium.* No adjustment in payments made by reason of this section may affect the monthly beneficiary premium for qualified prescription drug coverage.

§ 423.343 Retroactive adjustments and reconciliations.

(a) *Application of enrollee adjustment.* The provisions of § 422.308(f) of this chapter apply to payments to Part D sponsors under this section in the same manner as they apply to payments to MA organizations under section 1853(a) of the Act.

(b) *Health status.* CMS makes adjustments to payments made under § 423.329(a)(1) to account for updated health status risk adjustment data as provided under § 422.310(g)(2) of this chapter. CMS may recover payments associated with health status adjustments if the Part D sponsor fails to provide the information described in § 423.329(b)(3).

(c) *Reinsurance.* CMS makes final payment for reinsurance after a coverage year after obtaining all of the information necessary to determine the amount of payment.

(1) *Submission of cost data.* Within 6 months of the end of a coverage year, the Part D sponsor must provide the information that CMS requires.

(2) *Payments.* CMS at its discretion either makes lump-sum payments or adjusts monthly payments throughout the remainder of the payment year following the coverage year based on the difference between monthly reinsurance payments made during the coverage year and the amount payable in § 423.329(c) for the coverage year. CMS may recover payments made through a lump sum recovery or by adjusting monthly payments throughout the remainder of the coverage year if the monthly reinsurance payments made during the coverage year exceed the amount payable under § 423.329(c) or if the Part D sponsor does not provide the data in paragraph (c)(1) of this section.

(d) *Low-income cost-sharing subsidy.* CMS makes final payment for low-income cost-sharing subsidies after a coverage year after obtaining all of the information necessary to determine the amount of payment.

(1) *Submission of cost data.* Within 6 months of the end of a coverage year, the Part D sponsor must provide the information that CMS requires.

(2) *Payments.* CMS at its discretion either makes lump-sum payments or adjusts monthly payments throughout the remainder of the payment year following the coverage year based on the difference between interim low-income cost-sharing subsidy payments and total low-income cost-sharing subsidy costs eligible for subsidy under § 423.782 submitted by the plan for the coverage year. CMS may recover payments made through a lump sum recovery or by adjusting monthly payments throughout the remainder of the coverage year if interim low-income cost-sharing subsidy payments exceed the amount payable under § 423.782 or if the Part D sponsor does not provide the data in paragraph (d)(1) of this section. In the event adequate data is not provided for risk corridor costs, CMS assumes that the Part D plan's adjusted allowable risk corridor costs are 50 percent of the target amount.

§ 423.346 Reopening.

(a) CMS may conduct a global or targeted reopening to reopen and revise an initial or reconsidered final payment determination (including a determination on the final amount of direct subsidy described in § 423.329(a)(1), final reinsurance payments described in § 423.329(c), the final amount of the low income subsidy described in § 423.329(d), or final risk corridor payments as described in § 423.336) or the Coverage Gap Discount Reconciliation (as described at § 423.2320(b))—

(1) For any reason, within 12 months from the date of the notice of the final determination to the Part D sponsor

(2) After that 12-month period, but within 6 years after the date of the notice of the initial or reconsidered determination to the Part D sponsor, upon establishment of good cause for reopening; or

(3) At any time, in instances of fraud or similar fault of the Part D sponsor or any subcontractor of the Part D sponsor.

(b) For purposes of this section, CMS will find good cause if—

(1) New and material evidence that was not readily available at the time the final determination was made is furnished;

(2) A clerical error in the computation of payments was made; or

(3) The evidence that was considered in making the determination clearly shows on its face that an error was made.

(c) For purposes of this section, CMS will not find good cause if the only reason for reopening is a change of legal interpretation or administrative ruling upon which the final determination was made.

(d) A decision not to reopen under this section is final and is not subject to review.

(e) CMS notifies the sponsor(s) that will be included in the reopening of its intention to conduct a global or targeted reopening when it is necessary for the sponsor(s) to submit prescription drug event (PDE) data or direct and indirect remuneration (DIR) for

the reopening. The notification to sponsor(s) must include the following:

(1) The date by which PDE or DIR data must be accepted by CMS to be included in the reopening, which is at least 90 calendar days after the date of the notification.

(2) A statement indicating the Part D contracts or types of contracts that are included in the reopening.

(f) CMS announces when it has completed a reopening and provide the sponsor(s) with all of the following information:

(1) A description of the data used in the reopening.

(2) A statement indicating the Part D contracts or types of contracts that were included in the reopening.

(3) The date by which reports describing the reopening results is available to the sponsor.

(4) The date by which a sponsor must submit an appeal, in accordance with § 423.350, if the sponsor disagrees with the reopening results.

(g) Inclusion criteria—

(1) For a global reopening, CMS includes only those Part D sponsor contracts that were in effect for the contract year being reopened and for whom CMS has not sent the ''Notice of final settlement,'' as described at § 423.521(a), as of the date CMS announces the completion of the reopening in accordance with paragraph (f) of this section.

(2) For a target reopening, CMS includes only Part D sponsor contracts that meet the criteria for inclusion in a global reopening as specified in paragraph (1) of this section and that CMS specifies for inclusion in the reopening as provided in paragraph (e)(2) or (f)(2) of this section.

[70 FR 4525, Jan. 28, 2005, as amended at 80 FR 7964, Feb. 12, 2015; 89 FR 30837, Apr. 23, 2024; 89 FR 79452, Sept. 30, 2024]

§ 423.350 Payment appeals.

(a) *Payment determinations*—(1) *Payment methods subject to appeal.* If CMS did not apply its stated payment methodology correctly, a Part D sponsor may appeal the following:

(i) The reconciled health status risk adjustment of the direct subsidy as provided in § 423.343(b).

(ii) The reconciled reinsurance payments under § 423.343(c).

(iii) The reconciled final payments made for low-income cost sharing subsidies provided in § 423.343(d).

(iv) Final risk-sharing payments made under § 423.336.

(v) The reconciled coverage gap discount payment under § 423.2320(b).

(2) *Payment information not subject to appeal.* Payment information submitted to CMS under § 423.322 and reconciled under § 423.343 or submitted and reconciled under § 423.2320(b) is final and may not be appealed nor may the appeals process be used to submit new information after the submission of information necessary to determine retroactive adjustments and reconciliations.

(b) *Request for reconsideration*—(1) *Time for filing a request.* The request for reconsideration must be filed within 15 days from the date of the final payment. For purposes of this paragraph, the date of final payment is one of the following:

(i) For risk adjustment, the date of the final reconciled payment under § 423.343(b) of this subpart.

(ii) For reinsurance, the date of the final reconciled payment under § 423.343(c) of this subpart; for low-income cost sharing subsidies, the date of the final reconciled payment under § 423.343(d) of this subpart.

(iii) For risk-sharing payments, the date of the final payments under § 423.336 of this subpart.

(iv) For the Coverage Gap Discount Program, the date of the final reconciled payment under § 423.2320(b).

(2) *Content of request.* The request for reconsideration must specify the findings or issues with which the Part D sponsor disagrees and the reasons for the disagreements. Excluding new payment information, the request for reconsideration may include additional documentary evidence the sponsor wishes CMS to consider.

(3) *Conduct of informal written reconsideration.* In conducting the reconsideration, CMS reviews the payment determination, the evidence and findings upon which it was based, and any other written evidence submitted by the Part D sponsor or by CMS before notice of

the reconsidered determination is made.

(4) *Decision of the informal written reconsideration.* CMS informs the sponsor of the decision orally or through electronic mail. CMS sends a written decision to the Part D sponsor on the sponsor's request.

(5) *Effect of CMS informal written reconsideration.* A reconsideration decision, whether delivered orally or in writing, is final and binding unless a request for hearing is filed in accordance with paragraph (c) of this section, or it is revised in accordance with § 423.346.

(c) *Right to informal hearing.* A Part D sponsor dissatisfied with the CMS reconsideration decision is entitled to an informal hearing as provided in this section.

(1) *Manner and timing for request.* A request for a hearing must be made in writing and filed with CMS within 15 days of the date the Part D sponsor receives the CMS reconsideration decision.

(2) *Content of request.* The request for informal hearing must include a copy of the CMS reconsideration decision (if any) and must specify the findings or issues in the decision with which the Part D sponsor disagrees and the reasons for the disagreements.

(3) *Informal hearing procedures.* (i) CMS provides written notice of the time and place of the informal hearing at least 10 days before the scheduled date.

(ii) The hearing are conducted by a CMS hearing officer who neither receives testimony nor accepts any new evidence that was not presented with the reconsideration request. The CMS hearing officer is limited to the review of the record that was before CMS when CMS made both its initial and reconsideration determinations.

(iii) If CMS did not issue a written reconsideration decision, the hearing officer may request, but not require, a written statement from CMS or its contractors explaining CMS' determination, or CMS or its contractors may, on their own, submit the written statement to the hearing officer. Failure of CMS to submit a written statement does not result in any adverse findings against CMS and may not in any way be taken into account by the hearing officer in reaching a decision.

(4) *Decision of the CMS hearing officer.* The CMS hearing officer decides the case and sends a written decision to the Part D sponsor, explaining the basis for the decision.

(5) *Effecting of hearing officer decision.* The hearing officer decision is final and binding, unless the decision is reversed or modified by the Administrator in accordance with paragraph (d) of this section.

(d) *Review by the Administrator.* (1) A Part D sponsor that has received a hearing officer decision upholding a CMS initial or reconsidered determination may request review by the Administrator within 15 days of receipt of the hearing officer's decision.

(2) The Administrator may review the hearing officer's decision, any written documents submitted to CMS or to the hearing officer, as well as any other information included in the record of the hearing officer's decision and determine whether to uphold, reverse or modify the hearing officer's decision.

(3) The Administrator's determination is final and binding.

[70 FR 4525, Jan. 28, 2005, as amended at 73 FR 20506, Apr. 15, 2008; 80 FR 7964, Feb. 12, 2015]

§ 423.352 CMS-identified overpayments associated with payment data submitted by Part D sponsors.

(a) *Definitions.* For purposes of this section—

Applicable reconciliation date occurs on the later of either the annual deadline for submitting—

(1) Prescription drug event (PDE) data for the annual Part D payment reconciliations referred to in § 423.343(c) and (d); or

(2) Direct and indirect remuneration data.

Erroneous payment data means payment data that should not have been submitted either because the data submitted are inaccurate or because the data are inconsistent with Medicare Part D requirements.

Payment data means data submitted by a Part D sponsor to CMS and used for payment purposes, including enrollment data and data submitted under

§ 423.329(b)(3), § 423.336(c)(1), and § 423.343, and data provided for purposes of supporting allowable reinsurance costs and allowable risk corridor costs as defined in § 423.308, including data submitted to CMS regarding direct and indirect remuneration.

(b) *Request to correct payment data.* (1) When CMS identifies erroneous payment data submitted by a Part D sponsor, CMS may send a data correction notice to the Part D sponsor requesting that the Part D sponsor correct the payment data.

(2) The notice will include or make reference to the specific payment data that need to be corrected, the reason why CMS believes that the payment data are erroneous, and the timeframe for correcting the payment data.

(c) *Payment offset.* (1) If the Part D sponsor fails to submit the corrected payment data within the timeframe as requested in accordance with paragraph (b) of this section, CMS will conduct a payment offset against payments made to the Part D sponsor if—

(i) The payment error affects payments for any of the 6 most recently completed payment years; and

(ii) The payment error for a particular payment year is identified after the applicable reconciliation date for that payment year.

(2) CMS will calculate the payment offset amount using the correct payment data and a payment algorithm that applies the payment rules for the applicable year.

(d) *Payment offset notification.* CMS will issue a payment offset notice to the Part D sponsor that includes at least the following:

(1) The dollar amount of the offset from plan payments.

(2) An explanation of how the erroneous data were identified and used to calculate the payment offset amount.

(3) An explanation that, if the Part D sponsor disagrees with the payment offset, it may request an appeal within 30 days of issuance of the payment offset notification.

(e) *Appeals process.* If a Part D sponsor does not agree with the payment offset described in paragraph (c) of this section, it may appeal under the following three-level appeal process:

(1) *Reconsideration.* A Part D sponsor may request reconsideration of the payment offset described in paragraph (c) of this section, according to the following process:

(i) *Manner and timing of request.* A written request for reconsideration must be filed within 30 days from the date that CMS issued the payment offset notice to the Part D sponsor.

(ii) *Content of request.* The written request for reconsideration must specify the findings or issues with which the Part D sponsor disagrees and the reasons for its disagreement. As part of its request for reconsideration, the Part D sponsor may include any additional documentary evidence in support of its position. Any additional evidence must be submitted with the request for reconsideration. Additional information submitted after this time will be rejected as untimely.

(iii) *Conduct of reconsideration.* In conducting the reconsideration, the CMS reconsideration official reviews the underlying data that were used to determine the amount of the payment offset and any additional documentary evidence timely submitted by the Part D sponsor.

(iv) *Reconsideration decision.* The CMS reconsideration official informs the Part D sponsor of its decision on the reconsideration request.

(v) *Effect of reconsideration decision.* The decision of the CMS reconsideration official is final and binding unless a timely request for an informal hearing is filed in accordance with paragraph (e)(2) of this section.

(2) *Informal hearing.* A Part D sponsor dissatisfied with CMS' reconsideration decision made under paragraph (e)(1) of this section is entitled to an informal hearing as provided for under paragraphs (e)(2)(i) through (e)(2)(v) of this section.

(i) *Manner and timing for request.* A request for an informal hearing must be made in writing and filed with CMS within 30 days of the date of CMS' reconsideration decision.

(ii) *Content of request.* The request for an informal hearing must include a copy of the reconsideration decision and must specify the findings or issues in the decision with which the Part D

sponsor disagrees and the reasons for its disagreement.

(iii) *Informal hearing procedures.* The informal hearing will be conducted in accordance with the following:

(A) CMS provides written notice of the time and place of the informal hearing at least 30 days before the scheduled date.

(B) The informal hearing is conducted by a CMS hearing officer who neither receives testimony nor accepts any new evidence that was not timely presented with the reconsideration request. The CMS hearing officer is limited to the review of the record that was before the CMS reconsideration official when CMS made its reconsideration determination.

(C) The CMS hearing officer will review the proceeding before the CMS reconsideration official on the record made before the CMS reconsideration official using the clearly erroneous standard of review.

(iv) *Decision of the CMS hearing officer.* The CMS hearing officer decides the case and sends a written decision to the Part D sponsor explaining the basis for the decision.

(v) *Effect of hearing officer's decision.* The hearing officer's decision is final and binding, unless the decision is reversed or modified by the Administrator in accordance with paragraph (e)(3) of this section.

(3) *Review by the Administrator.* The Administrator review will be conducted in the following manner:

(i) A Part D sponsor that has received a hearing officer's decision may request review by the Administrator within 30 days of the date of issuance of the hearing officer's decision under paragraph (e)(2)(iv) of this section. The Part D sponsor may submit written arguments to the Administrator for review.

(ii) After receiving a request for review, the Administrator has the discretion to elect to review the hearing officer's determination in accordance with paragraph (e)(3)(iv) of this section or to decline to review the hearing officer's decision.

(iii) If the Administrator declines to review the hearing officer's decision, the hearing officer's decision is final and binding.

(iv) If the Administrator elects to review the hearing officer's decision, the Administrator will review the hearing officer's decision, as well as any information included in the record of the hearing officer's decision and any written argument submitted by the Part D sponsor, and determine whether to uphold, reverse, or modify the hearing officer's decision.

(v) The Administrator's determination is final and binding.

(f) *Matters subject to appeal and burden of proof.* (1) The Part D sponsor's appeal is limited to CMS' finding that the payment data submitted by the Part D sponsor are erroneous.

(2) The Part D sponsor bears the burden of proof by a preponderance of the evidence in demonstrating that CMS' finding that the payment data were erroneous was incorrect or otherwise inconsistent with applicable program requirements.

(g) *Applicability of appeals process.* The appeals process under paragraph (e) of this section applies only to payment offsets under paragraph (c) of this section.

[79 FR 67032, Nov. 10, 2014]

§ 423.360 Reporting and returning of overpayments.

(a) *Definitions.* For the purposes of this section the following definitions are applicable:

Applicable reconciliation means the later of either the annual deadline for submitting—

(i) PDE data for the annual Part D payment reconciliations referred to in § 423.343(c) and (d); or

(ii) Direct and indirect remuneration data.

Funds for purposes of this section, means any payment that a Part D sponsor has received that is based on data submitted by the Part D sponsor to CMS for payment purposes, including data submitted under § 423.329(b)(3), § 423.336(c)(1), § 423.343, and data provided for purposes of supporting allowable costs as defined in § 423.308 which includes data submitted to CMS regarding direct or indirect remuneration.

Overpayment means funds that a Part D sponsor has received or retained under title XVIII of the Act to which

the Part D sponsor, after applicable reconciliation, is not entitled under such title.

(b) *General rule.* If a Part D sponsor has identified that it has received an overpayment, the Part D sponsor must report and return that overpayment in the form and manner set forth in this section.

(c) *Identified overpayment.* The Part D sponsor has identified an overpayment when the Part D sponsor knowingly receives or retains an overpayment. The term ''knowingly'' has the meaning set forth in 31 U.S.C. 3729(b)(1)(A).

(d) *Reporting and returning of an overpayment.* A Part D sponsor must report and return any overpayment it received no later than 60 days after the date on which it identified it received an overpayment.

(1) *Reporting.* A Part D sponsor must notify CMS of the amount and reason for the overpayment, using the notification process determined by CMS.

(2) *Returning.* A Part D sponsor must return identified overpayments in a manner specified by CMS.

(e) *Enforcement.* Any overpayment retained by a Part D sponsor is an obligation under 31 U.S.C. 3729(b)(3) if not reported and returned in accordance with paragraph (d) of this section.

(f) *Look-back period.* A Part D sponsor must report and return any overpayment identified within the 6 most recent completed payment years.

[79 FR 29963, May 23, 2014, as amended at 89 FR 98565, Dec. 9, 2024]

Subpart H [Reserved]

Subpart I—Organization Compliance with State Law and Preemption by Federal Law

§ 423.401 General requirements for PDP sponsors.

(a) *General requirements.* Each PDP sponsor of a prescription drug plan must meet the following requirements:

(1) *Licensure.* Except in cases where there is a waiver as specified at § 423.410 or § 423.415, the sponsor is organized and licensed under State law as a risk bearing entity eligible to offer health insurance or health benefits coverage in each State in which it offers a prescription drug plan. If not otherwise licensed, the sponsor obtains certification from the State that the organization meets a level of financial solvency and other standards as the State may require for it to operate as a PDP sponsor.

(2) *Assumption of financial risk for unsubsidized coverage.* The PDP sponsor assumes financial risk on a prospective basis for benefits that it offers under a prescription drug plan and that is not covered under section 1860D–15(b) of the Act.

(b) *Reinsurance permitted.* The PDP sponsor may obtain insurance or make other arrangements for the cost of coverage provided to any enrollee to the extent that the sponsor is at risk for providing the coverage.

(c) *Solvency for unlicensed sponsors.* In the case of a PDP sponsor that is not described in § 423.401(a)(1) and for which a waiver is approved under § 423.410 or § 423.415, the sponsor must meet the requirements in § 423.420.

§ 423.410 Waiver of certain requirements to expand choice.

(a) *Authorizing waiver.* In the case of an entity that seeks to offer a prescription drug plan in a State, CMS waives the licensure requirement at § 423.401(a)(1), which requires that the etity be licensed in that State if CMS determines, based on the application and other evidence presented, that any of the grounds for approval of the application described in paragraphs (b), (c), or (d) of this section are met.

(b) *Grounds for approval of waivers.* Subject to the waiver requirements specified in § 423.410(e), waivers may be granted under any of the following conditions:

(1) *Failure to act on licensure application on a timely basis.* The State failed to complete action on the licensing application within 90 days of the date that the State received a substantially complete application.

(2) *Denial of application based on discriminatory treatment.* The State denied the license application on either of the following bases—-

(i) The State imposed material requirements, procedures, or standards (other than solvency requirements) not generally applied by the State to other

entities engaged in a substantially similar business; or

(ii) The State required, as a condition of licensure, that the organization offer any product or plan other than a prescription drug plan.

(3) *Denial of application based on application of solvency requirements.* The State denied the licensure application, in whole or in part, on the basis of the PDP sponsor's failure to meet solvency requirements and

(i) The solvency requirements are different from the solvency standards CMS establishes in accordance with § 423.420; or

(ii) CMS determines that the State imposed, as a condition of licensing, any documentation or information requirements relating to solvency that are different from the standards CMS establishes in accordance with § 423.420.

(4) *Grounds other than those required by Federal Law.* The application by a State of any grounds other than those required under Federal law.

(c) *Waiver when licensing process not in effect.* The grounds for approval specified in paragraph (b)(1) of this section are deemed met if CMS determines that the State does not have a licensing process in effect for PDP sponsors.

(d) *Special waiver for plan years beginning before January 1, 2008.* For plan years beginning before January 1, 2008, if the State has a prescription drug plan or PDP sponsor licensing process in effect, CMS grants a waiver upon a demonstration that an applicant to become a PDP sponsor has submitted a substantially completed application for licensure to the State.

(e) *Waiver requirements.* The following rules apply to waiver applications or waivers granted under this section.

(1) *Treatment of waiver.* The waiver applies only to that State, is effective for 36 months, and cannot be renewed.

(2) *Prompt action on application.* CMS grants or denies a waiver application under this section within 60 days after CMS determines that a substantially complete waiver application is received by CMS.

(3) *A State that does not have a PDP sponsor.* In the case of a State that does not have a PDP sponsor licensing process, the 36 month limitation on the waiver discussed in paragraph (e)(1) of this section does not apply, and the waiver may continue in effect for a given State as long as CMS determines that the State does not have a PDP sponsor licensing process in effect, and the PDP sponsor meets the solvency standards of § 423.420(a).

[70 FR 4525, Jan. 28, 2005, as amended at 73 FR 20506, Apr. 15, 2008]

§ 423.415 Temporary waivers for entities seeking to offer a prescription drug plan in more than one State in a region.

(a) *General rule.* Subject to paragraphs (b) and (c) of this section, if an applicant seeking to become a PDP sponsor wishes to operate in more than one State in a region, and is licensed as a risk bearing entity in at least one State in the region, then the applicant may receive a temporary regional plan waiver for the States in which it is not licensed.

(b) *Filing of application.* The applicant must demonstrate to the satisfaction of CMS that it filed the necessary licensure applications with each State in the region for which it does not already have State licensure, except that no application is necessary if CMS determines that the State does not have a licensing process for potential PDP sponsors.

(c) *Processing of application for temporary waiver.* The Secretary determines the time period appropriate for the timely processing of the application for temporary waiver.

(d) *Time limit for temporary waiver.* The temporary waiver expires at the end of time period that the Secretary determines is appropriate for timely processing of the application by the State or States, but in no case is a waiver extend beyond the end of the calendar year.

§ 423.420 Solvency standards for nonlicensed entities.

(a) *Establishment and publication.* CMS establishes and publishes reasonable financial solvency and capital adequacy standards for entities specified in paragraph (b) of this section.

(b) *Compliance with standards.* A PDP sponsor that is not licensed by a State and for which a waiver application is approved by CMS under § 423.410 or

§ 423.415 must maintain reasonable financial solvency and capital adequacy in accordance with the standards established by CMS under paragraph (a) of this section.

§ 423.425 Licensure does not substitute for or constitute certification.

The fact that a Part D sponsor is State licensed or has a waiver application approved under § 423.410 or § 423.415 does not deem the sponsor to meet other requirements imposed under this part for a Part D sponsor.

§ 423.440 Prohibition of State imposition of premium taxes; relation to State laws.

(a) *Federal preemption of State law.* The standards established under this part supersede any State law or regulation (other than State licensing laws or State laws relating to plan solvency) for Part D plans offered by Part D plan sponsors.

(b) *State premium taxes prohibited*—(1) *Basic rule.* No premium tax, fee, or other similar assessment may be imposed by any State, the District of Columbia, the Commonwealth of Puerto Rico, the Virgin Islands, Guam, and American Samoa, the Mariana Islands or any of their political subdivisions or other governmental authorities for any payment CMS makes on behalf of Part D plan or enrollees under this part (including the direct subsidy, reinsurance payments, and risk corridor payments); or for any payment made to Part D plans by a beneficiary or by a third party on behalf of a beneficiary.

(2) *Construction.* Nothing in this section may be construed to exempt any Part D plan sponsor from taxes, fees, or other monetary assessments related to the net income or profit that accrues to, or is realized by, the organization from business conducted under this part, if that tax, fee, or payment is applicable to a broad range of business activity.

Subpart J—Coordination of Part D Plans With Other Prescription Drug Coverage

§ 423.452 Scope.

This section sets forth the application of Part D rules to Part C plans; establishes waivers for MA-PD plans, employer-sponsored group prescription drug plans, cost plans, and PACE organizations; and establishes requirements for coordination of benefits with State Pharmaceutical Assistance Programs and other providers of prescription drug coverage.

§ 423.454 Definitions.

For purposes of this part, the following definitions apply—

Employer-sponsored group prescription drug plan means, prescription drug coverage offered to retirees who are Part D eligible individuals under employment-based retiree health coverage. For purposes of this subpart, employment-based retiree health coverage is such coverage (as defined in § 423.882) provided through a Medicare Part D plan, or for which a plan sponsor could qualify for payments under subpart R of this part.

State Pharmaceutical Assistance Program (SPAP) means a State program that meets the requirements described under § 423.464(e)(1).

[70 FR 4525, Jan. 28, 2005, as amended at 77 FR 1882, Jan. 12, 2012]

§ 423.458 Application of Part D rules to certain Part D plans on and after January 1, 2006.

(a) *Relationship to Part C.* Except as otherwise provided in this part, the requirements of this part apply to prescription drug coverage provided by MA-PD plans offered by MA organizations beginning on or after January 1, 2006.

(b) *MA waiver.* CMS waives any provision of this Part otherwise applicable to MA-PD plans or MA organizations under paragraph (a) of this section to the extent CMS determines that the provision duplicates, or is in conflict with, provisions otherwise applicable to the MA organizations or MA-PD plans under Part C of Medicare, or as may be necessary in order to improve coordination of this part with the benefits under Part C.

(1) *Application of waiver.* Any waiver or modification granted by CMS under this section applies to any other similarly situated organization offering or seeking to offer a MA-PD plan that meets the conditions of the waiver.

(2) *Request for waivers.* Organizations offering or seeking to offer a MA-PD plan may request from CMS in writing—

(i) A waiver of those requirements under this part otherwise applicable to the MA-PD plan or MA organization under paragraph (a) of this section that are duplicative of, or that are in conflict with, provisions otherwise applicable to the MA-PD plan, proposed MA-PD plan, or a MA organization under Part C of Medicare.

(ii) A waiver of a requirement under this part otherwise applicable to the MA-PD plan or MA organization under paragraph (a) of this section, if such waiver improves coordination of benefits provided under Part C of Medicare with benefits under this Part.

(c) *Employer group waiver*—(1) *General rule for employer-sponsored group prescription drug plans that are Medicare Part D plans.* CMS may waive or modify any requirement under this part that hinders the design of, the offering of, or the enrollment in an employer-sponsored group prescription drug plan, including authorizing the establishment of separate premium amounts for enrollees of the employer-sponsored group prescription drug plan and limitations on enrollment in such plan to Part D eligible individuals participating in the sponsor's employment-based retiree health coverage. Any entity seeking to offer, sponsor, or administer an employer-sponsored group prescription drug plan may request, in writing, a waiver or modification of additional requirements under this part that hinder its design of, the offering of, or the enrollment in, such employer-sponsored group prescription drug plan.

(2) *General rule for employer-sponsored group prescription drug plans for which a sponsor could qualify for payments under subpart R of this part.* CMS may waive or modify any requirement under this part that hinders the design of, the offering of, or the enrollment in an employer-sponsored group prescription drug plan.

(3) *Use of waiver.* Waivers or modifications approved by CMS under this section apply to any similarly situated entity seeking to offer, sponsor, or administer an employer-sponsored group prescription drug plan, meeting the conditions of the waiver or modification.

(4) Employer-sponsored group prescription drug plans must comply with all applicable requirements under this part that are not specifically waived or modified in accordance with in paragraph (c)(3) of this section.

(d) *Other waivers.* CMS waives any provision of this Part as applied to a cost plan (as defined in § 417.401 of this chapter) or PACE organization (as defined in § 460.6 of this chapter) that offers qualified prescription drug coverage under Part D to the extent CMS determines that the provision duplicates, or is in conflict with, provisions otherwise applicable to the cost plan under section 1876 of the Act or provisions applicable to PACE organizations under sections 1894 and 1934 of the Act, or as necessary in order to improve coordination of this Part with the benefits offered by cost plans or PACE organizations.

(1) *Application of waiver.* Any waiver or modification granted by CMS under this paragraph applies to any other similarly situated organization offering or seeking to offer qualified prescription drug coverage as a cost plan under section 1876 of the Act or as a PACE organization under sections 1894 and 1934 of the Act.

(2) *Request for waivers.* Cost plans or PACE organizations seeking to offer qualified prescription drug coverage may request from CMS in writing-

(i) A waiver of those requirements under this part otherwise applicable to cost plans or PACE organizations that are duplicative of, or that are in conflict with, provisions otherwise applicable to cost plans or PACE organizations.

(ii) A waiver of a requirement under this part otherwise applicable to cost plans or PACE organizations, if such waiver improves coordination of benefits provided by the cost plan under section 1876 of the Act, or by the PACE organization under sections 1894 and 1934 of the Act, with the benefits under Part D.

[70 FR 4525, Jan. 28, 2005, as amended at 73 FR 20506, Apr. 15, 2008; 77 FR 1882, Jan. 12, 2012; 77 FR 22170, Apr. 12, 2012]

§ 423.462 Medicare secondary payer procedures.

(a) *General rule.* The provisions of § 422.108 of this chapter regarding Medicare secondary payer procedures apply to Part D sponsors and Part D plans (with respect to the offering of qualified prescription drug coverage) in the same way as they apply to MA organizations and MA plans under Part C of title XVIII of the Act, except all references to MA organizations and MA plans are considered references to Part D sponsors and Part D plans.

(b) *Reporting requirements.* A Part D sponsor must report credible new or changed primary payer information to the CMS Coordination of Benefits Contractor in accordance with the processes and timeframes specified by CMS.

[70 FR 4525, Jan. 28, 2005, as amended at 75 FR 19819, Apr. 15, 2010]

§ 423.464 Coordination of benefits with other providers of prescription drug coverage.

(a) *General rule.* A Part D plan must permit SPAPs (described in paragraph (e)(1) of this section) and entities providing other prescription drug coverage (described in paragraph (f)(1) of this section) to coordinate benefits with such plan. A Part D plan must comply with all administrative processes and requirements established by CMS to ensure effective exchange of information and coordination between such plan and SPAPs and entities providing other prescription drug coverage for—

(1) Payment of premiums and coverage; and

(2) Payment for supplemental prescription drug benefits as described in § 423.104(f)(1)(ii)(including payment to a Part D plan on a lump sum per capita basis) for Part D eligible individuals enrolled in the Part D plan and the SPAP or entity providing other prescription drug coverage.

(3) Retroactive claims adjustments, underpayment reimbursements, and overpayment recoveries as described in paragraph (g) of this section and § 423.466(a) of this subpart.

(b) *Medicare as primary payer.* The requirements of this subpart do not change or affect the primary or secondary payer status of a Part D plan and a SPAP or other prescription drug coverage. A Part D plan is always the primary payer relative to a State Pharmaceutical Assistance Program.

(c) *User fees.* CMS may impose user fees on Part D plans for the transmittal of information necessary for benefit coordination in accordance with administrative processes and requirements established by CMS to ensure effective exchange of information and coordination between a Part D plan and SPAPs and entities providing other prescription drug coverage in a manner similar to the manner in which user fees are imposed under section 1842(h)(3)(B) of the Act, except that CMS may retain a portion of user fees to defray its costs in carrying out such procedures. CMS will not impose user fees under this subpart on a SPAP or entities providing other prescription drug coverage.

(d) *Cost management tools.* The requirements of this subpart do not prevent a Part D sponsor from using cost management tools (including differential payments) under all methods of operation.

(e) *Coordination with State Pharmaceutical Assistance Programs*—(1) *Requirements to be a State Pharmaceutical Assistance Program (SPAP).* A State program is considered to be a State Pharmaceutical Assistance Program for purposes of this part if it-

(i) Provides financial assistance for the purchase or provision of supplemental prescription drug coverage or benefits on behalf of Part D eligible individuals;

(ii) Provides assistance to Part D eligible individuals in all Part D plans without discriminating based upon the Part D plan in which an individual enrolls;

(iii) Meets the benefit coordination requirements specified in this subpart;

(iv) Does not follow or adopt rules that change or affect the primary payer status of a Part D plan.

The definition of SPAP excludes State Medicaid programs, section 1115 demonstration programs, and any other program where program funding is from Federal grants, awards, contracts, entitlement programs, or other Federal sources of funding; and

(v) Provides supplemental drug coverage to individuals based on financial

need, age, or medical condition, and not based on current or former employment status.

(vi) Does not engage in midyear plan or noncalendar year plan enrollment changes on behalf of a substantial number of its members when authorized to do so on the beneficiary's behalf.

(2) *Use of a single card.* A card that is issued under § 423.120(c) for use under a Part D plan may also be used in connection with coverage of benefits provided under a SPAP and, in such a case, may contain an emblem or symbol indicating such connection.

(3) *Construction.* Nothing in this subpart requires a SPAP to coordinate with, or provide financial assistance to enrollees in, any Part D plan.

(f) *Coordination with other prescription drug coverage*—(1) *Definition of other prescription drug coverage.* Entities that provide other prescription drug coverage include any of the following:

(i) *Medicaid programs.* A State plan under title XIX of the Act, including such a plan operating under a waiver under section 1115 of the Act, if it meets the requirements of paragraph (e)(1)(ii) of this section.

(ii) Group health plans.

(iii) *FEHBP.* The Federal Employee Health Benefits Program under chapter 89 of title 5, United States Code.

(iv) *Military coverage (including TRICARE).* Coverage under chapter 55 of title 10, United States Code.

(v) *Indian Health Service.* Coverage under Chapter 18 of title 28 of the United States Code.

(vi) *Federally qualified health centers.* Federally qualified health centers as defined under section 1861(aa)(4) of the Act.

(vii) *Rural health clinics.* Rural health clinics as defined under section 1861(aa)(2) of the Act.

(viii) Other Part D plans.

(ix) *Other prescription drug coverage.* Other health benefit plans or programs that provide coverage or financial assistance for the purchase or provision of Part D drugs on behalf of Part D eligible individuals as CMS may specify.

(2) *Treatment under out-of-pocket rule.* (i) For purposes of determining whether a Part D plan enrollee has satisfied the out-of-pocket threshold provided under § 423.104(d)(5)(iii), a Part D plan must do all of the following:

(A) Include the enrollee's incurred costs (as defined in § 423.100).

(B) Report, accept and apply benefit accumulator data in a timeframe and manner determined by CMS.

(C) Exclude expenditures for covered Part D drugs made by insurance or otherwise, a group health plan, or other third party payment arrangements, including expenditures by plans offering other prescription drug coverage.

(ii) A Part D enrollee must disclose all these expenditures to a Part D plan in accordance with requirements under § 423.32(b)(ii).

(3) *Imposition of fees.* A Part D sponsor may not impose fees on SPAPs and entities offering other prescription drug coverage that are unrelated to the cost of the coordination of benefits.

(4) *Authority to recover expenditures due to incorrect information on true out-of-pocket costs.* In the event that a Part D plan learns that it has made an erroneous payment due to inaccurate or incomplete information on the satisfaction of the out-of-pocket threshold under § 423.104(d)(5)(iii), that plan is authorized to recover such costs directly from the Part D enrollee on whose behalf the costs were incurred. A Part D enrollee must reimburse the Part D plan for payment made for these costs.

(5) *Plan-to-plan liability.* In the process of coordinating benefits between Part D plans when a Part D plan from which a beneficiary has transferred has incorrectly made payment for covered prescription drug costs incurred after the effective date of the Part D enrollee's enrollment in the new Part D plan of record, the new Part D plan of record must make the reconciling payments based on amounts reported to it by CMS without regard to the Part D plan's own formulary or drug utilization review edits.

(6) *Use of other reconciliation processes.* In the process of coordinating benefits between the correct Part D plan of record and another entity providing prescription drug coverage when that entity has incorrectly paid as primary payer for a covered Part D drug on behalf of a Part D enrollee, the correct Part D plan of record must achieve timely reconciliation through working

directly with the other entity that incorrectly paid as primary payer, unless CMS has established reconciliation processes for payment reconciliation, rather than requesting pharmacy claims reversal and re-adjudication.

(g) *Responsibility to account for other providers of prescription drug coverage when a retroactive claims adjustment creates an overpayment or underpayment.* When a Part D sponsor makes a retroactive claims adjustment, the sponsor has the responsibility to account for SPAPs and other entities providing prescription drug coverage in reconciling the claims adjustments that create overpayments or underpayments. In carrying out these reimbursements and recoveries, Part D sponsors must also account for payments made and for amounts being held for payment by other individuals or entities. Part D sponsors must have systems to track and report adjustment transactions and to support all of the following:

(1) Adjustments involving payments by other plans and programs providing prescription drug coverage have been made.

(2) Reimbursements for excess cost-sharing and premiums for low-income subsidy eligible individuals have been processed in accordance with the requirements in § 423.800(c).

(3) Recoveries of erroneous payments for enrollees as specified in § 423.464(f)(4) have been sought.

(h) *Reporting requirements.* A Part D sponsor must report credible new or changed supplemental prescription drug coverage information to the CMS Coordination of Benefits Contractor in accordance with the processes and timeframes specified by CMS.

[70 FR 4525, Jan. 28, 2005, as amended at 73 FR 20507, Apr. 15, 2008; 75 FR 19819, Apr. 15, 2010; 76 FR 21574, Apr. 15, 2011; 79 FR 29963, May 23, 2014; 80 FR 7964, Feb. 12, 2015]

§ 423.466 Timeframes for coordination of benefits and claims adjustments.

(a) *Retroactive claims adjustments, underpayment refunds, and overpayment recoveries.* Whenever a sponsor receives information that necessitates a retroactive claims adjustment, the sponsor must process the adjustment and issue refunds or recovery notices within 45 days of the sponsor's receipt of complete information regarding claims adjustment.

(b) *Coordination of benefits.* Part D sponsors must coordinate benefits with SPAPs, other entities providing prescription drug coverage, beneficiaries, and others paying on the beneficiaries' behalf for a period of 3 years from the date on which the prescription for a covered Part D drug was filled.

[75 FR 19819, Apr. 15, 2010, as amended at 80 FR 7964, Feb. 12, 2015]

Subpart K—Application Procedures and Contracts with Part D plan sponsors

§ 423.500 Scope.

This subpart sets forth application procedures and contracts with Part D plans: application procedures and requirements; contract terms; procedures for termination of contracts; reporting by Part D plans. For purposes of this subpart, Medicare Advantage (MA) organizations offering Part D plans follow the requirements of part 422 of this chapter for MA organizations, except in cases where the requirements for the qualified prescription drug coverage involve additional requirements.

§ 423.501 Definitions

For purposes of this subpart, the following definitions apply:

Bona fide service fees means fees paid by a manufacturer to an entity that represent fair market value for a bona fide, itemized service actually performed on behalf of the manufacturer that the manufacturer would otherwise perform (or contract for) in the absence of the service arrangement, and that are not passed on in whole or in part to a client or customer of an entity, whether or not the entity takes title to the drug.

Business transaction means any of the following kinds of transactions:

(1) Sale, exchange, or lease of property.

(2) Loan of money or extension of credit.

(3) Goods, services, or facilities furnished for a monetary consideration, including management services, but not including—

(i) Salaries paid to employees for services performed in the normal course of their employment; or

(ii) Health services furnished to the Part D plan sponsor's enrollees by pharmacies and other providers, by Part D plan sponsor staff, medical groups, or independent practice associations, or by any combination of those entities.

Downstream entity means any party that enters into a written arrangement, acceptable to CMS, below the level of the arrangement between a Part D plan sponsor (or applicant) and a first tier entity. These written arrangements continue down to the level of the ultimate provider of both health and administrative services.

Final settlement adjustment period means the period of time between when the contract terminates and the date the Part D sponsor is issued a notice of the final settlement amount.

Final settlement amount means the final payment amount that CMS owes and ultimately pays to a Part D sponsor, or that a Part D sponsor owes and ultimately pays to CMS, with respect to a Part D contract that has consolidated, nonrenewed, or terminated. The final settlement amount is calculated by summing final retroactive payment adjustments for a specific contract that accumulated after that contract ceases operation but before the calculation of the final settlement amount and all of the following applicable reconciliation amounts that have been completed as of the date the notice of final settlement has been issued, without accounting for any data submitted after the data submission deadlines for calculating these reconciliation amounts:

(1) Risk adjustment reconciliation, as applicable (described in § 422.310 of this chapter).

(2) Part D annual reconciliation (described in § 423.343).

(3) Coverage Gap Discount Program annual reconciliation (described in § 423.2320).

(4) MLR remittances (described in §§ 422.2470 of this chapter and 423.2470).

Final settlement process means for a contract that has been consolidated, nonrenewed, or terminated, the process by which CMS does all of the following:

(1) Calculates the final settlement amount.

(2) Issues the final settlement amount along with supporting documentation in the notice of final settlement to the Part D sponsor.

(3) Receives responses from the Part D sponsor requesting an appeal of the final settlement amount.

(4) Takes action to adjudicate an appeal (if requested) and make payments to or receive payments from the Part D sponsor. The final settlement amount is calculated after all applicable reconciliations have occurred after a contract has been consolidated, nonrenewed, or terminated.

First tier entity means any party that enters into a written arrangement, acceptable to CMS, with a Part D plan sponsor or applicant to provide administrative services or health care services for a Medicare eligible individual under Part D.

Party in interest means the following:

(1) Any director, officer, partner, or employee responsible for management or administration of a Part D plan sponsor.

(2) Any person who is directly or indirectly the beneficial owner of more than 5 percent of the organization's equity; or the beneficial owner of a mortgage, deed of trust, note, or other interest secured by and valuing more than 5 percent of the organization.

(3) In the case of a PDP sponsor organized as a nonprofit corporation, an incorporator or member of the corporation under applicable State corporation law.

(4) Any entity in which a person specified in paragraphs (1), (2), or (3) of this definition—

(i) Is an officer, director, or partner; or

(ii) Has the kind of interest described in paragraphs (1), (2), or (3) of this definition.

(5) Any person that directly or indirectly controls, is controlled by, or is under common control with the Part D plan sponsor.

(6) Any spouse, child, or parent of an individual specified in paragraphs (1), (2), or (3) of this definition.

Prescription drug pricing standard means any methodology or formula for varying the pricing of a drug or drugs

during the term of a pharmacy reimbursement contract that is based on the cost of a drug, which includes, but is not limited to, drug pricing references and amounts based on any of the following:

(1) Average wholesale price.
(2) Wholesale acquisition cost.
(3) Average manufacturer price.
(4) Average sales price.
(5) Maximum allowable cost.
(6) Other cost, whether publicly available or not.

Related entity means any entity that is related to the PDP sponsor by common ownership or control and—

(1) Performs some of the Part D plan sponsor's management functions under contract or delegation;

(2) Furnishes services to Medicare enrollees under an oral or written agreement; or

(3) Leases real property or sells materials to the Part D plan sponsor at a cost of more than $2,500 during a contract period.

Significant business transaction means any business transaction or series of transactions of the kind specified in the above definition of business transaction that, during any fiscal year of the Part D plan sponsor, have a total value that exceeds $25,000 or 5 percent of the PDP sponsor's total operating expenses, whichever is less.

[70 FR 4525, Jan. 28, 2005, as amended at 77 FR 22170, Apr. 12, 2012; 80 FR 29963, Nov. 6, 2015; 89 FR 30837, Apr. 23, 2024; 89 FR 63828, Aug. 6, 2024]

§ 423.502 Application requirements.

(a) *Scope.* This section sets forth application requirements for an entity that seeks a determination from CMS that it is qualified to contract as a sponsor of a Part D plan.

(b) *Completion of a notice of intent to apply.* (1) An organization submitting an application under this section for a particular contract year must first submit a completed Notice of Intent to Apply by the date established by CMS. CMS will not accept applications from organizations that do not submit a timely Notice of Intent to Apply.

(2) Submitting a Notice of Intent to Apply does not bind that organization to submit an application for the applicable contract year.

(3) An organization's decision not to submit an application after submitting an Notice of Intent to Apply will not form the basis of any action taken against the organization by CMS.

(c) *Completion of an application.* (1) In order to obtain a determination on whether it meets the requirements to become a Part D plan sponsor, an entity, or an individual authorized to act for the entity (the applicant), must fully complete all parts of a certified application in the form and manner required by CMS, including the following:

(i) Documentation of appropriate State licensure or State certification that the entity is able to offer health insurance or health benefits coverage that meets State-specified standards as specified in subpart I of this part; or

(ii) A Federal waiver as specified in subpart I of this part.

(2) The authorized individual must describe thoroughly how the entity is qualified to meet the all requirements described in this part.

(d) *Responsibility for making determinations.* (1) CMS is responsible for determining whether an entity is qualified to contract as a Part D plan sponsor and meets the requirements of this part.

(2) A CMS determination that an entity is qualified to act as a Part D plan sponsor is distinct from the bid negotiations that occur under subpart F of part 423 and such negotiations are not subject to the appeals provisions included in subpart N of this part.

(e) *Disclosure of application information under the Freedom of Information Act.* An applicant submitting material that he or she believes is protected from disclosure under 5 USC 552, the Freedom of Information Act, or because of exemptions provided in 45 CFR part 5 (the Department's regulations providing exemptions to disclosure), must label the material ''privileged'' and include an explanation of the applicability of an exemption specified in 45 CFR part 5.

[70 FR 4525, Jan. 28, 2005, as amended at 75 FR 19819, Apr. 15, 2010]

§ 423.503 Evaluation and determination procedures.

(a) *Basis for evaluation and determination.* (1) *Information used to evaluate applications.* With the exception of evaluations conducted under paragraph (b) of this section, CMS evaluates an entity's application solely on the basis of information contained in the application itself and any additional information that CMS obtains through on-site visits and any essential operations test.

(2) *Issuing application determination.* After evaluating all relevant information, CMS determines whether the application meets all the requirements described in this part.

(3) *Limitation on PDP contracts under a single parent organization* CMS does not approve an application when it would result in the applicant's parent organization, directly or through its subsidiaries, holding more than one PDP sponsor contract in the PDP Region for which the applicant is seeking qualification as a PDP sponsor.

(4) *Substantially incomplete applications.* (i) CMS does not evaluate or issue a notice of determination described in § 423.503(c) when an organization submits a substantially incomplete application.

(ii) An application is substantially incomplete when the submission as of the deadline for applications established by CMS is missing content or responsive materials for one or more sections of the application form required by CMS.

(iii) A determination that an application is substantially incomplete is not a contract determination as defined in § 423.641 and a determination that an organization submitted a substantially incomplete application is not subject to the appeals provisions of subpart N of this part.

(b) *Use of information from a current or prior contract.* (1) Except as provided in paragraphs (b)(2) through (4) of this section, if a Part D plan sponsor fails during the 12 months preceding the deadline established by CMS for the submission of contract qualification applications to comply with the requirements of the Part D program under any current or prior contract with CMS under title XVIII of the Act CMS may deny an application based on the applicant's failure to comply with the requirements of the Part D program under any current or prior contract with CMS even if the applicant currently meets all of the requirements of this part.

(i) An applicant may be considered to have failed to comply with a contract for purposes of an application denial under paragraph (b)(1) of this section if during the applicable review period the applicant:

(A) Was under an intermediate sanction under subpart O of this part, or a determination by CMS to prohibit the enrollment of new enrollees under § 423.2410(c).

(B) Failed to maintain a fiscally sound operation consistent with the requirements of § 423.505(b)(23).

(C) Filed for or is currently in federal or state bankruptcy proceedings.

(D) Received any combination of Part C or Part D summary ratings of 2.5 or less in both of the two most recent Star Rating periods, as identified in § 423.186.

(E) Met or exceeded 13 points for compliance actions on any one contract.

(*1*) CMS determines the number of points each Part D plan sponsor accumulated during the performance period for compliance actions based on the following point values:

(*i*) Each corrective action plan issued during the performance period under § 423.505(n) counts for 6 points.

(*ii*) Each warning letter issued during the performance period under § 423.505(n) counts for 3 points.

(*iii*) Each notice of noncompliance issued during the performance period under § 423.505(n) counts for 1 point.

(*2*) CMS adds all the point values for each Part D plan sponsor to determine if any organization meets CMS' identified threshold.

(ii) CMS may deny an application submitted by an organization that does not hold a Part D contract at the time of the submission when the applicant's parent organization or another subsidiary of the parent organization meets the criteria for denial stated in paragraph (b)(1)(i) of this section. This paragraph does not apply when the parent completed the acquisition of the

subsidiary that meets the criteria within the 24 months preceding the application submission deadline.

(2) In the absence of 12 months of performance history, CMS may deny an application based on a lack of information available to determine an applicant's capacity to comply with the requirements of the Part D program.

(3) If CMS has terminated, under § 423.509, or non-renewed, under § 423.507(b), a Part D plan sponsor's contract, effective within the 38 months preceding the deadline established by CMS for the submission of contract qualification applications, CMS may deny an application based on the applicant's substantial failure to comply with the requirements of the Part D program even if the applicant currently meets all of the requirements of this part.

(4) During the same 38-month period as specified in (b)(3) of this section, CMS may deny an application where the applicant's covered persons also served as covered persons for the terminated or non-renewed contract. A ''covered person'' as used in this paragraph means one of the following:

(i) All owners of terminated organizations who are natural persons, other than shareholders who have an ownership interest of less than 5 percent.

(ii) An owner in whole or part interest in any mortgage, deed of trust, note or other obligation secured (in whole or in part) by the organization, or any of the property or assets thereof, which whole or part interest is equal to or exceeds 5 percent of the total property, and assets of the organization.

(iii) A member of the board of directors or board of trustees of the entity, if the organization is organized as a corporation.

(c) *Notice of determination.* Except for fallback entities, which are governed under subpart Q of this part, CMS notifies each applicant that applies to be determined qualified to contract as a Part D plan sponsor, under this part, of its determination on the application and the basis for the determination. The determination may be one of the following:

(1) *Approval of application.* If CMS approves the application, it gives written notice to the applicant, indicating that it qualifies to contract as Part D plan sponsor.

(2) *Intent to deny.* (i) If CMS finds that the applicant does not appear qualified to contract as a Part D sponsor, it gives the applicant notice of intent to deny the application and a summary of the basis for this preliminary finding.

(ii) Within 10 days from the date of the notice, the applicant may respond in writing to the issues or other matters that were the basis for CMS's preliminary finding and may revise its application to remedy any defects CMS identified.

(iii) If CMS does not receive a revised application within 10 days from the date of the notice, or if after timely submission of a revised application, CMS still finds the applicant does not appear qualified to contract as a Part D plan sponsor or has not provided enough information to allow CMS to evaluate the application, CMS denies the application.

(3) Denial of application. If CMS denies the application, it gives written notice to the applicant indicating—

(i) That the applicant is not qualified to contract as a Part D sponsor under Part D of title XVIII of the Act;

(ii) The reasons why the applicant does is not so qualified; and

(iii) The applicant's right to request a hearing in accordance with the procedures specified in subpart N of this part.

(4) *Nullification of approval of application.* If CMS discovers through any means that an applicant is not qualified to contract based on information gained subsequent to application approval (for example, failure of an essential operations test, absence of required employees, etc.), CMS gives the applicant written notice indicating that the approval issued under paragraph (c)(1) of this section is nullified and the applicant no longer qualifies to contract as a Part D plan sponsor.

(i) This determination is not subject to the appeals provisions in subpart N of this part.

(ii) This provision only applies to applicants that have not previously entered into a Part D contract with CMS and neither it, nor another subsidiary of the applicant's parent organization,

is offering Part D benefits during the current year.

(d) *Withdrawal of application and bid in a previous year.* An applicant that withdraws its application and corresponding bid after the release of the low-income subsidy benchmark is not eligible to be approved as a Part D plan sponsor for the 2 succeeding annual contracting cycles.

[70 FR 4525, Jan. 28, 2005, as amended at 75 FR 19820, Apr. 15, 2010; 76 FR 21574, Apr. 15, 2011; 77 FR 22170, Apr. 12, 2012; 79 FR 29963, May 23, 2014; 80 FR 7964, Feb. 12, 2015; 83 FR 16750, Apr. 16, 2018; 86 FR 6118, Jan. 19, 2021; 87 FR 27900, May 9, 2022; 89 FR 30837, Apr. 23, 2024]

§ 423.504 General provisions.

(a) *General rule.* Subject to the provisions at § 423.265 of this part concerning submission of bids, to enroll beneficiaries in any Part D drug plan it offers and be paid on behalf of Part D eligible individuals enrolled in those plans, a Part D plan sponsor must enter into a contract with CMS. The contract may cover more than one Part D plan.

(b) *Conditions necessary to contract as a Part D plan sponsor.* Any entity seeking to contract as a Part D plan sponsor must—

(1) Complete an application as described in § 423.502 demonstrating that the entity has the capability to meet the requirements of this part, including those listed in § 423.505.

(2) Be organized and licensed under State law as a risk bearing entity eligible to offer health insurance or health benefits coverage in each State in which it offers a Part D plan, or have secured a Federal waiver, as described in subpart I of this part. (Fallback entity applicants need not be licensed as risk-bearing entities, nor are they required to obtain State licensure demonstrating that the applicant is eligible to offer health insurance or health benefits coverage in each State in which it applies to operate.)

(3) Meet the minimum enrollment requirements of § 423.512(a) unless waived under § 423.512(b).

(4) Have administrative and management arrangements satisfactory to CMS, as demonstrated by at least the following:

(i) A policy making body that exercises oversight and control over the Part D plan sponsor's policies and personnel to ensure that management actions are in the best interest of the organization and its enrollees.

(ii) Personnel and systems sufficient for the Part D plan sponsor to organize, implement, control, and evaluate financial and communication activities, the furnishing of prescription drug services, the quality assurance, medical therapy management, and drug and or utilization management programs, and the administrative and management aspects of the organization.

(iii) At a minimum, an executive manager whose appointment and removal are under the control of the policy making body.

(iv) A fidelity bond or bonds, procured and maintained by the Part D sponsor, in an amount fixed by its policymaking body but not less than $100,000 per individual, covering each officer and employee entrusted with the handling of its funds. The bond may have reasonable deductibles, based upon the financial strength of the Part D plan sponsor.

(v) Insurance policies or other arrangements, secured and maintained by the Part D plan sponsor and approved by CMS to insure the Part D plan sponsor against losses arising from professional liability claims, fire, theft, fraud, embezzlement, and other casualty risks.

(vi) Adopt and implement an effective compliance program, which must include measures that prevent, detect, and correct noncompliance with CMS' program requirements as well as measures that prevent, detect, and correct fraud, waste, and abuse. The compliance program must, at a minimum, include the following core requirements:

(A) Written policies, procedures, and standards of conduct that—

(*1*) Articulate the Part D plan sponsor's commitment to comply with all applicable Federal and State standards;

(*2*) Describe compliance expectations as embodied in the standards of conduct;

(*3*) Implement the operation of the compliance program;

(*4*) Provide guidance to employees and others on dealing with potential compliance issues;

(*5*) Identify how to communicate compliance issues to appropriate compliance personnel;

(*6*) Describe how potential compliance issues are investigated and resolved by the Part D plan sponsor; and

(*7*) Include a policy of non-intimidation and non-retaliation for good faith participation in the compliance program, including but not limited to reporting potential issues, investigating issues, conducting self-evaluations, audits and remedial actions, and reporting to appropriate officials.

(B) The designation of a compliance officer and a compliance committee who report directly and are accountable to the Part D plan sponsor's chief executive or other senior management.

(*1*) The compliance officer, vested with the day-to-day operations of the compliance program, must be an employee of the Part D plan sponsor, parent organization or corporate affiliate. The compliance officer may not be an employee of the Part D plan sponsor's first tier, downstream or related entity.

(*2*) The compliance officer and the compliance committee must periodically report directly to the governing body of the Part D plan sponsor on the activities and status of the compliance program, including issues identified, investigated, and resolved by the compliance program.

(*3*) The governing body of the Part D plan sponsor must be knowledgeable about the content and operation of the compliance program and must exercise reasonable oversight with respect to the implementation and effectiveness of the compliance programs.

(C)(*1*) Each Part D plan sponsor must establish and implement effective training and education for its compliance officer and organization employees, the Part D sponsor's chief executive and other senior administrators, managers and governing body members.

(*2*) Such training and education must occur at a minimum annually and must be made a part of the orientation for a new employee, and new appointment to a chief executive, manager, or governing body member.

(D) Establishment and implementation of effective lines of communication, ensuring confidentiality, between the compliance officer, members of the compliance committee, the Part D plan sponsor's employees, managers and governing body, and the Part D plan sponsor's first tier, downstream, and related entities. Such lines of communication must be accessible to all and allow compliance issues to be reported including a method for anonymous and confidential good faith reporting of potential compliance issues as they are identified.

(E) Well-publicized disciplinary standards through the implementation of procedures which encourage good faith participation in the compliance program by all affected individuals. These standards must include policies that—

(*1*) Articulate expectations for reporting compliance issues and assist in their resolution;

(*2*) Identify non-compliance or unethical behavior; and

(*3*) Provide for timely, consistent, and effective enforcement of the standards when non-compliance or unethical behavior is determined.

(F) Establishment and implementation of an effective system for routine monitoring and identification of compliance risks. The system should include internal monitoring and audits and, as appropriate, external audits, to evaluate the Part D plan sponsors, including first tier entities', compliance with CMS requirements and the overall effectiveness of the compliance program.

(G) Establishment and implementation of procedures and a system for promptly responding to compliance issues as they are raised, investigating potential compliance problems as identified in the course of self-evaluations and audits, correcting such problems promptly and thoroughly to reduce the potential for recurrence, and ensure ongoing compliance with CMS requirements.

(*1*) If the Part D sponsor discovers evidence of misconduct related to payment or delivery of prescription drug items or services under the contract, it

must conduct a timely, reasonable inquiry into that conduct;

(*2*) The Part D sponsor must conduct appropriate corrective actions (for example, repayment of overpayments and disciplinary actions against responsible individuals) in response to the potential violation referenced above.

(*3*) The Part D plan sponsor should have procedures to voluntarily self-report potential fraud or misconduct related to the Part D program to CMS or its designee.

(*4*) The Part D plan sponsor must have procedures to identify, and must report to CMS or its designee either of the following, in the manner described in paragraphs (b)(4)(vi)(G)(*4*) through (*6*) of this section:

(*i*) Any payment suspension implemented by a plan, pending investigation of credible allegations of fraud by a pharmacy, which must be implemented in the same manner as the Secretary does under section 1862(o)(1) of the Act.

(*ii*) Any information concerning investigations, credible evidence of suspicious activities of a provider of services (including a prescriber) or supplier, and other actions taken by the plan related to the inappropriate prescribing of opioids.

(*5*) The Part D plan sponsor must submit data, as specified in this section, in the program integrity portal when reporting payment suspensions pending investigations of credible allegations of fraud by pharmacies; information related to the inappropriate prescribing of opioids and concerning investigations and credible evidence of suspicious activities of a provider of services (including a prescriber) or supplier, and other actions taken by the plan sponsor; or if the plan reports a referral, through the portal, of substantiated or suspicious activities of a provider of services (including a prescriber) or a supplier related to fraud, waste or abuse to initiate or assist with investigations conducted by CMS, or its designee, a Medicare program integrity contractor, or law enforcement partners. The data categories, as applicable, include referral information and actions taken by the Part D plan sponsor on the referral. (*6*)(*i*) The plan sponsor is required to notify the Secretary, or its designee, of a payment suspension described in paragraph (b)(4)(vi)(G)(*4*) of this section 7 days prior to implementation of the payment suspension. The MA organization may request an exception to the 7day prior notification to the Secretary, or its designee, if circumstances warrant a reduced reporting time frame, such as potential beneficiary harm.

(*ii*) The plan sponsor is required to submit the information described in paragraph (b)(4)(vi)(G)(*4*)(*ii*) of this section no later than January 30, April 30, July 30, and October 30 of each year for the preceding periods, respectively, of October 1 through December 31, January 1 through March 31, April 1 through June 30, and July 1 through September 30. For the first reporting period (January 30, 2022), the reporting will reflect the data gathered and analyzed for the previous quarter in the calendar year (October 1–December 31).

(*7*)(*i*) CMS provides plan sponsors with data report(s) or links to the information described in paragraphs (b)(4)(vi)(G)(*4*)(*i*) and (*ii*) of this section no later than April 15, July 15, October 15, and January 15 of each year based on the information in the portal, respectively, as of the preceding October 1 through December 31, January 1 through March 31, April 1 through June 30, and July 1 through September 30.

(*ii*) Include administrative actions, pertinent information related to opioid overprescribing, and other data determined appropriate by the Secretary in consultation with stakeholders.

(*iii*) Are anonymized information submitted by plans without identifying the source of such information.

(*iv*) For the first quarterly report (April 15, 2022), that the report reflect the data gathered and analyzed for the previous quarter submitted by the plan sponsors on January 30, 2022.

(5) Not have non-renewed a contract under § 423.507 within the past 2 years unless—

(i) During the 6-month period, beginning on the date the entity notified CMS of the intention to non-renew the most recent previous contract, there was a change in the statute or regulations that had the effect of increasing Part D sponsor payments in the payment area or areas at issue; or

(ii) CMS has otherwise determined that circumstances warrant special consideration.

(6) Not have terminated a contract by mutual consent under which, as a condition of the consent, the Part D plan sponsor agreed that it was not eligible to apply for new contracts or service area expansions for a period up to 2 years per § 423.508(e) of this subpart.

(7) For a full risk or limited risk PDP applicant, not submitted a bid or offered a fallback prescription drug plan in accordance with the following rules.

(i) CMS does not contract with a potential PDP sponsor for the offering of a full risk or limited risk prescription drug plan in a PDP region for a year if the applicant—

(A) Submitted a bid under § 423.863 for the year (as the first year of a contract period under § 423.863 to offer a fallback prescription drug plan in any PDP region;

(B) Offers a fallback prescription drug plan in any PDP region during the year; or

(C) Offered a fallback prescription drug plan in that PDP region during the previous year.

(ii) *Construction.* For purposes of this paragraph (b)(6), an entity is treated as submitting an application to become qualified to contract as a full risk or limited risk PDP sponsor, if the entity is acting as a subcontractor for an integral part of the drug benefit management activities of a full risk or limited risk PDP sponsor or applicant. The previous sentence does not apply to entities that are subcontractors of an MA organization except insofar as the MA organization is applying to act as a full risk or limited risk PDP sponsor.

(8) If neither the applicant, nor its parent or another subsidiary of the same parent, holds a Part D sponsor contract that has been in effect for at least 1 year at the time it submits an application, the applicant must have arrangements in place such that the applicant and its contracted first tier, downstream, or related entities, in combination, have at least 1 full-benefit year of experience within the 2 years preceding the application submission performing at a minimum all of the following functions in support of the operation of another Part D contract:

(i) Authorization, adjudication, and processing of prescription drug claims at the point of sale.

(ii) Administration and tracking of enrollees' drug benefits in real time, including automated coordination of benefits with other payers.

(iii) Operation of an enrollee appeals and grievance process.

(9) For organizations applying to offer stand-alone prescription drug plans, the organization, its parent, or a subsidiary of the organization or its parent, must have either of the following:

(i) For 2 continuous years immediately prior to submitting an application, actively offered health insurance or health benefits coverage, including prescription drug coverage, as a risk-bearing entity in at least one State.

(ii) For 5 continuous years immediately prior to submitting an application, actively managed prescription drug benefits for an organization that offers health insurance or health benefits coverage, including at a minimum, all of the services listed in paragraph (b)(8) of this section.

(10) Pass an essential operations test prior to the start of the benefit year. This provision only applies to new sponsors that have not previously entered into a Part D contract with CMS when neither it, nor another subsidiary of the applicant's parent organization, is offering Part D benefits during the current year.

(c) *Contracting authority.* CMS may enter into contracts under this part, or in order to carry out this part, without regard to Federal and Departmental acquisition regulations set forth in Title 48 of the CFR and provisions of law or other regulations relating to the making, performance, amendment, or modification of contracts of the United States if CMS determines that those provisions are inconsistent with the efficient and effective administration of the Medicare program.

(d) *Protection against fraud and beneficiary protections.* (1) CMS annually audits the financial records (including, but not limited to, data relating to

Medicare utilization and costs, including allowable reinsurance and risk corridor costs as well as low income subsidies and other costs) under this part of at least one-third of the Part D sponsors offering Part D drug plans.

(2) Each contract under this section must provide that CMS, or any person or organization designated by CMS, has the right to—

(i) Inspect or otherwise evaluate the quality, appropriateness, and timeliness of services performed under the Part D plan sponsor's contract;

(ii) Inspect or otherwise evaluate the facilities of the Part D sponsor when there is reasonable evidence of some need for the inspection; and

(iii) Audit and inspect any books, contracts, and records of the Part D plan sponsor that pertain to—

(A) The ability of the organization or its first tier or downstream providers to bear the risk of potential financial losses; or

(B) Services performed or determinations of amounts payable under the contract.

(iv) CMS may require that the Part D Plan sponsor hire an independent auditor to provide CMS with additional information to determine if deficiencies found during an audit or inspection have been corrected and are not likely to recur. The independent auditor must work in accordance with CMS specifications and must be willing to attest that a complete and full independent review has been performed.

(e) *Severability of contracts.* The contract must provide that, upon CMS' request—

(1) The contract could be amended to exclude any State-licensed entity, or a Part D plan specified by CMS; and

(2) A separate contract for any excluded plan or entity must be deemed to be in place when a request is made.

[70 FR 4525, Jan. 28, 2005, as amended at 72 FR 68732, Dec. 5, 2007; 73 FR 20507, Apr. 15, 2008; 75 FR 19820, Apr. 15, 2010; 79 FR 29964, May 23, 2014; 80 FR 7964, Feb. 12, 2015; 83 FR 16750, Apr. 16, 2018; 86 FR 6118, Jan. 19, 2021]

§ 423.505 Contract provisions.

(a) *General rule.* The contract between the Part D plan sponsor and CMS must contain the provisions specified in paragraph (b) of this section.

(b) *Requirements for contracts.* The Part D plan sponsor agrees to—

(1) All the applicable requirements and conditions set forth in this part and in general instructions.

(2) Accept new enrollments, make enrollments effective, process voluntary disenrollments, and limit involuntary disenrollments, as provided in subpart B of this part.

(3) Comply with the prohibition in § 423.34(a) on discrimination in beneficiary enrollment.

(4) Provide the basic prescription drug coverage as defined under § 423.100 and, to the extent applicable, supplemental benefits as defined in § 423.100. (Fallback entities may offer only standard prescription drug coverage as specified in § 423.855.)

(5) Disclose information to beneficiaries in the manner and the form specified by CMS under § 423.128.

(6) Operate quality assurance, cost and utilization management, medication therapy management, and support e-prescribing as required under subpart D of this part.

(7) Comply with all requirements in subpart M of this part governing coverage determinations, grievances, and appeals, and formulary exceptions.

(8) Comply with the disclosure and reporting requirements in § 423.505(f), § 423.514, and the requirements in § 423.329(b) of this part for submitting current and prior drug claims and related information to CMS for its use in risk adjustment calculations and for the purposes of implementing § 423.505(f), (l), and (m) and § 423.329(b) of this part.

(9) Provide CMS with the information CMS determines is necessary to carry out payment provisions in subpart G of this part (or for fallback entities, the information necessary to carry out the payment provisions in subpart Q of this part).

(10) Allow CMS to inspect and audit any books and records of a Part D plan sponsor and its delegated first tier, downstream and related entities, that pertain to the information regarding costs provided to CMS under paragraph (b)(9) of this section, or, if a fallback entity, the information submitted under subpart Q of this part.

(11) Be paid under the contract in accordance with the payment rules in subpart G of this part, or, if a fallback entity, in accordance with the payment rules of subpart Q of this part.

(12) Except for fallback entities, submit a future year's bid, including all required information on premiums, benefits, and cost-sharing, by any applicable due date, as provided in subpart F so that CMS and the Part D plan sponsor may conduct negotiations regarding the terms and conditions of the proposed bid and benefit plan renewal.

(13) Permit CMS to determine that it is not qualified to renew its contract or that its contract may be terminated in accordance with this subpart and subpart N of this part. (Subpart N applies to fallback entities only to the extent a fallback contract is terminated.)

(14) Comply with the confidentiality and enrollee record accuracy specified in § 423.136.

(15) Comply with State law and preemption by Federal law requirements described in subpart I of this part.

(16) Comply with the coordination requirements with SPAPs and plans that provide other prescription drug coverage as described in subpart J of this part.

(17) Provide benefits by means of point of service systems to adjudicate in a drug claims in a timely and efficient manner in compliance with CMS standards, except when necessary to provide access in underserved areas, I/T/U pharmacies (as defined in § 423.100), and long-term care pharmacies (as defined in § 423.100).

(18) To agree to have a standard contract with reasonable and relevant terms and conditions of participation whereby any willing pharmacy may access the standard contract and participate as a network pharmacy including all of the following:

(i) Making standard contracts available upon request from interested pharmacies no later than September 15 of each year for contracts effective January 1 of the following year.

(ii) Providing a copy of a standard contract to a requesting pharmacy within 7 business days after receiving such a request from the pharmacy.

(19) Effective contract year 2010, include the prompt payment provisions described in § 423.520.

(20) Effective contract year 2010, provide that pharmacies located in, or having a contract with, a long-term care facility (as defined in § 423.100) must have not less than 30 days, nor more than 90 days, to submit to the Part D sponsor claims for reimbursement under the plan.

(21)(i) Update any prescription drug pricing standard (as defined in § 423.501) based on the cost of the drug used for reimbursement of network pharmacies by the Part D sponsor on January 1 of each contract year and not less frequently than once every 7 days thereafter;

(ii) Indicate the source used for making any such updates; and

(iii) Disclose all individual drug prices to be updated to the applicable pharmacies in advance of their use for reimbursement of claims, if the source for any prescription drug pricing standard is not publicly available.

(22) As described in § 423.129, address and resolve complaints received by CMS against the Part D sponsor in the Complaints Tracking Module.

(23) Maintain a fiscally sound operation by at least maintaining a positive net worth (total assets exceed total liabilities).

(24) Provide applicable beneficiaries with applicable discounts on applicable drugs in accordance with the requirements in subpart W of part 423.

(25) Maintain administrative and management capabilities sufficient for the organization to organize, implement, and control the financial, communication, benefit administration, and quality assurance activities related to the delivery of Part D services.

(26) Maintain a Part D summary plan rating score of at least 3 stars under the 5-star rating system specified in subpart 186 of this part 423. A Part D summary plan rating is calculated as provided in § 423.186.

(27) Pass an essential operations test prior to the start of the benefit year. This provision only applies to new sponsors that have not previously entered into a Part D contract with CMS and neither it, nor another subsidiary of the applicant's parent organization,

is offering Part D benefits during the current year.

(c) *Communication with CMS.* The Part D plan sponsor must have the capacity to communicate with CMS electronically in accordance with CMS requirements.

(d) *Maintenance of records.* The Part D plan sponsor agrees to maintain, for 10 years, books, records, documents, and other evidence of accounting procedures and practices that-

(1) Are sufficient to do the following:

(i) Accommodate periodic auditing of the financial records (including data related to Medicare utilization, costs, and computation of the bid of part D plan sponsors).

(ii) Enable CMS to inspect or otherwise evaluate the quality, appropriateness, and timeliness of services performed under the contract and the facilities of the organization.

(iii) Enable CMS to audit and inspect any books and records of the Part D plan sponsor that pertain to the ability of the organization to bear the risk of potential financial losses, or to services performed or determinations of amounts payable under the contract.

(iv) Except for fallback entities, properly reflect all direct and indirect costs claimed to have been incurred and used in the preparation of the Part D plan sponsor's bid and necessary for the calculation of gross covered prescription drug costs, allowable reinsurance costs, and allowable risk corridor costs (as defined in § 423.308).

(v) Except for fallback entities, establish the basis for the components, assumptions, and analysis used by the Part D plan in determining the actuarial valuation of standard, basic alternative, or enhanced alternative coverage offered in accordance with the CMS guidelines specified in § 423.265(c)(3).

(2) Include records of the following:

(i) Ownership and operation of the Part D sponsor's financial, medical, and other record keeping systems.

(ii) Financial statements for the current contract period and 10 prior periods.

(iii) Federal income tax or informational returns for the current contract period and 10 prior periods.

(iv) Asset acquisition, lease, sale, or other actions.

(v) Agreements, contracts, and subcontracts.

(vi) Franchise, marketing, and management agreements.

(vii) Matters pertaining to costs of operations.

(viii) Amounts of income received by source and payment.

(ix) Cash flow statements.

(x) Any financial reports filed with other Federal programs or State authorities.

(xi) All prescription drug claims for the current contract period and 10 prior periods.

(xii) All price concessions (including concessions offered by manufacturers) for the current contract period and 10 prior periods accounted for separately from other administrative fees.

(e) *Access to facilities and records.* The Part D plan sponsor agrees to the following:

(1) HHS, the Comptroller General, or their designee may evaluate, through audit, inspection, or other means—

(i) The quality, appropriateness, and timeliness of services furnished to Medicare enrollees under the contract;

(ii) Compliance with CMS requirements for maintaining the privacy and security of protected health information and other personally identifiable information of Medicare enrollees;

(iii) The facilities of the Part D sponsor to include computer and other electronic systems; and

(iv) The enrollment and disenrollment records for the current contract period and 10 prior periods.

(2) The Part D plan sponsor agrees to make available to HHS, the Comptroller General, or their designees, for the purposes specified in paragraph (d) of this section, its premises, physical facilities and equipment, records relating to its Medicare enrollees, and any additional relevant information that CMS may require. The Part D plan sponsor also agrees to make available any books, contracts, records and documentation of the Part D plan sponsor, first tier, downstream and related entity(s), or its transferee that pertain to any aspect of services performed, reconciliation of benefit liabilities, and determination of amounts payable

under the contract, or as the Secretary may deem necessary to enforce the contract.

(3) The Part D plan sponsor agrees to make available, for the purposes specified in paragraph (d) of this section, its premises, physical facilities and equipment, records relating to its Medicare enrollees, and any additional relevant information that CMS may require.

(4) HHS, the Comptroller General, or their designee's right to inspect, evaluate, and audit extends through 10 years from the end of the final contract period or completion of audit, whichever is later unless—

(i) CMS determines there is a special need to retain a particular record or group of records for a longer period and notifies the Part D plan sponsor at least 30 days before the normal disposition date;

(ii) There is a termination, dispute, or allegation of fraud or similar fault by the Part D plan sponsor, in which case the retention may be extended to 6 years from the date of any resulting final resolution of the termination, dispute, or fraud or similar fault; or

(iii) CMS determines that there is a reasonable possibility of fraud or similar fault, in which case CMS may inspect, evaluate, and audit the Part D plan sponsor at any time.

(f) *Disclosure of information.* The Part D plan sponsor agrees to submit to CMS—

(1) Certified financial information that must include the following:

(i) Information as CMS may require demonstrating that the organization has a fiscally sound operation.

(ii) Information as CMS may require pertaining to the disclosure of ownership and control of the Part D plan sponsor.

(2) All information to CMS that is necessary for CMS to administer and evaluate the program and to simultaneously establish and facilitate a process for current and prospective beneficiaries to exercise choice in obtaining prescription drug coverage. This information includes, but is not limited to:

(i) The benefits covered under a Part D plan.

(ii) The Part D plan monthly basic beneficiary premium and Part D plan monthly supplemental beneficiary premium, if any, for the plan. Fallback entities submit the monthly beneficiary premium for standard prescription drug coverage.

(iii) The service area of each plan.

(iv) Plan quality and performance indicators for the benefits under the plan including—

(A) Disenrollment rates for Medicare enrollees electing to receive benefits through the plan for the previous 2 years;

(B) Information on Medicare enrollee satisfaction;

(C) The recent records regarding compliance of the plan with requirements of this part, as determined by CMS; and

(D) Other information determined by CMS to be necessary to assist beneficiaries in making an informed choice regarding Part D plans.

(v) Information about beneficiary appeals and their disposition, and formulary exceptions.

(vi) Information regarding all formal actions, reviews, findings, or other similar actions by States, other regulatory bodies, or any other certifying or accrediting organization.

(vii) Information on other matters that CMS may require, including, but not limited to, program monitoring and oversight, performance measures, quality assessment, research and evaluation, CMS outreach activities, payment-related oversight*, and fraud, abuse, and waste*, as specified in CMS guidelines.

(viii) Any other information deemed necessary to CMS for the administration or evaluation of the Medicare program.

(3) All data elements included in all its drug claims for purposes deemed necessary and appropriate by the Secretary, including, but not limited to the following:

(i) Reporting to Congress and the public on overall statistics associated with the operation of the Medicare prescription drug program.

(ii) Conducting evaluations of the overall Medicare program, including the interaction between prescription drug coverage under Part D of Title XVIII of the Social Security Act and the services and utilization under Parts A, B, and C of title XVIII of the

Act and under titles XIX and XXI of the Act, as well as other studies addressing public health questions.

(iii) Making legislative proposals to the Congress regarding Federal health care programs and related programs.

(iv) Conducting demonstration and pilot projects and making recommendations for improving the economy, efficiency, or effectiveness of the Medicare program.

(v) Supporting care coordination and disease management programs.

(vi) Supporting quality improvement and performance measurement activities.

(vii) Populating personal health care records.

(viii) Supporting program integrity purposes, including coordination with the States.

(4) To its enrollees, all informational requirements under §423.128 and, upon an enrollee's request, the financial disclosure information required under §423.128(c)(4).

(g) *Beneficiary financial protections.* The Part D plan sponsor agrees to comply with the following requirements:

(1) Each Part D plan sponsor must adopt and maintain arrangements satisfactory to CMS to protect its enrollees from incurring liability for payment of any fees that are the legal obligation of the Part D sponsor. To meet this requirement, the Part D plan sponsor must—

(i) Ensure that all contractual or other written arrangements prohibit the sponsor's contracting agents from holding any beneficiary enrollee liable for payment of any such fees; and

(ii) Indemnify the beneficiary enrollee for payment of any fees that are the legal obligation of the Part D plan sponsor for covered prescription drugs furnished by non-contracting pharmacists, or that have not otherwise entered into an agreement with the Part D plan sponsor, to provide services to the organization's beneficiary enrollees.

(2) In meeting the requirements of this paragraph, other than the provider contract requirements specified in paragraph (g)(1)(i) of this section, the Part D plan sponsor may use—

(i) Contractual arrangements;

(ii) Insurance acceptable to CMS;

(iii) Financial reserves acceptable to CMS; or

(iv) Any other arrangement acceptable to CMS.

(h) *Requirements of other laws and regulations.* The Part D plan sponsor agrees to comply with—

(1) Federal laws and regulations designed to prevent fraud, waste, and abuse, including, but not limited to applicable provisions of Federal criminal law, the False Claims Act (31 U.S.C. 3729 *et seq.*), and the anti-kickback statute (section 1128B(b) of the Act).

(2) HIPAA Administrative Simplification rules at 45 CFR parts 160, 162, and 164.

(i) *Relationship with first tier, downstream, and related entities.* (1) Notwithstanding any relationship(s) that the Part D plan sponsor may have with first tier, downstream, and related entities, the Part D sponsor maintains ultimate responsibility for adhering to and otherwise fully complying with all terms and conditions of its contract with CMS.

(2) The Part D sponsor agrees to require all first tier, downstream, and related entities to agree that—

(i) HHS, the Comptroller General, or their designees have the right to audit, evaluate, collect, and inspect any books, contracts, computer or other electronic systems, including medical records and documentation of the first tier, downstream, and related entities related to CMS' contract with the Part D sponsor.

(ii) HHS, the Comptroller General or their designees have the right to audit, evaluate, collect, and inspect any records under paragraph (i)(2)(i) of this section directly from any first tier, downstream, or related entity.

(iii) For records subject to review under paragraph (i)(2)(ii) of this section, except in exceptional circumstances, CMS will provide notification to the Part D sponsor that a direct request for information has been initiated.

(iv) HHS', the Comptroller General's, or their designee's right to inspect, evaluate, and audit any pertinent information for any particular contract period exists through 10 years from the final date of the contract period or

from the date of completion of any audit, whichever is later.

(3) Each and every contract governing Part D sponsors and first tier, downstream, and related entities, must contain the following:

(i) Enrollee protection provisions that provide, consistent with paragraph (g)(1) of this section, arrangements that prohibit pharmacies or other providers from holding an enrollee liable for payment of any fees that are the obligation of the Part D plan sponsor.

(ii) Accountability provisions that indicate that the Part D sponsor may delegate activities or functions to a first tier, downstream, or related entity only in a manner consistent with requirements set forth at paragraph (i)(4) of this section.

(iii) A provision requiring that any services or other activity performed by a first tier, downstream, and related entity in accordance with a contract are consistent and comply with the Part D sponsor's contractual obligations.

(iv) Each and every contract must specify that first tier, downstream, and related entities must comply with all applicable Federal laws, regulations, and CMS instructions.

(v) A provision requiring prompt payment of clean claims by the Part D sponsor, consistent with § 423.520.

(vi) A provision that establishes timeframes, consistent with § 423.505(b)(20), for long-term care pharmacies to submit claims to the Part D sponsor for reimbursement under the plan.

(vii) If applicable, provisions addressing the drug pricing standard requirements of § 423.505(b)(21).

(4) If any of the Part D plan sponsors' activities or responsibilities under its contract with CMS is delegated to other parties, the following requirements apply to any first tier, downstream, and related entity:

(i) Each and every contract must specify delegated activities and reporting responsibilities.

(ii) Each and every contract must either provide for revocation of the delegation activities and reporting responsibilities described in paragraph (i)(4)(i) of this section or specify other remedies in instances when CMS or the Part D plan sponsor determine that the parties have not performed satisfactorily.

(iii) Each and every contract must specify that the Part D plan sponsor on an ongoing basis monitors the performance of the parties.

(iv) Each and every contract must specify that the related entity, contractor, or subcontractor must comply with all applicable Federal laws, regulations, and CMS instructions.

(5) If the Part D plan sponsor delegates selection of its prescription drug providers to another organization, the Part D sponsor's written arrangements with that organization must state that the CMS-contracting Part D plan sponsor retains the right to approve, suspend, or terminate any such arrangement.

(6) If the Part D plan sponsor delegates any of the following functions to a first tier, downstream, or related entity, the Part D sponsor's written arrangements must state that a termination initiated by such entity must provide, at minimum, 60-days' prior notice and have an effective termination date that coincides with the end of a calendar month:

(i) Authorization, adjudication, and processing of prescription drug claims at the point of sale.

(ii) Administration and tracking of enrollees' drug benefits in real time, including automated coordination of benefits with other payers.

(iii) Operation of an enrollee appeals and grievance process.

(iv) Contracting with or selection of prescription drug providers for inclusion in the Part D sponsor's network.

(j) *Additional contract terms.* The Part D plan sponsor agrees to include in the contract other terms and conditions as CMS may find necessary and appropriate in order to implement requirements in this part.

(k) *Certification of data that determine payment*—(1) *General rule.* As a condition for receiving a monthly payment under subpart G of this part (or for fallback entities, payment under subpart Q of this part),, the Part D plan sponsor agrees that its chief executive officer (CEO), chief financial officer (CFO), or an individual delegated the

authority to sign on behalf of one of these officers, and who reports directly to the officer, must request payment under the contract on a document that certifies (based on best knowledge, information, and belief) the accuracy, completeness, and truthfulness of all data related to payment. The data may include specified enrollment information, claims data, bid submission data, and other data that CMS specifies.

(2) *Certification of enrollment and payment information.* The CEO, CFO, or an individual delegated the authority to sign on behalf of one of these officers, and who reports directly to the officer, must certify (based on best knowledge, information, and belief) that each enrollee for whom the organization is requesting payment is validly enrolled in a program offered by the organization and the information CMS relies on in determining payment is accurate, complete, and truthful and acknowledge that this information will be used for the purposes of obtaining Federal reimbursement.

(3) *Certification of claims data.* The CEO, CFO, or an individual delegated with the authority to sign on behalf of one of these officers, and who reports directly to the officer, must certify (based on best knowledge, information, and belief) that the claims data it submits under § 423.329(b)(3) (or for fallback entities, under § 423.871(f)) are accurate, complete, and truthful and acknowledge that the claims data will be used for the purpose of obtaining Federal reimbursement. If the claims data are generated by a related entity, contractor, or subcontractor of a Part D plan sponsor, the entity, contractor, or subcontractor must similarly certify (based on best knowledge, information, and belief) the accuracy, completeness, and truthfulness of the data and acknowledge that the claims data will be used for the purposes of obtaining Federal reimbursement.

(4) *Certification of bid submission information.* The CEO, CFO, or an individual delegated the authority to sign on behalf of one of these officers, and who reports directly to the officer, must certify (based on best knowledge, information, and belief) that the information in its bid submission and assumptions related to projected reinsurance and low income cost sharing subsidies is accurate, complete, and truthful and fully conforms to the requirements in § 423.265.

(5) *Certification of allowable costs for risk corridor and reinsurance information.* The Chief Executive Officer, Chief Financial Officer, or an individual delegated the authority to sign on behalf of one of these officers, and who reports directly to the officer, must certify (based on best knowledge, information, and belief) that the information provided for purposes of supporting allowable costs as defined in § 423.308 of this part, including data submitted to CMS regarding direct or indirect remuneration (DIR) that serves to reduce the costs incurred by the Part D sponsor for Part D drugs, is accurate, complete, and truthful and fully conforms to the requirements in § 423.336 and § 423.343 of this part and acknowledge that this information will be used for the purposes of obtaining Federal reimbursement.

(6) *Certification of accuracy of data for price comparison.* The CEO, CFO, or an individual delegated the authority to sign on behalf of one of these officers, and who reports directly to the officer, must certify (based on best knowledge, information, and belief) that the information provided for purposes of price comparison is accurate, complete, and truthful.

(7) *Certification of accuracy of data for overpayments.* The CEO, CFO, or COO must certify (based on best knowledge, information, and belief) that the information provided for purposes of reporting and returning of overpayments under § 423.360 is accurate, complete, and truthful.

(l) CMS may use the information collected under paragraph (f)(3) of this section. Any restriction set forth by § 423.322(b) of this part must not be construed to limit the Secretary's authority to use the information collected under paragraph (f)(3).

(m) *Release of data.* (1) CMS may release the minimum data necessary for a given purpose from the data collected under paragraph (f)(3) of this section to Federal executive branch agencies, States, and external entities in accordance with the following:

(i) Applicable Federal laws.

(ii) CMS data sharing procedures.

(iii) Subject, in certain cases, to encryption of beneficiary identifiers and aggregation of cost data to protect beneficiary confidentiality and commercially sensitive data of Part D sponsors, in accordance with all of the following principles:

(A) Subject to the restrictions in this paragraph, all elements on the claim are available to HHS, other executive branch agencies, and the States.

(B) Cost data elements on the claim generally are aggregated for releases to other executive branch agencies, States, and external entities. Upon request, CMS excludes sales tax from the aggregation at the individual level if necessary for the project.

(C) Beneficiary identifier elements on the claim generally are encrypted for release, except in limited circumstances, such as the following:

(*1*) If needed, in the case of release to other HHS entities, Congressional oversight agencies, non-HHS executive agencies and the States.

(*2*) If needed to link to another dataset, in the case of release to external entities. Public disclosure of research results will not include beneficiary identifying information.

(iv) For purposes of paragraph (m)(1)(iii) of this section, States and executive-branch Federal agencies are not considered to be external entities.

(2) Any restriction set forth by § 423.322(b) of this part must not be construed to limit the Secretary's authority to release the information collected under paragraph (f)(3) of this section.

(3)(i) CMS must make available to Congressional support agencies (the Congressional Budget Office, the Government Accountability Office, the Medicare Payment Advisory Commission, and the Congressional Research Service when it is acting on behalf of a Congressional committee in accordance with 2 U.S.C. 166(d)(1)) all information collected under paragraph (f)(3) of this section for the purposes of conducting congressional oversight, monitoring, making recommendations, and analysis of the Medicare program.

(ii) The Congressional Research Service is considered an external entity when it is not acting on behalf of a Congressional committee in accordance with 2 U.S.C. 166(d)(1) for the purposes of paragraph (m)(1) of this section.

(n) *Issuance of compliance actions for failure to comply with the terms of the contract.* The Part D plan sponsor acknowledges that CMS may take compliance actions as described in this section or intermediate sanctions as defined in subpart O of this part.

(1) CMS may take compliance actions as described in paragraph (n)(3) of this section if it determines that the Part D plan sponsor has not complied with the terms of a current or prior Part D contract with CMS.

(i) CMS may determine that a Part D plans sponsor is out of compliance with a Part D requirement when the organization fails to meet performance standards articulated in the Part D statutes, regulations in this chapter, or guidance.

(ii) If CMS has not already articulated a measure for determining noncompliance, CMS may determine that a Part D plan sponsor is out of compliance when its performance in fulfilling Part D requirements represents an outlier relative to the performance of other Part D plan sponsors.

(2) CMS bases its decision on whether to issue a compliance action and what level of compliance action to take on an assessment of the circumstances surrounding the noncompliance, including all of the following:

(i) The nature of the conduct.

(ii) The degree of culpability of the Part D plan sponsor.

(iii) The adverse effect to beneficiaries which resulted or could have resulted from the conduct of the Part D plan sponsor.

(iv) The history of prior offenses by the Part D plan sponsor or its related entities.

(v) Whether the noncompliance was self-reported.

(vi) Other factors which relate to the impact of the underlying noncompliance or the lack of the Part D plan sponsor's oversight of its operations that contributed to the noncompliance.

(3) CMS may take one of three types of compliance actions based on the nature of the noncompliance.

(i) *Notice of noncompliance.* A notice of noncompliance may be issued for

any failure to comply with the requirements of the Part D plan sponsor's current or prior Part D contract with CMS, as described in paragraph (n)(1) of this section.

(ii) *Warning letter.* A warning letter may be issued for serious and/or continued noncompliance with the requirements of the Part D plan sponsor's current or prior Part D contract with CMS, as described in paragraph (n)(1) of this section and as assessed in accordance with paragraph (n)(2) of this section.

(iii) *Corrective action plan.* (A) Corrective action plans are issued for particularly serious and/or continued noncompliance with the requirements of the Part D plan sponsors' current or prior Part D contract with CMS, as described in paragraph (n)(1) of this section and as assessed in accordance with paragraph (n)(2) of this section.

(B) CMS issues a corrective action plan if CMS determines that the Part D plan sponsor has repeated or not corrected noncompliance identified in prior compliance actions, has substantially impacted beneficiaries or the program with its noncompliance, and/or must implement a detailed plan to correct the underlying causes of the noncompliance.

(o) *Acknowledgements of CMS release of data*—(1) *Summary CMS payment data.* The contract must provide that the Part D sponsor acknowledges that CMS releases to the public summary reconciled Part D payment data after the reconciliation of Part D payments for the contract year as follows:

(i) The average per member per month Part D direct subsidy standardized to the 1.0 (average risk score) beneficiary for each Part D plan offered.

(ii) The average Part D risk score for each Part D plan offered.

(iii) The average per member per month Part D plan low-income cost sharing subsidy for each Part D plan offered.

(iv) The average per member per month Part D Federal reinsurance subsidy for each Part D plan offered.

(v) The actual Part D reconciliation payment data summarized at the Parent Organization level including breakouts of risk sharing, reinsurance, and low income cost sharing reconciliation amounts.

(2) *Part D MLR data.* The contract must provide that the Part D sponsor acknowledges that CMS releases to the public data as described at § 423.2490.

(p) *Business continuity.* (1) The Part D sponsor agrees to develop, maintain, and implement a business continuity plan containing policies and procedures to ensure the restoration of business operations following disruptions to business operations during disruptions to business operations which would include natural or man-made disasters, system failures, emergencies, and other similar circumstances and the threat of such occurrences. To meet the requirement, the business continuity plan must, at a minimum, include the following:

(i) *Risk assessment.* Identify threats and vulnerabilities that might affect business operations.

(ii) *Mitigation strategy.* Design strategies to mitigate hazards. Identify essential functions in addition to those specified in paragraph (p)(2) of this section and prioritize the order in which to restore all other functions to normal operations. At a minimum, each Part D sponsor must do the following:

(A) Identify specific events that will activate the business continuity plan.

(B) Develop a contingency plan to maintain, during any business disruption, the availability and, as applicable, confidentiality of communication systems and essential records in all forms (including electronic and paper copies). The contingency plan must do the following:

(*1*) Ensure that during any business disruption the following systems will operate continuously or, should they fail, be restored to operational capacity on a timely basis:

(*i*) Information technology (IT) systems including those supporting claims processing at point of service.

(*ii*) Provider and enrollee communication systems including telephone, Web site, and email.

(*2*) With respect to electronic protected health information, comply with the contingency plan requirements of the Health Insurance Portability and Accountability Act of 1996 Security

Regulations at 45 CFR parts 160 and 164, subparts A and C.

(C) Establish a chain of command.

(D) Establish a business communication plan that includes emergency capabilities and procedures to contact and communicate with the following:

(*1*) Employees.

(*2*) First tier, downstream, and related entities.

(*3*) Other third parties (including pharmacies, providers, suppliers, and government and emergency management officials).

(E) Establish employee and facility management plans to ensure that essential operations and job responsibilities can be assumed by other employees or moved to alternate sites as necessary or both.

(F) Establish a restoration plan including procedures to transition to normal operations.

(G) Comply with all applicable Federal, State, and local laws.

(iii) *Testing and revision.* On at least an annual basis, test and update the business operations continuity plan to ensure the following:

(A) That it can be implemented in emergency situations.

(B) That employees understand how it is to be executed.

(iv) *Training.* On at least an annual basis, educate appropriate employees about the business continuity plan and their own respective roles.

(v) *Records.* (A) Develop and maintain records documenting the elements of the business continuity plan described in paragraph (p)(1)(i) through (iv) of this section.

(B) Make the information specified in paragraph (p)(1)(v)(A) of this section available to CMS upon request.

(2) *Restoration of essential functions.* Every Part D sponsor must plan to restore essential functions within 72 hours after any of the essential functions fail or otherwise stop functioning as usual. In addition to any essential functions that the Part D sponsor identifies under paragraph (p)(1)(ii) of this section, for purposes of this paragraph (p)(2) of this section essential functions include at a minimum, the following:

(i) Benefit authorization (if not waived), adjudication, and processing of prescription drug claims at the point of sale.

(ii) Administration and tracking of enrollees' drug benefits in real time, including automated coordination of benefits with other payers.

(iii) Provision of pharmacy technical assistance.

(iv) Operation of an enrollee exceptions and appeals process including coverage determinations.

(v) Operation of call center customer services.

(q) *Enrollment in the Medicare Transaction Facilitator Data Module for the Medicare Drug Price Negotiation Program.* For contract year 2026 and all subsequent years, any contract between the sponsor and a pharmacy, or between a first tier, downstream, or related entity and a pharmacy on the sponsor's behalf, for participation in one or more of the Part D sponsor's networks must include a provision requiring the pharmacy to be enrolled in the Medicare Transaction Facilitator Data Module (MTF DM) (or any successor to the MTF DM) in a form and manner determined by CMS. Such provision must also require the pharmacy to maintain and certify up-to-date, complete, and accurate enrollment information with the MTF DM, in accordance with applicable terms and conditions of participation with the MTF DM, including but not limited to contact, third-party support entity or entities, and banking information, in a form and manner determined by CMS.

[70 FR 4525, Jan. 28, 2005, as amended at 73 FR 20507, Apr. 15, 2008; 73 FR 30683, May 28, 2008; 73 FR 54251, Sept. 18, 2008; 73 FR 70599, Nov. 21, 2008; 74 FR 1545, Jan. 12, 2009; 75 FR 19821, Apr. 15, 2010; 76 FR 21574, Apr. 15, 2011; 76 FR 54634, Sept. 1, 2011; 77 FR 22170, Apr. 12, 2012; 79 FR 29964, May 23, 2014; 80 FR 7964, Feb. 12, 2015; 81 FR 80557, Nov. 15, 2016; 83 FR 16750, Apr. 16, 2018; 86 FR 6119, Jan. 19, 2021; 87 FR 27900, May 9, 2022; 88 FR 22340, Apr. 12, 2023; 89 FR 30838, Apr. 23, 2024; 90 FR 15919, Apr. 15, 2025]

§ 423.506 Effective date and term of contract.

(a) *Effective date.* The contract is effective on the date specified in the contract between the Part D plan sponsor and CMS.

(b) *Term of contract.* Each contract is for a period of 12 months.

(c) *Qualification to renew a contract.* In accordance with 423.507, an entity is determined qualified to renew its contract annually only if the Part D plan sponsor has not provided CMS with a notice of intention not to renew and CMS has not provided the Part D organization with a notice of intention not to renew.

(d) *Renewal of contract contingent on reaching agreement on the bid.* Although a Part D plan sponsor may be determined qualified to renew its contract under this section, if the sponsor and CMS cannot reach agreement on the bid under subpart F, no renewal takes place, and the failure to reach agreement is not subject to the appeals provisions in subpart N of this part.

(e) The provisions of this section do not apply to fallback entities.

[70 FR 4525, Jan. 28, 2005, as amended at 72 FR 68732, Dec. 5, 2007]

§ 423.507 Nonrenewal of contract.

(a) *Nonrenewal by a Part D plan sponsor.* (1) Except for fallback entities, a Part D plan sponsor may elect not to renew its contract with CMS, effective at the end of the term of the contract for any reason provided it meets the timeframes for doing so set forth in paragraphs (a)(2) and (a)(3) of this section.

(2) If a Part D plan sponsor does not intend to renew its contract, it must notify—

(i) CMS in writing by the first Monday of June in the year in which the contract ends;

(ii) Each Medicare enrollee by mail at least 90 calendar days before the date on which the nonrenewal is effective. The sponsor must also provide information about alternative enrollment options by doing one or more of the following:

(A) Provide a CMS approved written description of alternative MA plan and PDP options available for obtaining qualified prescription drug coverage within the beneficiaries' region.

(B) Place outbound calls to all affected enrollees to ensure beneficiaries know who to contact to learn about their enrollment options.

(3)(i) If a Part D plan sponsor does not renew a contract under this paragraph (a), CMS cannot enter into a contract with the organization for 2 years in the PDP region or regions served by the contract unless there are circumstances that warrant special consideration, as determined by CMS.

(ii) If a PDP sponsor does not renew any of its PBPs in a PDP region, CMS does not approve plan bids submitted by the organization in that PDP region for 2 years unless there are circumstances that warrant special consideration, as determined by CMS.

(iii) The provisions of this paragraph do not apply to employer group waiver plans offered by a Part D plan sponsor.

(4) During the same 2-year period specified under paragraph (a)(3) of this section, CMS will not contract with an organization whose covered persons also served as covered persons for the non-renewing sponsor. A ''covered person'' as used in this paragraph means one of the following:

(i) All owners of nonrenewed or terminated organizations who are natural persons, other than shareholders who have an ownership interest of less than 5 percent.

(ii) An owner of a whole or part interest in a mortgage, deed of trust, note or other obligation secured (in whole or in part) by the organization, or by any of the property or assets thereof, which whole or part interest is equal to or exceeds 5 percent of the total property and assets of the organization.

(iii) A member of the board of directors or board of trustees of the entity, if the organization is organized as a corporation.

(5) If a Part D plan sponsor does not renew a contract under this paragraph (a), it must ensure the timely transfer of any data or files.

(b) [Reserved]

[70 FR 4525, Jan. 28, 2005, as amended at 72 FR 68733, Dec. 5, 2007; 74 FR 1546, Jan. 12, 2009; 75 FR 19821, Apr. 15, 2010; 76 FR 21575, Apr. 15, 2011; 83 FR 16750, Apr. 16, 2018; 89 FR 30838, Apr. 23, 2024]

§ 423.508 Modification or termination of contract by mutual consent.

(a) *General rule.* A contract may be modified or terminated at any time by written mutual consent. If the PDP sponsor submits a request to end the term of its contract after the deadline

provided in § 423.507(a)(2)(i), the contract may be terminated by mutual consent in accordance with paragraphs (b) through (f) of this section. CMS may mutually consent to the contract termination if the contract termination does not negatively affect the administration of the Medicare Part D program.

(b) *Notification of termination.* If the contract is terminated by mutual consent, the Part D plan sponsor must provide notice to its Medicare enrollees and the general public as provided in paragraph (c) of this section.

(c) *Notification of modification.* If the contract is modified by mutual consent, the Part D plan sponsor must notify its Medicare enrollees of any changes that CMS determines are appropriate for notification within timeframes specified by CMS.

(d) *Timely transfer of data and files.* If a contract is terminated under paragraph (a) of this section, the Part D plan sponsor must ensure the timely transfer of any data or files.

(e) *Agreement to limit new Part D applications.* (1) As a condition of the consent to a mutual termination, CMS requires, as a provision of the termination agreement, language prohibiting the Part D plan sponsor from applying for new contracts or service area expansions in the PDP region or regions served by the contract for a period up to 2 years unless there are circumstances that warrant special consideration, as determined by CMS.

(2) A PDP sponsor that agrees to terminate its offering of PBPs in a PDP region also agrees that it is not eligible to apply to resume offering plans in that region for 2 years.

(3) The provisions of this paragraph do not apply to employer group waiver plans offered by a Part D plan sponsor.

(f) *Prohibition against Part D program participation by organizations whose owners, directors, or management employees served in a similar capacity with another organization that mutually terminated its Medicare contract within the previous 2 years.* During the 2-year period specified in paragraph (e) of this section, CMS will not contract with an organization whose covered persons also served as covered persons for the mutually terminating sponsor. A ''covered person'' as used in this paragraph means one of the following:

(1) All owners of nonrenewed or terminated organizations who are natural persons, other than shareholders who have an ownership interest of less than 5 percent.

(2) An owner of a whole or part interest in a mortgage, deed of trust, note or other obligation secured (in whole or in part) by the organization, or any of the property or assets thereof, which whole or part interest is equal to or exceeds 5 percent of the total property, and assets of the organization.

(3) A member of the board of directors or board of trustees of the entity, if the organization is organized as a corporation.

[70 FR 4525, Jan. 28, 2005, as amended at 75 FR 19821, Apr. 15, 2010; 76 FR 21575, Apr. 15, 2011; 83 FR 16750, Apr. 16, 2018; 89 FR 30838, Apr. 23, 2024]

§ 423.509 Termination of contract by CMS.

(a) *Termination by CMS.* CMS may at any time terminate a contract if CMS determines that the Part D plan sponsor meets any of the following:

(1) Has failed substantially to carry out the contract.

(2) Is carrying out the contract in a manner that is inconsistent with the efficient and effective administration of this part.

(3) No longer substantially meets the applicable conditions of this part.

(4) CMS may make a determination under paragraph (a)(1), (2) or (3) of this section if the Part D Plan sponsor has had one or more of the following occur:

(i) Based on credible evidence, has committed or participated in false, fraudulent, or abusive activities affecting the Medicare, Medicaid, or other State or Federal health care programs, including submission of false or fraudulent data.

(ii) Substantially failed to comply with the requirements in subpart M of this part relating to grievances and appeals.

(iii) Failed to provide CMS with valid risk adjustment, reinsurance and risk corridor related data as required under §§ 423.322 and 423.329 (or, for fallback entities, failed to provide the information in § 423.871(f)).

(iv) Substantially failed to comply with the service access requirements in § 423.120.

(v) Substantially failed to comply with either of the following:

(A) Requirements in subpart V of this part.

(B) Information dissemination requirements of § 423.128 of this part.

(vi) Substantially failed to comply with the coordination with plans and programs that provide prescription drug coverage as described in subpart J of this part.

(vii) Substantially failed to comply with the cost and utilization management, quality improvement, medication therapy management and fraud, abuse and waste program requirements as specified in subparts D and K of this part.

(viii) Failed to comply with the regulatory requirements contained in this part.

(ix) Failed to meet CMS performance requirements in carrying out the regulatory requirements contained in this part.

(x) Achieves a Part D summary plan rating of less than 3 stars for 3 consecutive contract years. Plan ratings issued by CMS before September 1, 2012 are not included in the calculation of the 3-year period.

(xi)(A) Has failed to report MLR data in a timely and accurate manner in accordance with § 423.2460; or

(B) That any MLR data required by this subpart is found to be materially incorrect or fraudulent.

(xii) Failure of an essential operations test before the start of the benefit year by an organization that has entered into a Part D contract with CMS when neither it, nor another subsidiary of the organization's parent organization, is offering Part D benefits during the current year.

(xiii) The Part D plan sponsor has committed any of the acts in § 423.752 that support the imposition of intermediate sanctions or civil money penalties under § 423.750.

(xiv) Following the issuance of a notice to the sponsor no later than August 1, CMS must terminate, effective December 31 of the same year, an individual PDP if that plan does not have a sufficient number of enrollees to establish that it is a viable independent plan option.

(b) *Notice.* If CMS decides to terminate a contract it gives notice of the termination as follows:

(1) *Termination of contract by CMS.* (i) CMS notifies the Part D plan sponsor in writing at least 45 calendar days before the intended date of the termination.

(ii) The Part D plan sponsor notifies its Medicare enrollees of the termination by mail at least 30 calendar days before the effective date of the termination.

(iii) The Part D plan sponsor notifies the general public of the termination at least 30 calendar days before the effective date of the termination by releasing a press statement to news media serving the affected community or county and posting the press statement prominently on the organization's Web site.

(iv) CMS notifies the general public of the termination no later than 30 calendar days after notifying the plan of CMS's decision to terminate the Part D plan sponsor's contract by releasing a press statement.

(v) In the event that CMS issues a termination notice to a Part D plan sponsor on or before August 1 with an effective date of the following December 31, the Part D plan sponsor must issue notification to its Medicare enrollees at least 90 days prior to the effective date of the termination.

(2) *Immediate termination of contract by CMS.* (i) The procedures specified in (b)(1) of this section do not apply if—

(A) CMS determines that a delay in termination, resulting from compliance with the procedures provided in this part prior to termination, would pose an imminent and serious risk to the health of the individuals enrolled with the Part D plan sponsor;

(B) The Part D plan sponsor experiences financial difficulties so severe that its ability to make necessary health services available is impaired to the point of posing an imminent and serious risk to the health of its enrollees, or otherwise fails to make services available to the extent that such a risk to health exists; or

(C) The contract is being terminated based on the grounds specified in paragraphs (a)(4)(i) and (xii) of this section.

(ii) CMS notifies the Part D plan sponsor in writing that its contract will be terminated on a date specified by CMS. If a termination in is effective in the middle of a month, CMS has the right to recover the prorated share of the capitation payments made to the Part D plan sponsor covering the period of the month following the contract termination.

(iii) CMS notifies the Part D plan sponsor's Medicare enrollees in writing of CMS's decision to terminate the Part D plan sponsor's contract. This notice occurs no later than 30 days after CMS notifies the plan of its decision to terminate the Part D plan sponsor's contract. CMS simultaneously informs the Medicare enrollees of alternative options for obtaining qualified prescription drug coverage, including alternative PDP sponsors and MA-PDs in a similar geographic area.

(iv) CMS notifies the general public of the termination no later than 30 days after notifying the plan of CMS's decision to terminate the Part D plan sponsor's contract. This notice is published in one or more newspapers of general circulation in each community or county located in the Part D plan sponsor's service area.

(c) *Opportunity to develop and implement a corrective action plan*—(1) *General.* (i) Before providing a notice of intent to terminate the contract, CMS will provide the Part D plan sponsor with notice specifying the Part D plan sponsor's deficiencies and a reasonable opportunity of at least 30 calendar days to develop and implement a corrective action plan to correct the deficiencies.

(ii) The Part D plan sponsor is solely responsible for the identification, development, and implementation of its corrective action plan and for demonstrating to CMS that the underlying deficiencies have been corrected within the time period specified by CMS in the notice requesting corrective action.

(2) *Exceptions.* The Part D plan sponsor will not be provided with an opportunity to develop and implement a corrective action plan prior to termination if—

(i) CMS determines that a delay in termination, resulting from compliance with the procedures provided in this part prior to termination, would pose an imminent and serious risk to the health of the individuals enrolled with the Part D plan sponsor;

(ii) The Part D plan sponsor experiences financial difficulties so severe that its ability to make necessary health services available is impaired to the point of posing an imminent and serious risk to the health of its enrollees, or otherwise fails to make services available to the extent that such a risk to health exists; or

(iii) The contract is being terminated based on the violation specified in (a)(4)(i) of this section.

(d) *Appeal rights.* If CMS decides to terminate a contract, it sends written notice to the Part D plan sponsor informing it of its termination appeal rights in accordance with subpart N of this part.

(e) *Timely transfer of data and files.* If a contract is terminated under paragraph (a) of this section, the Part D plan sponsor must ensure the timely transfer of any data or files.

(f) If CMS makes a determination to terminate a Part D sponsor's contract under § 423.509(a), CMS also imposes the intermediate sanctions at § 423.750(a)(1) and (3) in accordance with the following procedures:

(1) The sanction will go into effect 15 days after the termination notice is sent.

(2) The Part D sponsor will have a right to appeal the intermediate sanction in the same proceeding as the termination appeal specified in paragraph (d) of this section.

(3) A request for a hearing does not delay the date specified by CMS when the sanction becomes effective.

(4) The sanction will remain in effect—

(i) Until the effective date of the termination; or

(ii) If the termination decision is overturned on appeal, when a final decision is made by the hearing officer or Administrator.

[70 FR 4525, Jan. 28, 2005, as amended at 72 FR 68733, Dec. 5, 2007; 73 FR 20507, Apr. 15, 2008; 75 FR 19822, Apr. 15, 2010; 76 FR 21575, Apr. 15, 2011; 77 FR 22170, Apr. 12, 2012; 78 FR 31310, May 23, 2013; 79 FR 29965, May 23, 2014; 80 FR 7965, Feb. 12, 2015; 83 FR 16750, Apr. 16, 2018; 89 FR 30838, Apr. 23, 2024]

§ 423.510 Termination of contract by the Part D sponsor.

(a) *Cause for termination.* The Part D plan sponsor may terminate its contract if CMS fails to substantially carry out the terms of the contract.

(b) *Notice of termination.* The Part D plan sponsor must give advance notice as follows:

(1) To CMS, at least 90 days before the intended date of termination. This notice must specify the reasons why the Part D sponsor is requesting contract termination.

(2) To its Medicare enrollees, at least 60 days before the termination effective date. This notice must include a written description of alternatives available for obtaining qualified prescription drug coverage within the services area, including alternative PDPs, MA-PDPs, and original Medicare and must receive CMS approval.

(3) To the general public, at least 60 days before the termination effective date by publishing a CMS-approved notice in one or more newspapers of general circulation in each community or county located in the Part D plan sponsor's geographic area.

(c) *Effective date of termination.* The effective date of the termination is determined by CMS and is at least 90 days after the date CMS receives the Part D plan sponsor's notice of intent to terminate.

(d) *CMS's liability.* CMS's liability for payment to the Part D plan sponsor ends as of the first day of the month after the last month for which the contract is in effect.

(e) *Effect of termination by the organization.* (1) CMS does not enter into an agreement with an organization that has terminated its contract within the preceding 2 years unless there are circumstances that warrant special consideration, as determined by CMS.

(2) During the same 2-year period specified in (e)(1) of this section, CMS will not contract with an organization whose covered persons also served as covered persons for the terminating sponsor. A ''covered person'' as used in this paragraph means one of the following:

(i) All owners of nonrenewed or terminated organizations who are natural persons, other than shareholders who have an ownership interest of less than 5 percent.

(ii) An owner of a whole or part interest in a mortgage, deed of trust, note or other obligation secured (in whole or in part) by the organization, or any of the property or assets thereof, which whole or part interest is equal to or exceeds 5 percent of the total property and assets of the organization.

(iii) A member of the board of directors or board of trustees of the entity, if the organization is organized as a corporation.

(f) *Timely transfer of data and files.* If a contract is terminated under paragraph (a) of this section, the Part D plan sponsor must ensure the timely transfer of any data or files.

[70 FR 4525, Jan. 28, 2005, as amended at 76 FR 21575, Apr. 15, 2011]

§ 423.512 Minimum enrollment requirements.

(a) *Basic rule.* Except as provided in paragraph (b) of this section, CMS does not enter into a contract under this subpart unless the organization meets the following minimum enrollment requirement:

(1) At least 5,000 individuals are enrolled for the purpose of receiving prescription drug benefits from the organization; or

(2) At least 1,500 individuals are enrolled for purposes of receiving prescription drug benefits from the organization and the organization primarily serves individuals residing outside of urbanized areas as defined in § 412.62(f) of this chapter;

(3) Except as provided for in paragraph (b) of this section, a Part D plan sponsor must maintain a minimum enrollment as defined in paragraphs (a)(1)

and (a)(2) of this section for the duration of its contract.

(b) *Minimum enrollment waiver.* CMS waives the requirement of paragraphs (a)(1) and (a)(2) of this section during the first contract year for a sponsor in a region.

§423.514 Validation of Part D reporting requirements.

(a) *Required information.* Each Part D plan sponsor must have an effective procedure to develop, compile, evaluate, and report to CMS, to its enrollees, and to the general public, at the times and in the manner that CMS requires, information indicating the following—

(1) The cost of its operations.

(2) The procedures related to and utilization of its services and items.

(3) The availability, accessibility, and acceptability of its services.

(4) Information demonstrating that the Part D plan sponsor has a fiscally sound operation.

(5) Pharmacy performance measures.

(6) Other matters that CMS may require.

(b) *Significant business transactions.* Each Part D plan sponsor must report to CMS annually, within 120 days of the end of its fiscal year (unless, for good cause shown, CMS authorizes an extension of time), the following:

(1) A description of significant business transactions, as defined in §423.501, between the Part D plan sponsor and a party in interest, including the following:

(i) Indication that the costs of the transactions listed in paragraph (c) of this section do not exceed the costs that would be incurred if these transactions were with someone who is not a party in interest; or

(ii) If they do exceed, a justification that the higher costs are consistent with prudent management and fiscal soundness requirements.

(2) A combined financial statement for the Part D plan sponsor and a party in interest if either of the following conditions is met:

(i) Thirty five percent or more of the costs of operation of the Part D sponsor go to a party in interest.

(ii) Thirty five percent or more of the revenue of a party in interest is from the Part D plan sponsor.

(c) *Requirements for combined financial statements.* (1) The combined financial statements required by paragraph (b)(2) of this section must display in separate columns the financial information for the Part D plan sponsor and each of the parties in interest.

(2) Inter-entity transactions must be eliminated in the consolidated column.

(3) The statements must be examined by an independent auditor in accordance with generally accepted accounting principles and must include appropriate opinions and notes.

(4) Upon written request from a Part D plan sponsor showing good cause, CMS may waive the requirement that the organization's combined financial statement include the financial information required in this paragraph (c) of this section for a particular entity.

(d) *Reporting requirements for pharmacy benefits manager data.* Each entity that provides pharmacy benefits management services must provide to the Part D sponsor, and each Part D sponsor must provide to CMS, in a manner specified by CMS, the following:

(1) The total number of prescriptions that were dispensed.

(2) The percentage of all prescriptions that were provided through retail pharmacies compared to mail order pharmacies.

(3) The percentage of prescriptions for which a generic drug was available and dispensed (generic dispensing rate), by pharmacy type (which includes an independent pharmacy, chain pharmacy, supermarket pharmacy, or mass merchandiser pharmacy that is licensed as a pharmacy by the State and that dispenses medication to the general public), that is paid by the Part D sponsor or PBM under the contract.

(4) The aggregate amount and type of rebates, discounts, or price concessions (excluding bona fide service fees as defined in §423.501) that the PBM negotiates that are attributable to patient utilization under the plan.

(5) The aggregate amount of the rebates, discounts, or price concessions that are passed through to the plan sponsor, and the total number of prescriptions that were dispensed.

(6) The aggregate amount of the difference between the amount the Part D sponsor pays the PBM and the amount that the PBM pays retail pharmacies, and mail order pharmacies.

(e) *Confidentiality of pharmacy benefits manager data.* Information disclosed by a Part D sponsor or PBM as specified in paragraph (d) of this section is confidential and must not be disclosed by the Secretary or by a plan receiving the information, except that the Secretary may disclose the information in a form which does not disclose the identity of a specific PBM, plan, or prices charged for drugs, for the following purposes:

(1) As the Secretary determines necessary to carry out section 1150A of the Act or Part D of Title XVIII.

(2) To permit the Comptroller General to review the information provided.

(3) To permit the Director of the Congressional Budget Office to review the information provided.

(f) *Penalties for failure to provide pharmacy benefits manager data.* The provisions of section 1927(b)(3)(C) of the Act are applicable to a Part D sponsor or PBM that fails to provide the required information on a timely basis or knowingly provides false information in the same manner as such provisions apply to a manufacturer with an agreement under section 1927 of the Act.

(g) *Reporting and disclosure under Employee Retirement Income Security Act of 1974 (ERISA).* (1) For any employees' health benefits plan that includes a Part D plan sponsor in its offerings, the PDP sponsor must furnish, upon request, the information the plan needs to fulfill its reporting and disclosure obligations (for the particular PDP sponsor) under the Employee Retirement Income Security Act of 1974 (ERISA).

(2) The PDP sponsor must furnish the information to the employer or the employer's designee, or to the plan administrator, as the term ''administrator'' is defined in ERISA.

(h) *Loan information.* Each Part D plan sponsor must notify CMS of any loans or other special financial arrangements it makes with contractors, subcontractors and related entities.

(i) *Enrollee access to information.* Each Part D plan sponsor must make the information reported to CMS under this section available to its enrollees upon reasonable request.

(j) *Data validation.* Each Part D sponsor must subject information collected under paragraph (a) of this section to a yearly independent audit to determine its reliability, validity, completeness, and comparability in accordance with specifications developed by CMS.

[70 FR 4525, Jan. 28, 2005, as amended at 75 FR 19822, Apr. 15, 2010; 77 FR 22171, Apr. 12, 2012; 86 FR 6119, Jan. 19, 2021; 89 FR 30838, Apr. 23, 2024]

§ 423.516 Prohibition of midyear implementation of significant new regulatory requirements.

CMS may not implement, other than at the beginning of a calendar year, regulations under this section that impose new, significant regulatory requirements on a PDP sponsor or a prescription drug plan.

§ 423.520 Prompt payment by Part D sponsors.

(a) *Contract between CMS and the Part D sponsor.* (1) Effective contract year 2010, the contract between the Part D sponsor and CMS must provide that the Part D sponsor will issue, mail, or otherwise transmit payment with respect to all clean claims, as defined in paragraph (b) of this section, submitted by network pharmacies (other than mail-order and long-term care pharmacies) within—

(i) 14 days after the date on which the claim is received, as defined in paragraph (a)(2)(i) of this section, for an electronic claim; or

(ii) 30 days after the date on which the claim is received, as defined in paragraph (a)(2)(ii) of this section, for any other claim.

(2) *Date of receipt of claim.* A claim is considered to have been received—

(i) On the date on which the claim is transferred, for an electronic claim; or

(ii) On the 5th day after the postmark day of the claim or the date specified in the time stamp of the transmission, for any other claim, whichever is sooner.

(b) *Clean claim.* A clean claim means a claim that has no defect or impropriety (including any lack of any required substantiating documentation) or particular circumstance requiring special treatment that prevents timely payment of the claim from being made under this section.

(c) *Procedures involving claims*—(1) *Claims determined to be clean.* A claim is deemed to be a clean claim if the Part D sponsor receiving the claim does not provide notice to the submitting network pharmacy of any deficiency in the claim within—

(i) 10 days after the date on which the claim is received, as defined in paragraph (a)(2)(i) of this section, for an electronic claim; or

(ii) 15 days after the date on which the claim is received, as defined in paragraph (a)(2)(ii) of this section, for any other claim.

(2) *Claims determined not to be clean*—(i) *General.* If a Part D sponsor determines that a submitted claim is not a clean claim, as defined in paragraph (b) of this section, the Part D sponsor must notify the submitting network pharmacy of such determination within the period described in paragraph (c)(1) of this section. Such notification must specify all defects or improprieties in the claim and must list all additional information necessary for the proper processing and payment of the claim.

(ii) *Determination after submission of additional information.* A claim is deemed to be a clean claim under paragraph (b) of this section if the Part D sponsor that receives the claim does not provide notice to the submitting network pharmacy of any remaining defect or impropriety, or of any new defect or impropriety raised by the additional information, in the claim within 10 days of the date on which additional information is received under paragraph (c)(2)(i) of this section. A Part D sponsor may not provide notice of a new deficiency or impropriety in the claim that could have been identified by the sponsor in the original claim submission under this paragraph.

(3) *Obligation to pay.* A claim submitted to a Part D sponsor that is not paid by the Part D sponsor within the timeframes specified in paragraphs (a)(1)(i) and (ii) or contested by the Part D sponsor within the timeframe specified in paragraph (c)(1)(i) and (ii) of this section must be deemed to be a clean claim and must be paid by the Part D sponsor in accordance with paragraph (a) of this section.

(d) *Date of payment of claim.* Payment of a clean claim under paragraph (c)(3) of this section is considered to have been made on the date on which—

(1) The payment is transferred, for an electronic claim; or

(2) The payment is submitted to the United States Postal Service or common carrier for delivery, for any other claim.

(e) *Interest payment*—(1) *General.* Subject to paragraph (e)(2) of this section, if payment is not issued, mailed or otherwise transmitted for a clean claim as required under paragraph (a) of this section, the Part D sponsor must pay interest to the network pharmacy that submitted the claim at a rate equal to the weighted average of interest on 3-month marketable Treasury securities determined for such period, increased by 0.1 percentage point for the period beginning on the day after the required payment date and ending on the date on which the payment is made, as determined under paragraph (d). Interest amounts paid under this paragraph will not count against the Part D sponsor's administrative costs, as defined in § 423.308, and will not be treated as allowable risk corridor costs, as defined in § 423.308.

(2) *Authority not to charge interest.* As CMS determines, a Part D sponsor is not charged interest under paragraph (e)(1) in exigent circumstances that prevent the timely processing of claims, including natural disasters and other unique and unexpected events.

(f) *Electronic transfer of funds.* A Part D sponsor must pay all clean claims submitted electronically by electronic transfer of funds provided the submitting network pharmacy so requests or has so requested previously that contract year. When such payment is made electronically, remittance may also be made electronically by the Part D sponsor.

(g) *Protecting the rights of the claimants*—(1) *General.* Nothing in this section may be construed to prohibit or

limit a claim or action that any individual or organization has against a pharmacy, provider, or Part D sponsor that is not covered by the subject matter of this section.

(2) *Anti-retaliation.* Consistent with applicable Federal or State law, a Part D sponsor may not retaliate against an individual, pharmacy, or provider for exercising a right of action under paragraph (g)(1) of this section.

(h) *Construction.* A determination under this section that a claim submitted by a network pharmacy is a clean claim shall not be construed as a positive determination regarding eligibility for payment under title XVIII of the Act, nor is it an indication of government approval of, or acquiescence regarding, the claim submitted. The determination does not relieve any party of civil or criminal liability with respect to the claim, nor does it offer a defense to any administrative, civil, or criminal action with respect to the claim.

[73 FR 54252, Sept. 18, 2008, as amended at 76 FR 54634, Sept. 1, 2011]

§ 423.521 Final settlement process and payment.

(a) *Notice of final settlement.* After the calculation of the final settlement amount, CMS sends the Part D sponsor a notice of final settlement. The notice of final settlement contains at least the following information:

(1) A final settlement amount for the contract that has been consolidated, nonrenewed, or terminated, which may be one of the following:

(i) An amount due to the Part D sponsor.

(ii) An amount due from the Part D sponsor.

(iii) $0 if nothing is due to or from the Part D sponsor.

(2) Relevant banking and financial mailing instructions for Part D sponsors that owe CMS a final settlement amount.

(3) Relevant CMS contact information.

(4) A description of the steps for requesting an appeal of the final settlement amount calculation, in accordance with the requirements specified in § 423.522.

(b) *Request for an appeal.* A Part D sponsor that disagrees with the final settlement amount has 15 calendar days from issuance of the notice of final settlement, as described in paragraph (a) of this section, to request an appeal of the final settlement amount under the process described in § 423.522.

(1) If a Part D sponsor agrees with the final settlement amount, no response is required.

(2) If a Part D sponsor disagrees with the final settlement amount but does not request an appeal within 15 calendar days from the date of the issuance of the notice of final settlement, CMS does not consider subsequent requests for appeal.

(c) *Actions if a Part D sponsor does not request an appeal.* (1) For Part D sponsors that are owed money by CMS, CMS remits payment to the Part D sponsor within 60 calendar days from the date of the issuance of the notice of final settlement.

(2) For Part D sponsors that owe CMS money, the Part D sponsor is required to remit payment to CMS within 120 calendar days from issuance of the notice of final settlement. If the Part D sponsor fails to remit payment within that 120-calendar-day period, CMS refers the debt owed to CMS to the Department of the Treasury for collection.

(d) *Actions following a request for appeal.* If a Part D sponsor responds to the notice of final settlement disagreeing with the final settlement amount and requesting appeal, CMS conducts a review process under the process described at § 423.522.

(e) *No additional payment adjustments.* After the final settlement amount is calculated and the notice of final settlement, as described under § 423.521(a), is issued to the Part D sponsor, CMS—

(1) No longer applies retroactive payment adjustments to the terminated, consolidated or nonrenewed contract; and

(2) There are no adjustments applied to amounts used in the calculation of the final settlement amount.

[89 FR 30838, Apr. 23, 2024]

§ 423.522 Requesting an appeal of the final settlement amount.

(a) *Appeals process.* If a Part D sponsor does not agree with the final settlement amount described in § 423.521(a) of this section, it may appeal under the following three-level appeal process:

(1) *Reconsideration.* A Part D sponsor may request reconsideration of the final settlement amount described in § 423.521(a) according to the following process:

(i) *Manner and timing of request.* A written request for reconsideration must be filed within 15 days from the date that CMS issued the notice of final settlement to the Part D sponsor.

(ii) *Content of request.* The written request for reconsideration must do all of the following:

(A) Specify the calculation with which the Part D sponsor disagrees and the reasons for its disagreement.

(B) Include evidence supporting the assertion that CMS's calculation of the final settlement amount is incorrect.

(C) Not include new reconciliation data or data that was submitted to CMS after the final settlement notice was issued. CMS does not consider information submitted for the purposes of retroactively adjusting a prior reconciliation.

(iii) *Conduct of reconsideration.* In conducting the reconsideration, the CMS reconsideration official reviews the calculations that were used to determine the final settlement amount and any additional evidence timely submitted by the Part D sponsor.

(iv) *Reconsideration decision.* The CMS reconsideration official informs the Part D sponsor of its decision on the reconsideration in writing.

(v) *Effect of reconsideration decision.* The decision of the CMS reconsideration official is final and binding unless a timely request for an informal hearing is filed in accordance with paragraph (a)(2) of this section.

(2) *Informal hearing.* A Part D sponsor dissatisfied with CMS's reconsideration decision made under paragraph (a)(1) of this section is entitled to an informal hearing as provided for under paragraphs (a)(2)(i) through (a)(2)(iv) of this section.

(i) *Manner and timing of request.* A request for an informal hearing must be made in writing and filed with CMS within 15 calendar days of the date of CMS's reconsideration decision.

(ii) *Content of request.* The request for an informal hearing must include a copy of the reconsideration decision and must specify the findings or issues in the decision with which the Part D sponsor disagrees and the reasons for its disagreement.

(iii) *Informal hearing procedures.* The informal hearing is conducted in accordance with the following:

(A) The CMS Hearing Officer provides written notice of the time and place of the informal hearing at least 30 calendar days before the scheduled date.

(B) The CMS reconsideration official provides a copy of the record that was before CMS when CMS made its decision to the hearing officer.

(C) The hearing officer review is conducted by a CMS hearing officer who neither receives testimony nor accepts any new evidence. The CMS hearing officer is limited to the review of the record that was before CMS when CMS made its decision.

(iv) *Decision of the CMS hearing officer.* The CMS hearing officer decides the case and sends a written decision to the Part D sponsor explaining the basis for the decision.

(v) *Effect of hearing officer's decision.* The hearing officer's decision is final and binding, unless the decision is reversed or modified by the CMS Administrator in accordance with paragraph (a)(3) of this section.

(3) *Review by the Administrator.* The Administrator's review is conducted in the following manner:

(i) *Manner and timing of request.* A Part D sponsor that has received a hearing officer's decision may request review by the Administrator within 15 calendar days of the date of issuance of the hearing officer's decision under paragraph (a)(2)(iv) of this section. The Part D sponsor may submit written arguments to the Administrator for review.

(ii) *Discretionary review.* (A) After receiving a request for review, the Administrator has the discretion to elect to review the hearing officer's determination in accordance with paragraph (a)(3)(iii) of this section or to decline to review the hearing officer's decision

within 30 calendar days of receiving the request for review.

(B) If the Administrator declines to review the hearing officer's decision, the hearing officer's decision is final and binding.

(iii) *Electing to review.* If the Administrator elects to review the hearing officer's decision, the Administrator reviews the hearing officer's decision, as well as any information included in the record of the hearing officer's decision and any written argument submitted by the Part D sponsor, and determine whether to uphold, reverse, or modify the hearing officer's decision.

(iv) *Effect of Administrator's decision.* The Administrator's decision is final and binding.

(b) *Matters subject to appeal and burden of proof.* (1) The Part D sponsor's appeal is limited to CMS's calculation of the final settlement amount. CMS does not consider information submitted for the purposes of retroactively adjusting a prior reconciliation.

(2) The Part D sponsor bears the burden of proof by providing evidence demonstrating that CMS' calculation of the final settlement amount is incorrect.

(c) *Stay of financial transaction until appeals are exhausted.* If a Part D sponsor requests review of the final settlement amount, the financial transaction associated with the issuance or payment of the final settlement amount is stayed until all appeals are exhausted. Once all levels of appeal are exhausted or the Part D sponsor fails to request further review within the applicable 15-calendar-day timeframe, CMS communicates with the Part D sponsor to complete the financial transaction associated with the issuance or payment of the final settlement amount, as appropriate.

(d) *Continued compliance with other law required.* Nothing in this section limits a Part D sponsor's responsibility to comply with any other statute or regulation.

[89 FR 30839, Apr. 23, 2024, as amended at 89 FR 63828, Aug. 6, 2024]

§ 423.530 Plan crosswalks.

(a) *General rules*—(1) *Definition of plan crosswalk.* A plan crosswalk is the movement of enrollees from one plan benefit package (PBP) in a PDP contract to another PBP under a PDP contract between a Part D Sponsor and CMS. To crosswalk enrollees from one PBP to another is to change the enrollment from the first PBP to the second.

(2) *Prohibitions.* (i) Plan crosswalks between PBPs under one PDP contract and PBPs under another PDP contract are prohibited unless both the PDP sponsors with which CMS contracts are the same legal entity or have the same parent organization.

(ii) Plan crosswalks are prohibited that split the enrollment of one PBP into multiple PBPs.

(iii) Plan crosswalks are prohibited from a PBP offering basic prescription drug coverage to a PBP offering enhanced alternative coverage.

(3) *Compliance with renewal/non-renewal rules.* The PDP sponsor must comply with renewal and non-renewal rules in §§ 423.506 and 423.507 in order to complete plan crosswalks.

(4) *Eligibility.* Enrollees must be eligible for enrollment under § 423.30 in order to be moved from one PBP to another PBP.

(5) *Applicability to Employer group health or waiver plans.* Nothing in this section permits the crosswalk of enrollees in an employer group health or waiver plan PBP to another PBP outside the usual process for enrollment in employer group health or waiver plans.

(b) *Mandatory plan crosswalks.* A Part D sponsor of a PDP must perform a plan crosswalk in the following circumstances:

(1) *Renewal of a PBP offering basic prescription drug coverage.* A PDP sponsor that plans to continue operating a PBP offering basic prescription coverage in the same service area for the upcoming contract year must crosswalk enrollment from the PBP offering basic prescription drug coverage in the current contract year into a PBP offering basic prescription drug coverage under the same PDP contract in the upcoming contract year. The PBP for the upcoming contract year must retain the same plan ID as the PBP for the current contract year.

(2) *Renewal of a PBP offering enhanced alternative drug coverage.* A PDP sponsor that plans to continue operating a

PBP offering enhanced alternative coverage in the same service area for the upcoming contract year must crosswalk enrollment from the PBP offering enhanced alternative drug coverage in the current contract year into a PBP offering enhanced alternative drug coverage in the upcoming contract year. The PBP for the upcoming contract year PBP must retain the same plan ID as the PBP for the current contract year.

(c) *Plan crosswalk exceptions.* A Part D sponsor of a PDP may perform a plan crosswalk in the following circumstances after receiving approval from CMS under the procedures described in paragraph (d) of this section.

(1) *Consolidated renewals.* If a PDP sponsor wishes to non-renew a PBP offering enhanced alternative prescription drug coverage under a PDP contract that is not non-renewing or reducing its service area so that the contract no longer includes the service area of the non-renewing PBP, it may crosswalk enrollment from the non-renewing PBP into a PBP offered under the contract in the upcoming contract year.

(i) The plan ID for the upcoming contract year PBP must be the same plan ID as one of PBPs for the current contract year.

(ii) The PBPs being consolidated must be under the same PDP contract.

(iii) A PBP offering basic prescription drug coverage may not be discontinued if the PDP contract continues to offer coverage (other than employer group waiver plans) in the service area of the PBP.

(iv) Enrollment from a PBP offering enhanced alternative coverage may be crosswalked into a PBP offering either enhanced alternative or basic prescription drug coverage.

(v) If the PDP contract includes more than one renewing PBP into which enrollment of the non-renewing PBP can be crosswalked, the enrollment of the non-renewing PBP must be crosswalked into the renewing PBP that will result in lowest increase in monthly premiums for the enrollees.

(vi) A plan crosswalk is not approved under this paragraph if it will result in a premium increase for the following benefit year (as reflected in the bid for the receiving PBP submitted on the first Monday in June) that is higher than the greater of the following:

(A) The current year's premium for the non-renewing PBP.

(B) The current year's average base beneficiary premium, as described in § 423.286(c) of this part, for the PDP region in which the PBP operates.

(vii) If an organization that non-renews an enhanced alternative PBP does not request and receive a plan crosswalk exception as provided in paragraph (d) of this section, CMS does not approve a new enhanced alternative PBP in the same service area as the non-renewing PBP in the following contract year.

(2) *Contract consolidations.* If a PDP sponsor non-renews all or part of the service area of its contract with CMS in accordance with §§ 423.507 or 423.508, the enrollees of the non-renewing PBPs may be crosswalked into one or more PBPs in another PDP contract (the surviving contract).

(i) The non-renewing PDP contract and the surviving contract must be held by the same legal entity or by legal entities with the same parent organization.

(ii) The approved service area of the surviving contract must include the service area of the non-renewing PBPs whose enrollment will be crosswalked into the surviving contract.

(iii) Enrollment may be crosswalked between PBPs offering the same type of prescription drug coverage (basic or enhanced alternative).

(iv) Enrollment from a PBP offering enhanced alternative coverage may be crosswalked into a PBP offering basic prescription drug coverage.

(v) Enrollment from a PBP offering enhanced alternative coverage must be crosswalked into the PBP in the surviving contract that will result in the lowest premium increase.

(vi) A plan crosswalk is not approved under this paragraph if it will result in a premium increase for the following benefit year (as reflected in the bid for the receiving PBP submitted on the first Monday in June) that is higher than the greater of:

(A) The current year's premium for the non-renewing PBP, or

(B) The current year's average base beneficiary premium, as described in § 423.286(c), for the region in which the PBP operates.

(d) *Procedures.* (1) A PDP sponsor must submit the following:

(i) All plan crosswalks described in paragraph (b) of this section in writing through the bid submission process in HPMS by the bid submission deadline.

(ii) All plan crosswalk exception requests described in paragraph (c) of this section in writing through the plan crosswalk exceptions process in HPMS by the plan crosswalk exception request deadline announced annually by CMS.

(2) CMS verifies the requests and notifies a requesting PDP sponsor of the approval or denial after the crosswalk exception request deadline.

[89 FR 30839, Apr. 23, 2024]

Subpart L—Effect of Change of Ownership or Leasing of Facilities During Term of Contract

§ 423.551 General provisions.

(a) *Change of ownership.* The following constitute a change of ownership:

(1) *Partnership.* The removal, addition, or substitution of a partner, unless the partners expressly agree otherwise as permitted by applicable State law, constitutes a change of ownership.

(2) *Asset transfer.* Transfer of substantially all the assets of the sponsor to another party constitutes a change of ownership.

(3) *Corporation.* The merger of the PDP sponsor's corporation into another corporation or the consolidation of the PDP sponsor's organization with one or more other corporations, resulting in a new corporate body.

(b) *Change of ownership, exception.* Transfer of corporate stock or the merger of another corporation into the PDP sponsor's corporation, with the PDP sponsor surviving, does not ordinarily constitute change of ownership.

(c) *Advance notice requirement.* (1) A PDP sponsor that has a Medicare contract in effect under § 423.502 and is considering or is negotiating a change in ownership must notify CMS at least 60 days before the anticipated effective date of the change. The PDP sponsor must also provide updated financial information and a discussion of the financial and solvency impact of the change of ownership on the surviving organization.

(2) If the PDP sponsor fails to give CMS the required notice in a timely manner, it continues to be liable for payments that CMS makes to it on behalf of Medicare enrollees after the date of change of ownership.

(d) *Novation agreement defined.* A novation agreement is an agreement among the current owner of the PDP sponsor, the prospective new owner, and CMS that—

(1) Is embodied in a document executed and signed by all 3 parties;

(2) Meets the requirements of § 423.552; and

(3) Recognizes the new owner as the successor in interest to the current owner's Medicare contract.

(e) *Effect of change of ownership without novation agreement.* Except to the extent provided in paragraph (c)(2) of this section, the effect of a change of ownership without a novation agreement is that—

(1) The current PDP sponsor, with respect to the affected contract, has substantially failed to comply with the regulatory requirements as described in § 423.509(a)(4)(ix) and the contract may be subject to intermediate enrollment and marketing sanctions as outlined in § 423.750(a)(1) and (a)(3). Intermediate sanctions imposed as part of this section remain in place until CMS approves the change of ownership (including execution of an approved novation agreement), or the contract is terminated.

(i)(A) If the new owner does not participate in the Medicare program in the same service area as the affected contract, it must apply for, and enter into, a contract in accordance with subpart K of this part and part 422 if applicable; and

(B) If the application is conditionally approved, must submit, within 30 days of the conditional approval, the documentation required under § 423.551(d) for review and approval by CMS; or

(ii) If the new owner currently participates in the Medicare program and

operates in the same service area as the affected contract, it must, within 30 days of imposition of intermediate sanctions as outlined in paragraph (e)(1) of this section, submit the documentation required under § 423.551(d) for review and approval by CMS.

(2) If the new owner fails to begin the processes required under paragraph (e)(1)(i) or (e)(1)(ii) of this section, within 30 days of imposition of intermediate sanctions as outlined in paragraph (e)(1) of this section, the existing contract is subject to termination in accordance with § 423.509(a)(4)(ix).

(f) *Effect of change of ownership with novation agreement.* If the PDP sponsor submits a novation agreement that meets the requirements of § 423.552 and CMS signs it, the new owner becomes the successor in interest to the current owner's Medicare contract under § 423.502.

(g) *Sale of beneficiaries not permitted.* (1) CMS will only recognize the sale or transfer of an organization's entire PDP line of business, consisting of all PDP contracts held by the PDP sponsor with the exception of the sale or transfer of a full contract between wholly owned subsidiaries of the same parent organization which will be recognized and allowed by CMS.

(2) CMS does not recognize or allow a sale or transfer that consists solely of the sale or transfer of individual beneficiaries or groups of beneficiaries enrolled in a plan benefit package.

[70 FR 4525, Jan. 28, 2005, as amended at 74 FR 1546, Jan. 12, 2009; 75 FR 19822, Apr. 15, 2010; 75 FR 32860, June 10, 2010; 86 FR 6119, Jan. 19, 2021; 89 FR 30840, Apr. 23, 2024]

§ 423.552 Novation agreement requirements.

(a) *Conditions for CMS approval of a novation agreement.* CMS approves a novation agreement if the following conditions are met:

(1) *Advance notification.* The PDP sponsor notifies CMS at least 60 days before the date of the proposed change of ownership. The PDP sponsor also provides CMS with updated financial information and a discussion of the financial and solvency impact of the change of ownership on the surviving organization.

(2) *Advance submittal of agreement.* The PDP sponsor submits to CMS, at least 30 days before the proposed change of ownership date, three signed copies of the novation agreement containing the provisions specified in paragraph (b) of this section, and one copy of other relevant documents required by CMS.

(3) *CMS's determination.* When reviewing a novation agreement, CMS makes a determination concerning the following:

(i) The proposed new owner is in fact a successor in interest to the contract.

(ii) Recognition of the new owner as a successor in interest to the contract is in the best interest of the Medicare program.

(iii) The successor organization meets the requirements to qualify as a PDP sponsor under subpart K of this part.

(b) *Provisions of a novation agreement.* A valid novation agreement requires the following:

(1) *Assumption of contract obligations.* The new owner must assume all obligations under the contract.

(2) *Waiver of right to reimbursement.* The previous owner must waive its rights to reimbursement for covered services furnished during the rest of the current contract period.

(3) *Guarantee of performance.* The previous owner must—

(i) Guarantee performance of the contract by the new owner during the contract period; or

(ii) Post a performance bond that is satisfactory to CMS.

(4) *Records access.* The previous owner must agree to make its books and records and other necessary information available to the new owner and to CMS to permit an accurate determination of costs for the final settlement of the contract period.

§ 423.553 Effect of leasing of a PDP sponsor's facilities.

(a) *General effect of leasing.* If a PDP sponsor leases all or part of its facilities to another entity, the other entity does not acquire PDP sponsor status under section 1860D–12(b) of the Act.

(b) *Effect of lease of all facilities.* (1) If a PDP sponsor leases all of its facilities

to another entity, the contract terminates.

(2) If the other entity wishes to participate in Medicare as a PDP sponsor, it must apply for and enter into a contract in accordance with § 423.502.

(c) *Effect of partial lease of facilities.* If the PDP sponsor leases part of its facilities to another entity, its contract with CMS remains in effect while CMS surveys the PDP sponsor to determine whether it continues to be in compliance with the applicable requirements and qualifying conditions specified in subpart K of this part.

Subpart M—Grievances, Coverage Determinations, Redeterminations, and Reconsiderations

§ 423.558 Scope.

(a) This subpart sets forth the requirements relating to the following:

(1) Part D plan sponsors with respect to grievances, coverage determinations, and redeterminations.

(2) Part D IRE with respect to reconsiderations.

(3) Part D enrollees' rights with respect to grievances, coverage determinations, redeterminations, and reconsiderations.

(4) Review of at-risk determinations made under a drug management program in accordance with § 423.153(f).

(b) The requirements regarding reopenings, ALJ hearings and ALJ and attorney adjudicator decisions, Council review, and judicial review are set forth in subpart U of this chapter.

[74 FR 65363, Dec. 9, 2009, as amended at 82 FR 5125, Jan. 17, 2017; 83 FR 16750, Apr. 16, 2018]

§ 423.560 Definitions.

As used in this subpart, unless the context indicates otherwise—

Appeal means any of the procedures that deal with the review of adverse coverage determinations made by the Part D plan sponsor on the benefits under a Part D plan the enrollee believes he or she is entitled to receive, including delay in providing or approving the drug coverage (when a delay would adversely affect the health of the enrollee), or on any amounts the enrollee must pay for the drug coverage, as defined in § 423.566(b). Appeal also includes the review of at-risk determinations made under a drug management program in accordance with § 423.153(f). These procedures include redeterminations by the Part D plan sponsor, reconsiderations by the independent review entity, ALJ hearings, reviews by the Medicare Appeals Council (Council), and judicial reviews.

At-risk determination means a decision made under a plan sponsor's drug management program in accordance with § 423.153(f) that involves the identification of an individual as an at-risk beneficiary for prescription drug abuse; a limitation, or the continuation of a limitation, on an at-risk beneficiary's access to coverage for frequently abused drugs (that is, a beneficiary specific point-of-sale edit or the selection of a prescriber and/or pharmacy and implementation of lock-in, or); and information sharing for subsequent plan enrollments.

Drug Use means an enrollee is receiving the drug in the course of treatment, including time off if it is part of the treatment.

Enrollee means a Part D eligible individual who has elected or has been enrolled in a Part D plan.

Grievance means any complaint or dispute, other than one that involves a coverage determination or at-risk determination, expressing dissatisfaction with any aspect of the operations, activities, or behavior of a Part D plan sponsor, regardless of whether remedial action is requested.

Other prescriber means a health care professional other than a physician who is authorized under State law or other applicable law to write prescriptions.

Physician has the meaning given the term in section 1861(r) of the Act.

Projected value of a Part D drug or drugs includes any costs the enrollee could incur based on the number of refills prescribed for the drug(s) in dispute during the plan year. Projected value includes enrollee co-payments, all expenditures incurred after an enrollee's expenditures exceed the initial coverage limit, and expenditures paid by other entities.

Reconsideration means a review of an adverse coverage determination or at-risk determination by an independent review entity (IRE), the evidence and findings upon which it was based, and any other evidence the enrollee submits or the IRE obtains.

Redetermination means a review of an adverse coverage determination or at-risk determination by a Part D plan sponsor, the evidence and findings upon which it is based, and any other evidence the enrollee submits or the Part D plan sponsor obtains.

Representative means an individual either appointed by an enrollee or authorized under State or other applicable law to act on behalf of the enrollee in filing a grievance, obtaining a coverage determination, or in dealing with any of the levels of the appeals process. Unless otherwise stated in this subpart, the representative has all of the rights and responsibilities of an enrollee in filing a grievance, obtaining a coverage determination, or in dealing with any of the levels of the appeals process, subject to the rules described in part 422, subpart M, of this chapter.

Specialty tier: (1) Before January 1, 2022, means a formulary cost-sharing tier dedicated to very high cost Part D drugs that exceed a cost threshold established by the Secretary; and

(2) Beginning January 1, 2022, has the meaning given the term in § 423.104.

[70 FR 4525, Jan. 28, 2005, as amended at 73 FR 20507, Apr. 15, 2008; 74 FR 1546, Jan. 12, 2009; 82 FR 5125, Jan. 17, 2017; 83 FR 16750, Apr. 16, 2018; 86 FR 6119, Jan. 19, 2021]

§ 423.562 General provisions.

(a) *Responsibilities of the Part D plan sponsor.* A Part D plan sponsor must meet all of the following requirements.

(1) A Part D plan sponsor, for each Part D plan that it offers, must establish and maintain—

(i) A grievance procedure as described in § 423.564 for addressing issues that do not involve coverage determinations;

(ii) Use a single, uniform exceptions and appeals process which includes procedures for accepting oral and written requests for coverage determinations and redeterminations that are in accordance with § 423.128(b)(7) and (d)(1)(iv).

(iii) A procedure for making timely coverage determinations, including determinations on requests for exceptions to a tiered cost-sharing structure or to a formulary; and

(iv) Appeal procedures that meet the requirements of this subpart for issues that involve coverage determinations.

(v) Appeal procedures that meet the requirements of this subpart for issues that involve at-risk determinations. Determinations made in accordance with the processes at § 423.153(f) are collectively referred to as an at-risk determination, defined at § 423.560, made under a drug management program.

(2) A Part D plan sponsor must ensure that all enrollees receive written information about the—

(i) Grievance and appeal procedures that are available to them through the Part D plan sponsor; and

(ii) Complaint process available to the enrollee under the QIO process as set forth under section 1154(a)(14) of the Act.

(3) A Part D plan sponsor must arrange with its network pharmacies to distribute notices instructing enrollees how to contact their plans to obtain a coverage determination or request an exception. These notices must comply with the standards established in § 423.128(b)(7)(iii).

(4) In accordance with subpart K of this part, if the Part D plan sponsor delegates any of its responsibilities under this subpart to another entity or individual through which the Part D plan sponsor provides covered benefits, the Part D plan sponsor is ultimately responsible for ensuring that the entity or individual satisfies the relevant requirements of this subpart.

(5) A Part D plan sponsor must employ a medical director who is responsible for ensuring the clinical accuracy of all coverage determinations and redeterminations involving medical necessity. The medical director must be a physician with a current and unrestricted license to practice medicine in a State, Territory, Commonwealth of the United States (that is, Puerto Rico), or the District of Columbia.

(b) *Rights of enrollees.* In accordance with the provisions of this subpart, enrollees have all of the following rights under Part D plans:

(1) The right to have grievances between the enrollee and the Part D plan sponsor heard and resolved by the plan sponsor, as described in § 423.564.

(2) The right to a timely coverage determination by the Part D plan sponsor, as specified in § 423.566 and § 423.568, including the right to request from the Part D plan sponsor an exception to its tiered cost-sharing structure or formulary, as specified in § 423.578.

(3) The right to request from the Part D plan sponsor an expedited coverage determination, as specified in § 423.570.

(4) If dissatisfied with any part of a coverage determination or an at-risk determination under a drug management program in accordance with § 423.153(f), all of the following appeal rights:

(i) The right to a redetermination of the adverse coverage determination or at-risk determination by the Part D plan sponsor, as specified in § 423.580.

(ii) The right to request an expedited redetermination, as provided under § 423.584.

(iii) If, as a result of the redetermination, a Part D plan sponsor affirms, in whole or in part, its adverse coverage determination or at-risk determination, the right to a reconsideration or expedited reconsideration by an independent review entity (IRE) contracted by CMS, as specified in § 423.600.

(iv) If the IRE affirms the plan's adverse coverage determination or at-risk determination, in whole or in part, the right to an ALJ hearing if the amount in controversy meets the requirements in § 423.2006.

(v) If the ALJ or attorney adjudicator affirms the IRE's adverse coverage determination or at-risk determination, in whole or in part, the right to request Council review of the ALJ's or attorney adjudicator's decision, as specified in § 423.2100.

(vi) If the Council affirms the ALJ's or attorney adjudicator's adverse coverage determination or at-risk determination, in whole or in part, the right to judicial review of the decision if the amount in controversy meets the requirements in § 423.2006.

(c) *When other regulations apply.* Unless this subpart provides otherwise, the regulations in part 422, subpart M of this chapter (concerning the administrative review and hearing processes under titles II and XVIII, and representation of parties under title XVIII of the Act) and any interpretive rules or CMS rulings issued under these regulations, apply under this subpart to the extent they are appropriate.

(d) *Relation to ERISA Requirements.* Consistent with section 1860D–22(b) of the Act, provisions of this subpart may, to the extent applicable under the regulations adopted by the Secretary of Labor, apply to claims for benefits under group health plans subject to the Employee Retirement Income Security Act.

[70 FR 4525, Jan. 28, 2005, as amended at 74 FR 65363, Dec. 9, 2009; 76 FR 21575, Apr. 15, 2011; 80 FR 7965, Feb. 12, 2015; 82 FR 5125, Jan. 17, 2017; 83 FR 16751, Apr. 16, 2018; 84 FR 19872, May 7, 2019; 89 FR 30841, Apr. 23, 2024]

§ 423.564 Grievance procedures.

(a) *General rule.* Each Part D plan sponsor must provide meaningful procedures for timely hearing and resolving grievances between enrollees and the Part D plan sponsor or any other entity or individual through whom the Part D plan sponsor provides covered benefits under any Part D plan it offers.

(b) *Distinguished from appeals.* Grievance procedures are separate and distinct from appeal procedures, which address coverage determinations as defined in § 423.566(b) and at-risk determinations made under a drug management program in accordance with § 423.153(f). Upon receiving a complaint, a Part D plan sponsor must promptly determine and inform the enrollee whether the complaint is subject to its grievance procedures or its appeal procedures.

(c) *Distinguished from the quality improvement organization complaint process.* Under section 1154(a)(14) of the Act, the quality improvement organization (QIO) must review enrollees' written complaints about the quality of services they have received under the Medicare program. This process is separate and distinct from the grievance procedures of the Part D plan sponsor. For quality of care issues, an enrollee may file a grievance with the Part D plan sponsor, file a written complaint with the QIO, or both. For any complaint

submitted to a QIO, the Part D plan sponsor must cooperate with the QIO in resolving the complaint.

(d) *Method for filing a grievance.* (1) An enrollee may file a grievance with the Part D plan sponsor either orally or in writing.

(2) An enrollee must file a grievance no later than 60 calendar days after the event or incident that precipitates the grievance.

(e) *Grievance disposition and notification.* (1) The Part D plan sponsor must notify the enrollee of its decision as expeditiously as the case requires, based on the enrollee's health status, but no later than 30 calendar days after the date the Part D plan sponsor receives the oral or written grievance.

(2) The Part D plan sponsor may extend the 30 calendar day timeframe by up to 14 calendar days if the enrollee requests the extension or if the Part D plan sponsor justifies a need for additional information and documents how the delay is in the interest of the enrollee. When the Part D plan sponsor extends the deadline, it must immediately notify the enrollee in writing of the reason(s) for the delay.

(3) The Part D plan sponsor must inform the enrollee of the disposition of the grievance in accordance with the following procedures:

(i) All grievances submitted in writing must be responded to in writing.

(ii) Grievances submitted orally may be responded to either orally or in writing, unless the enrollee requests a written response.

(iii) All grievances related to quality of care, regardless of how the grievance is filed, must be responded to in writing. The response must include a description of the enrollee's right to file a written complaint with the QIO. For any complaint submitted to a QIO, the Part D plan sponsor must cooperate with the QIO in resolving the complaint.

(f) *Expedited grievances.* A Part D plan sponsor must respond to an enrollee's grievance within 24 hours if the complaint involves a refusal by the Part D plan sponsor to grant an enrollee's request for an expedited coverage determination under § 423.570 or an expedited redetermination under § 423.584, and the enrollee has not yet purchased or received the drug that is in dispute.

(g) *Record keeping.* The Part D plan sponsor must have an established process to track and maintain records on all grievances received both orally and in writing, including, at a minimum, the date of receipt, final disposition of the grievance, and the date that the enrollee was notified of the disposition.

[70 FR 4525, Jan. 28, 2005, as amended at 74 FR 65363, Dec. 9, 2009; 83 FR 16751, Apr. 16, 2018]

§ 423.566 Coverage determinations.

(a) *Responsibilities of the Part D plan sponsor.* Each Part D plan sponsor must have a procedure for making timely coverage determinations in accordance with the requirements of this subpart regarding the prescription drug benefits an enrollee is entitled to receive under the plan, including basic prescription drug coverage as specified in § 423.100 and supplemental benefits as specified in § 423.104(f)(1)(ii), and the amount, including cost sharing, if any, that the enrollee is required to pay for a drug. The Part D plan sponsor must have a standard procedure for making determinations, in accordance with § 423.568, and an expedited procedure for situations in which applying the standard procedure may seriously jeopardize the enrollee's life, health, or ability to regain maximum function, in accordance with § 423.570.

(b) *Actions that are coverage determinations.* The following actions by a Part D plan sponsor are coverage determinations:

(1) A decision not to provide or pay for a Part D drug (including a decision not to pay because the drug is not on the plan's formulary, because the drug is determined not to be medically necessary, because the drug is furnished by an out-of-network pharmacy, or because the Part D plan sponsor determines that the drug is otherwise excludable under section 1862(a) of the Act if applied to Medicare Part D) that the enrollee believes may be covered by the plan;

(2) Failure to provide a coverage determination in a timely manner, when a delay would adversely affect the health of the enrollee;

(3) A decision concerning an exceptions request under § 423.578(a);

(4) A decision concerning an exceptions request under § 423.578(b); or

(5) A decision on the amount of cost sharing for a drug.

(c) Who can request a coverage determination. Individuals who can request a standard or expedited coverage determination are—

(1) The enrollee;

(2) The enrollee's representative, on behalf of the enrollee; or

(3) The prescribing physician or other prescriber, on behalf of the enrollee.

(d) *Who must review coverage determinations.* If the Part D plan sponsor expects to issue a partially or fully adverse medical necessity (or any substantively equivalent term used to describe the concept of medical necessity) decision based on the initial review of the request, the coverage determination must be reviewed by a physician or other appropriate health care professional with sufficient medical and other expertise, including knowledge of Medicare coverage criteria, before the Part D plan sponsor issues the coverage determination decision. The physician or other health care professional must have a current and unrestricted license to practice within the scope of his or her profession in a State, Territory, Commonwealth of the United States (that is, Puerto Rico), or the District of Columbia.

[70 FR 4525, Jan. 28, 2005, as amended at 74 FR 1546, Jan. 12, 2009; 76 FR 21576, Apr. 15, 2011; 86 FR 6119, Jan. 19, 2021]

§ 423.568 Standard timeframe and notice requirements for coverage determinations.

(a) *Method and place for filing a request.* An enrollee must ask for a standard coverage determination by making a request with the Part D plan sponsor in accordance with the following:

(1) Except as specified in paragraph (a)(2) of this section, the request may be made orally or in writing.

(2) Requests for payment must be made in writing (unless the Part D plan sponsor has implemented a voluntary policy of accepting oral payment requests).

(3) The Part D plan sponsor must establish and maintain a method of documenting all oral requests and retain the documentation in the case file.

(b) *Timeframe for requests for drug benefits.* When a party makes a request for a drug benefit, the Part D plan sponsor must notify the enrollee (and the prescribing physician or other prescriber involved, as appropriate) of its determination as expeditiously as the enrollee's health condition requires, but no later than 72 hours after receipt of the request. For an exceptions request, the Part D plan sponsor must notify the enrollee (and the prescribing physician or other prescriber involved, as appropriate) of its determination as expeditiously as the enrollee's health condition requires, but no later than 72 hours after receipt of the physician's or other prescriber's supporting statement. If a supporting statement is not received by the end of 14 calendar days from receipt of the exceptions request, the Part D plan sponsor must notify the enrollee (and the prescribing physician or other prescriber involved, as appropriate) of its determination as expeditiously as the enrollee's health condition requires, but no later than 72 hours from the end of 14 calendar days from receipt of the exceptions request.

(c) *Timeframe for requests for payment.* When a party makes a request for payment, the Part D plan sponsor must notify the enrollee of its determination and make payment (when applicable) no later than 14 calendar days after receipt of the request.

(d) *Written notice for favorable decisions by a Part D plan sponsor.* If a Part D plan sponsor makes a completely favorable decision under paragraph (b) of this section, it must give the enrollee written notice of the determination. The initial notice may be provided orally, so long as a written follow-up notice is sent within 3 calendar days of the oral notification.

(e) *Form and content of the approval notice.* The notice of any approval under paragraph (d) of this section must explain the conditions of the approval in a readable and understandable form.

(f) *Written notice for denials by a Part D plan sponsor.* If a Part D plan sponsor decides to deny a drug benefit, in whole or in part, it must give the enrollee written notice of the determination.

The initial notice may be provided orally, so long as a written follow-up notice is mailed to the enrollee within 3 calendar days of the oral notification.

(g) *Form and content of the denial notice.* The notice of any denial under paragraph (f) of this section must meet the following requirements:

(1) Use approved notice language in a readable and understandable form.

(2) State the specific reasons for the denial.

(i) For drug coverage denials, describe both the standard and expedited redetermination processes, including the enrollee's right to, and conditions for, obtaining an expedited redetermination and the rest of the appeals process.

(ii) For payment denials, describe the standard redetermination process and the rest of the appeals process.

(3) Inform the enrollee of his or her right to a redetermination.

(4) Comply with any other notice requirements specified by CMS.

(h) *Effect of failure to meet the adjudicatory timeframes.* If the Part D plan sponsor fails to notify the enrollee of its determination in the appropriate timeframe under paragraphs (b) or (c) of this section, the failure constitutes an adverse coverage determination, and the plan sponsor must forward the enrollee's request to the IRE within 24 hours of the expiration of the adjudication timeframe.

(i) *Dismissing a request.* The Part D plan sponsor dismisses a coverage determination request, either entirely or as to any stated issue, under any of the following circumstances:

(1) When the individual making the request is not permitted to request a coverage determination under § 423.566(c).

(2) When the Part D plan sponsor determines the party failed to make out a valid request for a coverage determination that substantially complies with paragraph (a) of this section.

(3) When an enrollee or the enrollee's representative files a request for a coverage determination, but the enrollee dies while the request is pending, and both of the following criteria apply:

(i) The enrollee's surviving spouse or estate has no remaining financial interest in the case.

(ii) The enrollee's representative, if any, does not wish to pursue the request for coverage.

(4) When a party filing the coverage determination request submits a timely request for withdrawal of the request for a coverage determination with the Part D plan sponsor.

(j) *Notice of dismissal.* The Part D plan must mail or otherwise transmit a written notice of the dismissal of the coverage determination request to the parties. The notice must state all of the following:

(1) The reason for the dismissal.

(2) The right to request that the Part D plan sponsor vacate the dismissal action.

(3) The right to request redetermination of the dismissal.

(k) *Vacating a dismissal.* If good cause is established, the Part D plan sponsor may vacate its dismissal of a request for coverage determination within 6 months from the date of the notice of dismissal.

(l) *Effect of dismissal.* The Part D plan sponsor's dismissal is binding unless it is modified or reversed by the Part D plan sponsor or vacated under paragraph (k) of this section.

(m) *Withdrawing a request.* A party that requests a coverage determination may withdraw its request at any time before the decision is issued by filing a request with the Part D plan sponsor.

[75 FR 19823, Apr. 15, 2010, as amended at 76 FR 21576, Apr. 15, 2011; 84 FR 15843, Apr. 16, 2019; 86 FR 6119, Jan. 19, 2021; 86 FR 29528, June 2, 2021]

§ 423.570 Expediting certain coverage determinations.

(a) *Request for expedited determination.* An enrollee or an enrollee's prescribing physician or other prescriber may request that a Part D plan sponsor expedite a coverage determination involving issues described in § 423.566(b) of this part. This does not include requests for payment of Part D drugs already furnished.

(b) *How to make a request.* (1) To ask for an expedited determination, an enrollee or an enrollee's prescribing physician or other prescriber on behalf of the enrollee must submit an oral or written request directly to the Part D plan sponsor or, if applicable, to the

entity responsible for making the determination, as directed by the Part D plan sponsor.

(2) A prescribing physician or other prescriber may provide oral or written support for an enrollee's request for an expedited determination.

(c) *How the Part D plan sponsor must process requests.* The Part D plan sponsor must establish and maintain the following procedures for processing requests for expedited determinations:

(1) An efficient and convenient means for accepting oral or written requests submitted by enrollees, prescribing physicians, or other prescribers.

(2) A method for documenting all oral requests and maintaining the documentation in the case file; and

(3) A means for issuing prompt decisions on expediting a determination, based on the following requirements:

(i) For a request made by an enrollee, provide an expedited determination if it determines that applying the standard timeframe for making a determination may seriously jeopardize the life or health of the enrollee or the enrollee's ability to regain maximum function.

(ii) For a request made or supported by an enrollee's prescribing physician or other prescriber, provide an expedited determination if the physician or other prescriber indicates that applying the standard timeframe for making a determination may seriously jeopardize the life or health of the enrollee or the enrollee's ability to regain maximum function.

(d) *Actions following denial.* If a Part D plan sponsor denies a request for expedited determination, it must take the following actions:

(1) Make the determination within the 72-hour timeframe established in §423.568(b) for a standard determination. The 72-hour period begins on the day the Part D plan sponsor receives the request for expedited determination. For an exceptions request, the Part D plan sponsor must notify the enrollee (and the prescribing physician or other prescriber involved, as appropriate) of its determination as expeditiously as the enrollee's health condition requires, but no later than 72 hours after receipt of the physician's or other prescriber's supporting statement. If a supporting statement is not received by the end of 14 calendar days from receipt of the exceptions request, the Part D plan sponsor must notify the enrollee (and the prescribing physician or other prescriber involved, as appropriate) of its determination as expeditiously as the enrollee's health condition requires, but no later than 72 hours from the end of 14 calendar days from receipt of the exceptions request.

(2) Give the enrollee and prescribing physician or other prescriber prompt oral notice of the denial that—

(i) Explains that the Part D plan sponsor must process the request using the 72 hour timeframe for standard determinations;

(ii) Informs the enrollee of the right to file an expedited grievance if he or she disagrees with the decision by the Part D plan sponsor not to expedite;

(iii) Informs the enrollee of the right to resubmit a request for an expedited determination with the prescribing physician's or other prescriber's support and

(iv) Provides instructions about the plan's grievance process and its timeframes.

(3) Subsequently deliver to the enrollee, within 3 calendar days, equivalent written notice.

(e) *Actions on accepted requests for expedited determination.* If a Part D plan sponsor grants a request for expedited determination, it must make the determination and give notice in accordance with §423.572.

(f) *Dismissing a request.* The Part D plan sponsor dismisses an expedited coverage determination in accordance with §423.568.

[70 FR 4525, Jan. 28, 2005, as amended at 73 FR 20507, Apr. 15, 2008; 74 FR 1546, Jan. 12, 2009; 75 FR 19823, Apr. 15, 2010; 84 FR 15843, Apr. 16, 2019; 86 FR 6120, Jan. 19, 2021]

§ 423.572 Timeframes and notice requirements for expedited coverage determinations.

(a) *Timeframe for determination and notification.* Except as provided in paragraph (b) of this section, a Part D plan sponsor that approves a request for expedited determination must make its determination and notify the enrollee (and the prescribing physician or other prescriber involved, as appropriate) of

its decision, whether adverse or favorable, as expeditiously as the enrollee's health condition requires, but no later than 24 hours after receiving the request. For an exceptions request, the Part D plan sponsor must notify the enrollee (and the prescribing physician or other prescriber involved, as appropriate) of its determination as expeditiously as the enrollee's health condition requires, but no later than 24 hours after receipt of the physician's or other prescriber's supporting statement. If a supporting statement is not received by the end of 14 calendar days from receipt of the exceptions request, the Part D plan sponsor must notify the enrollee (and the prescribing physician or other prescriber involved, as appropriate) of its determination as expeditiously as the enrollee's health condition requires, but no later than 24 hours from the end of 14 calendar days from receipt of the exceptions request.

(b) *Confirmation of oral notice.* If the Part D plan sponsor first notifies an enrollee of an adverse or favorable expedited determination orally, it must mail written confirmation to the enrollee within 3 calendar days of the oral notification.

(c) *Content of the notice of expedited determination.* (1) If the determination is completely favorable to the enrollee, the notice must explain the conditions of the approval in a readable and understandable form.

(2) If the determination is not completely favorable to the enrollee, the notice must—

(i) Use approved language in a readable and understandable form;

(ii) State the specific reasons for the denial;

(iii) Inform the enrollee of his or her right to a redetermination;

(iv) Describe—

(A) Both the standard and expedited redetermination processes, including the enrollee's right to request an expedited redetermination;

(B) Conditions for obtaining an expedited redetermination; and

(C) Other aspects of the appeal process.

(d) *Effect of failure to meet the adjudicatory timeframes.* If the Part D plan sponsor fails to notify the enrollee of its determination in the timeframe specified in paragraph (a) of this section, the failure constitutes an adverse coverage determination, and the Part D plan sponsor must forward the enrollee's request to the IRE within 24 hours of the expiration of the adjudication timeframe.

[70 FR 4525, Jan. 28, 2005, as amended at 74 FR 1564, Jan. 12, 2009; 75 FR 19823, Apr. 15, 2010; 84 FR 15843, Apr. 16, 2019]

§ 423.576 Effect of a coverage determination.

The coverage determination is binding on the Part D plan sponsor and the enrollee unless it is reviewed and revised under §§ 423.580 through 423.604 and §§ 423.2000 through 423.2140 or is reopened and revised under § 423.1978.

[70 FR 4525, Jan. 28, 2005, as amended at 74 FR 65363, Dec. 9, 2009; 84 FR 19872, May 7, 2019]

§ 423.578 Exceptions process.

(a) *Requests for exceptions to a plan's tiered cost-sharing structure.* Each Part D plan sponsor that provides prescription drug benefits for Part D drugs and manages this benefit through the use of a tiered formulary must establish and maintain reasonable and complete exceptions procedures subject to CMS' approval for this type of coverage determination. The Part D plan sponsor grants an exception whenever it determines that the requested non-preferred drug for treatment of the enrollee's condition is medically necessary, consistent with the physician's or other prescriber's statement under paragraph (a)(4) of this section.

(1) The tiering exceptions procedures must address situations where a formulary's tiering structure changes during the year and an enrollee is using a drug affected by the change.

(2) Part D plan sponsors must establish criteria that provide for a tiering exception, consistent with paragraphs (a)(3) through (6) of this section.

(3) An enrollee or the enrollee's prescribing physician or other prescriber may file a request for an exception.

(4) A prescribing physician or other prescriber must provide an oral or written supporting statement that the preferred drug(s) for the treatment of the enrollee's condition—

(i) Would not be as effective for the enrollee as the requested drug;

(ii) Would have adverse effects for the enrollee; or

(iii) Both paragraphs (a)(4)(i) and (a)(4)(ii) of this section apply.

(5) If the physician or other prescriber provides an oral supporting statement, the Part D plan sponsor may require the physician or other prescriber to subsequently provide a written supporting statement. The Part D plan sponsor may require the prescribing physician or other prescriber to provide additional supporting medical documentation as part of the written follow-up.

(6) Limitations on tiering exceptions: A Part D plan sponsor is permitted to design its tiering exceptions procedures such that an exception is not approvable in the following circumstances:

(i) To cover a brand name drug, as defined in § 423.4, at a preferred cost-sharing level that applies only to alternative drugs that are—

(A) Generic drugs, for which an application is approved under section 505(j) of the Federal Food, Drug, and Cosmetic Act; or

(B) Authorized generic drugs as defined in section 505(t)(3) of the Federal Food, Drug, and Cosmetic Act.

(ii) To cover a biological product licensed under section 351 of the Public Health Service Act at a preferred cost-sharing level that does not contain any alternative drug(s) that are biological products.

(iii)(A) Before January 1, 2022, if a Part D plan sponsor maintains a specialty tier, as defined in § 423.560, the Part D sponsor may design its exception process so that Part D drugs on the specialty tier are not eligible for a tiering exception.

(B) Beginning January 1, 2022, if a Part D sponsor maintains one or two specialty tiers, as defined in § 423.104, the Part D sponsor may design its exception process so that Part D drugs on the specialty tier(s) are not eligible for tiering exception(s) to non-specialty tiers.

(b) *Request for exceptions involving a non-formulary Part D drug.* Each Part D plan sponsor that provides prescription drug benefits for Part D drugs and manages this benefit through the use of a formulary must establish and maintain exceptions procedures subject to CMS' approval for receipt of an off-formulary drug. The Part D plan sponsor must grant an exception whenever it determines that the drug is medically necessary, consistent with the physician's or other prescriber's statement under paragraph (b)(5) of this section, and that the drug would be covered but for the fact that it is an off-formulary drug. Formulary use includes the application of cost utilization tools, such as a dose restriction, including the dosage form, that causes a particular Part D drug not to be covered for the number of doses prescribed or a step therapy requirement that causes a particular Part D drug not to be covered until the requirements of the plan's coverage policy are met, or a therapeutic substitution requirement.

(1) The plan's formulary exceptions process must address each of the following circumstances:

(i) Situations where a formulary changes during the year, and situations where an enrollee is already using a given drug.

(ii) Continued coverage of a particular Part D prescription drug that the Part D plan sponsor is discontinuing coverage on the formulary for reasons other than safety or because the Part D prescription drug cannot be supplied by or was withdrawn from the market by the drug's manufacturer.

(iii) An exception to a plan's coverage policy that causes a Part D prescription drug not to be covered because of cost utilization tools, such as a requirement for step therapy, dosage limitations, or therapeutic substitution.

(2) The exception criteria of a Part D plan sponsor must include, but are not limited to—

(i) A description of the criteria a Part D plan sponsor uses to evaluate a prescribing physician's or other prescriber's determination made under paragraph (b)(5) of this section;

(ii) A process for gathering and comparing applicable medical and scientific evidence on the safety and effectiveness of the requested non-formulary drug with the formulary drug

for the enrollee, including safety information generated by an authoritative government body; and

(iii) A description of the cost-sharing scheme that will be applied when coverage is provided for a non-formulary drug.

(3) If the Part D plan sponsor covers a non-formulary drug, the cost(s) incurred by the enrollee for that drug are treated as being included for purposes of calculating and meeting the annual out-of-pocket threshold.

(4) An enrollee, the enrollee's representative, or the prescribing physician or other prescriber (on behalf of the enrollee) may file a request for an exception.

(5) A prescribing physician or other prescriber must provide an oral or written supporting statement that the requested prescription drug is medically necessary to treat the enrollee's disease or medical condition because—

(i) All of the covered Part D drugs on any tier of a plan's formulary for treatment for the same condition would not be as effective for the enrollee as the non-formulary drug, would have adverse effects for the enrollee, or both;

(ii) The prescription drug alternative(s) listed on the formulary or required to be used in accordance with step therapy requirements—

(A) Has been ineffective in the treatment of the enrollee's disease or medical condition or, based on both sound clinical evidence and medical and scientific evidence and the known relevant physical or mental characteristics of the enrollee and known characteristics of the drug regimen, is likely to be ineffective or adversely affect the drug's effectiveness or patient compliance; or

(B) Has caused or based on sound clinical evidence and medical and scientific evidence, is likely to cause an adverse reaction or other harm to the enrollee; or

(iii) The number of doses that is available under a dose restriction for the prescription drug has been ineffective in the treatment of the enrollee's disease or medical condition or, based on both sound clinical evidence and medical and scientific evidence and the known relevant physical or mental characteristics of the enrollee and known characteristics of the drug regimen, is likely to be ineffective or adversely affect the drug's effectiveness or patient compliance.

(6) If the physician or other prescriber provides an oral supporting statement, the Part D plan sponsor may require the physician or other prescriber to subsequently provide a written supporting statement. The Part D plan sponsor may require the prescribing physician or other prescriber to provide additional supporting medical documentation as part of the written follow-up.

(c) *Requirements for exceptions*—(1) *General rule.* A decision by a Part D plan sponsor concerning an exceptions request under this section constitutes a coverage determination as specified at §423.566.

(2) When a Part D plan sponsor does not make a timely decision. If the Part D plan sponsor fails to make a decision on an exceptions request and provide notice of the decision within the timeframe required under §423.568(a) or §423.572(a), as applicable, the failure constitutes an adverse coverage determination, and the Part D plan sponsor must forward the enrollee's request to the IRE within 24 hours of the expiration of the adjudication timeframe.

(3) *When a tiering exceptions request is approved.* Whenever an exceptions request made under paragraph (a) of this section is approved—

(i) The Part D plan sponsor may not require the enrollee to request approval for a refill, or a new prescription to continue using the Part D prescription drug after the refills for the initial prescription are exhausted, as long as—

(A) The enrollee's prescribing physician or other prescriber continues to prescribe the drug;

(B) The drug continues to be considered safe for treating the enrollee's disease or medical condition; and

(C) The enrollment period has not expired. If an enrollee renews his or her membership after the plan year, the plan may choose to continue coverage into the subsequent plan year.

(ii) The Part D plan sponsor must provide coverage for the approved prescription drug at the cost-sharing level that applies to preferred alternative drugs. If the plan's formulary contains

alternative drugs on multiple tiers, cost-sharing must be assigned at the lowest applicable tier, under the requirements in paragraph (a) of this section.

(4) *When a non-formulary exceptions request is approved.* Whenever an exceptions request made under § 423.578(b) is approved—

(i) The Part D plan sponsor may not require the enrollee to request approval for a refill, or a new prescription to continue using the Part D prescription drug after the refills for the initial prescription are exhausted, as long as—

(A) The enrollee's prescribing physician or other prescriber continues to prescribe the drug;

(B) The drug continues to be considered safe for treating the enrollee's disease or medical condition; and

(C) The enrollment period has not expired. If an enrollee renews his or her membership after the plan year, the plan may choose to continue coverage into the subsequent plan year.

(ii) The Part D plan sponsor must not establish a special formulary tier or co-payment or other cost-sharing requirement that is applicable only to prescription drugs approved for coverage under this section.

(iii) An enrollee may not request a tiering exception for a non-formulary prescription drug approved under § 423.578(b).

(d) Notice regarding formulary changes. Whenever a Part D plan sponsor makes any negative formulary change, as defined in § 423.100, to its CMS-approved formulary, the Part D plan sponsor must provide notice in accordance with the requirements at § 423.120(b)(5) and (f).

(e) *Limitation of the exceptions procedures to Part D drugs.* Nothing in this section may be construed to allow an enrollee to use the exceptions processes set out in this section to request or be granted coverage for a prescription drug that does not meet the definition of a Part D drug.

(f) *Implication of the physician's or other prescriber's supporting statement.* Nothing in this section should be construed to mean that the physician's or other prescriber's supporting statement required for an exceptions request will result in an automatic favorable decision.

[70 FR 4525, Jan. 28, 2005, as amended at 74 FR 1546, Jan. 12, 2009; 83 FR 16751, Apr. 16, 2018; 86 FR 6120, Jan. 19, 2021; 89 FR 30841, Apr. 23, 2024]

§ 423.580 Right to a redetermination.

An enrollee who has received a coverage determination (including one that is reopened and revised as described in § 423.1978) or an at-risk determination under a drug management program in accordance with § 423.153(f) may request that it be redetermined under the procedures described in § 423.582, which address requests for a standard redetermination. The prescribing physician or other prescriber (acting on behalf of an enrollee), upon providing notice to the enrollee, may request a standard redetermination under the procedures described in § 423.582. An enrollee or an enrollee's prescribing physician or other prescriber (acting on behalf of an enrollee) may request an expedited redetermination as specified in § 423.584.

[83 FR 16752, Apr. 16, 2018]

§ 423.582 Request for a standard redetermination.

(a) *Method and place for filing a request.* An enrollee or an enrollee's prescribing physician or other prescriber (acting on behalf of the enrollee) must ask for a redetermination by making a written request with the Part D plan sponsor that made the coverage determination or the at-risk determination under a drug management program in accordance with § 423.153(f). The Part D plan sponsor may adopt a policy for accepting oral requests.

(b) *Timeframe for filing a request.* Except as provided in paragraph (c) of this section, a request for a redetermination must be filed within 60 calendar days after receipt of the written coverage determination notice or the at-risk determination under a drug management program in accordance with § 423.153(f).

(1) The date of receipt of the coverage determination or at-risk determination is presumed to be 5 calendar days after the date of the written coverage determination or at-risk determination, unless there is evidence to the contrary.

(2) For purposes of meeting the 60-calendar day filing deadline, the request is considered as filed on the date it is received by the Part D plan sponsor or delegated entity specified in the Part D plan sponsor's written coverage determination or at-risk determination.

(c) *Extending the time for filing a request*—(1) *General rule.* If an enrollee or prescribing physician or other prescriber acting on behalf of an enrollee shows good cause, the Part D plan sponsor may extend the timeframe for filing a request for redetermination.

(2) *How to request an extension of timeframe.* If the 60 calendar day period in which to file a request for a redetermination has expired, an enrollee or a prescribing physician or other prescriber acting on behalf of an enrollee may file a request for redetermination and extension of time frame with the Part D plan sponsor. The request for redetermination and to extend the timeframe must—

(i) Be in writing; and

(ii) State why the request for redetermination was not filed on time.

(d) *Withdrawing a request.* The person who files a request for redetermination may withdraw it by filing a request with the Part D sponsor.

(e) *Dismissing a request.* A Part D plan sponsor dismisses a redetermination request, either entirely or as to any stated issue, under any of the following circumstances:

(1) When the person or entity requesting a redetermination is not a proper party under § 423.580.

(2) When the Part D plan sponsor determines the party failed to make out a valid request for redetermination that substantially complies with paragraph (a) of this section.

(3) When the party fails to file the redetermination request within the proper filing time frame in accordance with paragraph (b) of this section.

(4) When the enrollee or the enrollee's representative files a request for redetermination, but the enrollee dies while the request is pending, and both of the following criteria apply:

(i) The enrollee's surviving spouse or estate has no remaining financial interest in the case.

(ii) The enrollee's representative, if any, does not wish to pursue the request for coverage.

(5) When a party filing the redetermination request submits a timely request for withdrawal of the request for a redetermination with the Part D plan sponsor.

(f) *Notice of dismissal.* The Part D plan sponsor must mail or otherwise transmit a written notice of the dismissal of the redetermination request to the parties. The notice must state all of the following:

(1) The reason for the dismissal.

(2) The right to request that the Part D plan sponsor vacate the dismissal action.

(3) The right to request review of the dismissal by the independent entity.

(g) *Vacating a dismissal.* If good cause is established, a Part D sponsor may vacate its dismissal of a request for redetermination within 6 months from the date of the notice of dismissal.

(h) *Effect of dismissal.* The dismissal of a request for redetermination is binding unless the enrollee or other party requests review by the IRE or the decision is vacated under paragraph (g) of this section.

[74 FR 1547, Jan. 12, 2009, as amended at 74 FR 65363, Dec. 9, 2009; 83 FR 16752, Apr. 16, 2018; 86 FR 6120, Jan. 19, 2021; 89 FR 30841, Apr. 23, 2024]

§ 423.584 Expediting certain redeterminations.

(a) *Who may request an expedited redetermination.* An enrollee or an enrollee's prescribing physician or other prescriber may request that a Part D plan sponsor expedite a redetermination that involves the issues specified in § 423.566(b) or an at-risk determination made under a drug management program in accordance with § 423.153(f). (This does not include requests for payment of drugs already furnished.)

(b) *Procedure and timeframe for filing a request.* A request for a redetermination must be filed within 60 calendar days after receipt of the written coverage determination notice or at-risk determination notice. (1) To ask for an expedited redetermination, an enrollee or a prescribing physician or other prescriber acting on behalf of an enrollee must submit an oral or written request

directly to the Part D plan sponsor or, if applicable, to the entity responsible for making the redetermination, as directed by the Part D plan sponsor.

(2) A prescribing physician or other prescriber may provide oral or written support for an enrollee's request for an expedited redetermination.

(3) The date of receipt of the coverage determination or at-risk determination is presumed to be 5 calendar days after the date of the written coverage determination or at-risk determination, unless there is evidence to the contrary.

(4) For purposes of meeting the 60-calendar day filing deadline, the request is considered as filed on the date it is received by the Part D plan sponsor or delegated entity specified in the Part D plan sponsor's written coverage determination or at-risk determination.

(c) *How the Part D plan sponsor must process requests.* The Part D plan sponsor must establish and maintain the following procedures for processing requests for expedited redetermination:

(1) *Handling of requests.* The Part D plan sponsor must establish an efficient and convenient means for individuals to submit oral or written requests, document all oral requests in writing, and maintain the documentation in the case file.

(2) *Prompt decision making.* The Part D plan sponsor must promptly decide whether to expedite the redetermination or follow the timeframe for standard redetermination based on the following requirements:

(i) For a request made by an enrollee, the Part D plan sponsor must provide an expedited redetermination if it determines that applying the standard timeframe for making a redetermination may seriously jeopardize the life or health of the enrollee or the enrollee's ability to regain maximum function.

(ii) For a request made or supported by a prescribing physician or other prescriber, the Part D plan sponsor must provide an expedited redetermination if the physician or other prescriber indicates that applying the standard timeframe for conducting a redetermination may seriously jeopardize the life or health of the enrollee or the enrollee's ability to regain maximum function.

(d) *Actions following denial of a request.* If a Part D plan sponsor denies a request for expedited redetermination, it must take the following actions:

(1) Make the determination within the 7 calendar day timeframe established in § 423.590(a). The 7 calendar day period begins the day the Part D plan sponsor receives the request for expedited redetermination.

(2) Give the enrollee prompt oral notice of the denial that—

(i) Explains that the Part D plan sponsor processes the enrollee's request using the 7 calendar day timeframe for standard redetermination;

(ii) Informs the enrollee of the right to file an expedited grievance if he or she disagrees with the decision by the Part D plan sponsor not to expedite;

(iii) Informs the enrollee of the right to resubmit a request for an expedited redetermination with the prescribing physician's or other prescriber's support; and

(iv) Provides instructions about the expedited grievance process and its timeframes.

(3) Subsequently deliver, within three calendar days, equivalent written notice.

(e) *Action following acceptance of a request.* If a Part D plan sponsor grants a request for expedited redetermination, it must conduct the redetermination and give notice in accordance with § 423.590(d).

(f) *Dismissing a request.* The Part D plan sponsor dismisses an expedited redetermination in accordance with § 423.582.

[70 FR 4525, Jan. 28, 2005, as amended at 73 FR 20507, Apr. 15, 2008; 74 FR 1547, Jan. 12, 2009; 74 FR 65363, Dec. 9, 2009; 83 FR 16752, Apr. 16, 2018; 86 FR 6120, Jan. 19, 2021; 89 FR 30841, Apr. 23, 2024; 89 FR 63828, Aug. 6, 2024]

§ 423.586 Opportunity to submit evidence.

The Part D plan sponsor must provide the enrollee or the prescribing physician or other prescriber, as appropriate, with a reasonable opportunity to present evidence and allegations of fact or law, related to the issue in dispute, in person as well as in writing. In

the case of an expedited redetermination, the opportunity to present evidence is limited by the short timeframe for making a decision. Therefore, the Part D plan sponsor must inform the enrollee or the prescribing physician or other prescriber of the conditions for submitting the evidence.

[74 FR 1548, Jan. 12, 2009]

§ 423.590 Timeframes and responsibility for making redeterminations.

(a) *Standard redetermination—request for covered drug benefits or review of an at-risk determination.* (1) If the Part D plan sponsor makes a redetermination that is completely favorable to the enrollee, the Part D plan sponsor must notify the enrollee in writing of its redetermination (and effectuate it in accordance with § 423.636(a)(1) or (3) as expeditiously as the enrollee's health condition requires, but no later than 7 calendar days from the date it receives the request for a standard redetermination.

(2) If the Part D plan sponsor makes a redetermination that affirms, in whole or in part, its adverse coverage determination or at-risk determination, it must notify the enrollee in writing of its redetermination as expeditiously as the enrollee's health condition requires, but no later than 7 calendar days from the date it receives the request for a standard redetermination.

(b) *Standard redetermination—request for payment.* (1) If the Part D plan sponsor makes a redetermination that is completely favorable to the enrollee, the Part D plan sponsor must issue its redetermination (and effectuate it in accordance with § 423.636(a)(2)) no later than 14 calendar days from the date it receives the request for redetermination.

(2) If the Part D plan sponsor affirms, in whole or in part, its adverse coverage determination, it must notify the enrollee in writing of its redetermination no later than 14 calendar days from the date it receives the request for redetermination.

(c) *Effect of failure to meet timeframe for standard redeterminations.* If the Part D plan sponsor fails to provide the enrollee with a redetermination within the timeframes specified in paragraphs (a) or (b) of this section, the failure constitutes an adverse redetermination decision, and the Part D plan sponsor must forward the enrollee's request to the IRE within 24 hours of the expiration of the adjudication timeframe.

(d) *Expedited redetermination*—(1) *Timeframe.* A Part D plan sponsor that approves a request for expedited redetermination must complete its redetermination and give the enrollee (and the prescribing physician or other prescriber involved, as appropriate), notice of its decision as expeditiously as the enrollee's health condition requires but no later than 72 hours after receiving the request.

(2) *Confirmation of oral notice.* If the Part D plan sponsor first notifies an enrollee of an adverse or favorable expedited redetermination orally, it must mail written confirmation to the enrollee within 3 calendar days of the oral notification.

(3) How the Part D plan sponsor must request additional information. If the Part D plan sponsor must receive medical information, the Part D plan sponsor must request the necessary information within 24 hours of the initial request for an expedited redetermination. Regardless of whether the Part D plan sponsor requests additional information, the Part D plan sponsor is responsible for meeting the timeframe and notice requirements.

(e) *Failure to meet timeframe for expedited redetermination.* If the Part D plan sponsor fails to provide the enrollee or the prescribing physician or other prescriber, as appropriate, with the results of its expedited redetermination within the timeframe described in paragraph (d) of this section, the failure constitutes an adverse redetermination decision, and the Part D plan sponsor must forward the enrollee's request to the IRE within 24 hours of the expiration of the adjudication timeframe.

(f) *Who must conduct the review of an adverse coverage determination or at-risk determination.* (1) A person or persons who were not involved in making the coverage determination or an at-risk determination under a drug management program in accordance with § 423.153(f) must conduct the redetermination.

(2) When the issue is the denial of coverage based on a lack of medical necessity (or any substantively equivalent term used to describe the concept of medical necessity), the redetermination must be made by a physician with expertise in the field of medicine that is appropriate for the services at issue. The physician making the redetermination need not, in all cases, be of the same specialty or subspecialty as the prescribing physician or other prescriber.

(g) *Form and content of an adverse redetermination notice.* The notice of any adverse determination under paragraphs (a)(2), (b)(2), (d)(1) or (d)(2) of this section must—

(1) Use approved notice language in a readable and understandable form;

(2) State the specific reasons for the denial;

(3) Inform the enrollee of his or her right to a reconsideration;

(i) For adverse drug coverage redeterminations, or redeterminations related to a drug management program in accordance with § 423.153(f), describe both the standard and expedited reconsideration processes, including the enrollee's right to, and conditions for, obtaining an expedited reconsideration and the rest of the appeals process;

(ii) For adverse payment redeterminations, describe the standard reconsideration process and the rest of the appeals process; and

(4) Comply with any other notice requirements specified by CMS.

(h) *Form and content of a completely favorable redetermination notice.* The notice of any completely favorable determination under paragraphs (a)(1), (d)(1) or (d)(2) of this section must explain the conditions of the approval in a readable and understandable form.

(i) *Automatic forwarding of redeterminations made under a drug management program.* If on redetermination the plan sponsor affirms, in whole or in part, its denial related to an at-risk determination under a drug management program in accordance with § 423.153(f), the Part D plan sponsor must forward the case to the IRE contracted with CMS within 24 hours of the expiration of the applicable adjudication timeframe under paragraph (a)(2), (b)(2), or (d)(1) of this section.

(j) *Requests for review of a dismissal by the independent entity.* If the Part D plan sponsor dismisses a request for a reconsideration in accordance with § 423.582(e) or § 423.584(f), the enrollee or other proper party has the right to request review of the dismissal by the independent entity. A request for review of a dismissal must be filed in writing with the independent entity within 60 calendar days from the date of the Part D plan sponsor's dismissal notice.

[70 FR 4525, Jan. 28, 2005, as amended at 74 FR 1548, Jan. 12, 2009; 75 FR 19823, Apr. 15, 2010; 83 FR 16752, Apr. 16, 2018; 86 FR 6120, Jan. 19, 2021]

§ 423.600 Reconsideration by an independent review entity (IRE).

(a) An enrollee who is dissatisfied with the redetermination of a Part D plan sponsor has a right to a reconsideration by an independent review entity that contracts with CMS. The prescribing physician or other prescriber (acting on behalf of an enrollee), upon providing notice to the enrollee, may request an IRE reconsideration. The enrollee, or the enrollee's prescribing physician or other prescriber (acting on behalf of the enrollee) must file a written request for reconsideration with the IRE within 60 calendar days after receipt of the written redetermination by the Part D plan sponsor.

(1) The date of receipt of the redetermination is presumed to be 5 calendar days after the date of the Part D plan sponsor's written redetermination, unless there is evidence to the contrary.

(2) For purposes of meeting the 60-calendar day filing deadline, the request is considered as filed on the date it is received by the IRE specified in the Part D plan sponsor's written redetermination.

(b) When an enrollee, or an enrollee's prescribing physician or other prescriber (acting on behalf of the enrollee), files an appeal or a determination is forwarded to the IRE by a Part D plan sponsor, the IRE is required to solicit the views of the prescribing physician or other prescriber.

(1) The IRE may solicit the views of the prescribing physician or other prescriber orally or in writing.

(2) A written account of the prescribing physician's or other prescriber's views (prepared by either the prescribing physician, other prescriber, or IRE, as appropriate) must be contained in the IRE record.

(c) In order for an enrollee or a prescribing physician or other prescriber (acting on behalf of an enrollee) to request an IRE reconsideration of a determination by a Part D plan sponsor not to provide for a Part D drug that is not on the formulary, the prescribing physician or other prescriber must determine that all covered Part D drugs on any tier of the formulary for treatment of the same condition would not be as effective for the individual as the non-formulary drug, would have adverse effects for the individual, or both.

(d) The independent review entity must conduct the reconsideration as expeditiously as the enrollee's health condition requires but must not exceed the deadlines applicable in § 423.590, including those deadlines that are applicable when a request for an expedited reconsideration is received and granted.

(e) When the issue is the denial of coverage based on a lack of medical necessity (or any substantively equivalent term used to describe the concept of medical necessity), the reconsideration must be made by a physician with expertise in the field of medicine that is appropriate for the services at issue. The physician making the reconsideration need not, in all cases, be of the same specialty or subspecialty as the prescribing physician or other prescriber.

(f) The party who files a request for reconsideration may withdraw it by filing a request with the IRE.

(g) The independent entity dismisses a reconsideration request, either entirely or as to any stated issue, under any of the following circumstances:

(1) When the person or entity requesting a reconsideration is not a proper party under paragraph (a) of this section.

(2) When the IRE determines the party failed to make out a valid request for reconsideration that substantially complies with paragraph (a) of this section.

(3) When the party fails to file the reconsideration request within the proper filing time frame in accordance with paragraph (a) of this section.

(4) When an enrollee or the enrollee's representative files a request for reconsideration, but the enrollee dies while the request is pending, and both of the following criteria apply:

(i) The enrollee's surviving spouse or estate has no remaining financial interest in the case.

(ii) The enrollee's representative, if any, does not wish to continue the appeal.

(5) When a party filing the reconsideration request submits a timely request for withdrawal of the request for a reconsideration with the IRE.

(h) The IRE mails or otherwise transmits a written notice of the dismissal of the reconsideration request to the parties. The notice must state all of the following:

(1) The reason for the dismissal.

(2) That there is a right to request that the IRE vacate the dismissal action.

(3) The right to a review of the dismissal in accordance with § 423.2004.

(i) If good cause is established, the IRE may vacate its dismissal of a request for redetermination within 6 months from the date of the notice of dismissal.

(j) An enrollee has a right to have an IRE's dismissal reconsidered in accordance with § 423.2004.

(k) If the IRE determines that the Part D plan sponsor's dismissal was in error, the IRE vacates the dismissal and remands the case to the Part D plan sponsor for reconsideration consistent with § 423.590. The IRE's decision regarding an Part D plan sponsor's dismissal, including a decision to deny a request for review of a dismissal, is binding and not subject to further review.

[70 FR 4525, Jan. 28, 2005, as amended at 74 FR 1548, Jan. 12, 2009; 74 FR 65363, Dec. 9, 2009; 77 FR 22171, Apr. 12, 2012; 86 FR 6120, Jan. 19, 2021; 89 FR 30841, Apr. 23, 2024]

§ 423.602 Notice of reconsideration determination by the independent review entity.

(a) *Responsibility for the notice.* When the IRE makes its reconsideration determination, it is responsible for mailing a notice of its determination to the enrollee and the Part D plan sponsor, and for sending a copy to CMS. When the prescribing physician or other prescriber requests the reconsideration on behalf of the enrollee, the IRE is also responsible for notifying the prescribing physician or other prescriber of its decision.

(b) *Content of the notice.* The notice must—

(1) State the specific reasons for the IRE's decision in understandable language;

(2) If the reconsideration determination is adverse (that is, does not completely reverse the adverse coverage determination or redetermination by the Part D plan sponsor), inform the enrollee of his or her right to an ALJ hearing if the amount in controversy meets the threshold requirement under § 423.2006;

(3) Describe the procedures that must be followed to obtain an ALJ hearing; and

(4) Comply with any other requirements specified by CMS.

[70 FR 4525, Jan. 28, 2005, as amended at 74 FR 65363, Dec. 9, 2009; 77 FR 22171, Apr. 12, 2012; 83 FR 16752, Apr. 16, 2018; 84 FR 19872, May 7, 2019]

§ 423.604 Effect of a reconsideration determination.

A reconsideration determination is final and binding on the enrollee and the Part D plan sponsor, unless the enrollee files a request for a hearing under the provisions of § 423.2014.

[70 FR 4525, Jan. 28, 2005, as amended at 74 FR 65363, Dec. 9, 2009; 84 FR 19872, May 7, 2019]

§§ 423.610–423.634 [Reserved]

§ 423.636 How a Part D plan sponsor must effectuate standard redeterminations, reconsiderations, or decisions.

(a) *Reversals by the Part D plan sponsor*—(1) *Requests for benefits.* If, on redetermination of a request for benefit, the Part D plan sponsor reverses its coverage determination, the Part D plan sponsor must authorize or provide the benefit under dispute as expeditiously as the enrollee's health condition requires, but no later than 7 calendar days from the date it receives the request for redetermination.

(2) *Requests for payment.* If, on redetermination of a request for payment, the Part D plan sponsor reverses its coverage determination, the Part D plan sponsor must authorize payment for the benefit within 14 calendar days from the date it receives the request for redetermination, and make payment no later than 30 calendar days after the date the plan sponsor receives the request for redetermination.

(3) *Review of an at-risk determination.* If, on redetermination of an at-risk determination made under a drug management program in accordance with § 423.153(f), the Part D plan sponsor reverses its at-risk determination, the Part D plan sponsor must implement the change to the at-risk determination as expeditiously as the enrollee's health condition requires, but no later than 7 calendar days from the date it receives the request for redetermination.

(b) *Reversals other than by the Part D plan sponsor*—(1) *Requests for benefits.* If, on appeal of a request for benefit, the determination by the Part D plan sponsor is reversed in whole or in part by the independent review entity, or at a higher level of appeal, the Part D plan sponsor must authorize or provide the benefit under dispute within 72 hours from the date it receives notice reversing the determination. The Part D plan sponsor must inform the independent review entity that the Part D plan sponsor has effectuated the decision.

(2) *Requests for payment.* If, on appeal of a request for payment, the determination by the Part D plan sponsor is reversed in whole or in part by the independent review entity, or at a higher level of appeal, the Part D plan sponsor must authorize payment for the benefit within 72 hours, but make payment no later than 30 calendar days from the date it receives notice reversing the coverage determination. The Part D plan sponsor must inform the independent review entity that the

Part D plan sponsor has effectuated the decision.

(3) *Review of an at-risk determination.* If, on appeal of an at-risk determination made under a drug management program in accordance with § 423.153(f), the determination by the Part D plan sponsor is reversed in whole or in part by the independent review entity, or at a higher level of appeal, the Part D plan sponsor must implement the change to the at-risk determination within 72 hours from the date it receives notice reversing the determination. The Part D plan sponsor must inform the independent review entity that the Part D plan sponsor has effectuated the decision.

[70 FR 4525, Jan. 28, 2005, as amended at 83 FR 16752, Apr. 16, 2018]

§ 423.638 How a Part D plan sponsor must effectuate expedited redeterminations or reconsiderations.

(a) *Reversals by the Part D plan sponsor*—(1) *Requests for benefits.* If, on an expedited redetermination of a request for benefits, the Part D plan sponsor reverses its coverage determination, the Part D plan sponsor must authorize or provide the benefit under dispute as expeditiously as the enrollee's health condition requires, but no later than 72 hours after the date the Part D plan sponsor receives the request for redetermination.

(2) *Review of an at-risk determination.* If, on an expedited redetermination of an at-risk determination made under a drug management program in accordance with § 423.153(f), the Part D plan sponsor reverses its at-risk determination, the Part D plan sponsor must implement the change to the at-risk determination as expeditiously as the enrollee's health condition requires, but no later than 72 hours after the date the Part D plan sponsor receives the request for redetermination.

(b) *Reversals other than by the Part D plan sponsor*—(1) *Requests for benefits.* If the expedited determination or expedited redetermination for benefits by the Part D plan sponsor is reversed in whole or in part by the independent review entity, or at a higher level of appeal, the Part D plan sponsor must authorize or provide the benefit under dispute as expeditiously as the enrollee's health condition requires but no later than 24 hours from the date it receives notice reversing the determination. The Part D plan sponsor must inform the independent review entity that the Part D plan sponsor has effectuated the decision.

(2) *Review of an at-risk determination.* If the expedited redetermination of an at-risk determination made under a drug management program in accordance with § 423.153(f) by the Part D plan sponsor is reversed in whole or in part by the independent review entity, or at a higher level of appeal, the Part D plan sponsor must implement the change to the at-risk determination as expeditiously as the enrollee's health condition requires but no later than 24 hours from the date it receives notice reversing the determination. The Part D plan sponsor must inform the independent review entity that the Part D plan sponsor has effectuated the decision.

[83 FR 16753, Apr. 16, 2013]

Subpart N—Medicare Contract Determinations and Appeals

§ 423.641 Contract determinations.

This subpart establishes the procedures for reviewing the following contract determinations:

(a) A determination that an entity is not qualified to enter into a contract with CMS under Part D of title XVIII of the Act.

(b) A determination not to authorize a renewal of a contract with a PDP sponsor in accordance with § 423.507(b).

(c) A determination to terminate a contract with a PDP sponsor in accordance with § 423.509.

(d) Fallback entities are governed under subpart Q of this part, and are not subject to this subpart, except to the extent a fallback prescription drug plan contract is terminated by CMS.

§ 423.642 Notice of contract determination.

(a) When CMS makes a contract determination under § 423.641, it gives the PDP sponsor written notice.

(b) The notice specifies the—

(1) Reasons for the determination; and

(2) The Part D sponsor's right to request a hearing.

(c) *CMS-initiated terminations*—(1) *General rule.* Except as provided in (c)(2) of this section, CMS mails notice to the Part D plan sponsor 45 calendar days before the anticipated effective date of the termination.

(2) *Exception.* If a contract is terminated in accordance with § 423.509(b)(2)(i) of this part, CMS notifies the Part D plan sponsor of the date that it will terminate the Part D plan sponsor's contract.

(d) When CMS determines that it will not authorize a contract renewal, CMS mails the notice to the Part D sponsor by August 1 of the current contract year.

[70 FR 4525, Jan. 28, 2005, as amended at 72 FR 68733, Dec. 5, 2007; 75 FR 19823, Apr. 15, 2010; 79 FR 29965, May 23, 2014]

§ 423.643 Effect of contract determination.

The contract determination is final and binding unless a timely request for a hearing is filed under 423.651.

[72 FR 68733, Dec. 5, 2007]

§ 423.650 Right to a hearing, burden of proof, standard of proof, and standards of review.

(a) *Right to a hearing.* The following parties are entitled to a hearing:

(1) A contract applicant that has been determined to be unqualified to enter into a contract with CMS under Part D of Title XVIII of the Act in accordance with § 423.502 and § 423.503 of this part.

(2) A Part D sponsor whose contract has been terminated in accordance with § 423.509 of this part.

(3) A Part D sponsor whose contract has not been renewed in accordance with § 423.507 of this part.

(4) A Part D sponsor who has had an intermediate sanction imposed in accordance with § 423.752(a) through (b).

(b) *Burden of proof, standard of proof, and standard of review at hearing.* (1) During a hearing to review a contract determination as described at § 423.641(a) of this subpart, the applicant has the burden of proving by a preponderance of the evidence that CMS' determination was inconsistent with the requirements of § 423.502 and § 423.503 of this part.

(2) During a hearing to review a contract determination as described at § 423.641(b) of this part, the Part D plan sponsor has the burden of proving by a preponderance of the evidence that CMS' determination was inconsistent with the requirements of § 423.507 of this part.

(3) During a hearing to review a contract determination as described at § 423.641(c) of this subpart, the Part D plan sponsor has the burden of proving by a preponderance of the evidence that CMS' determination was inconsistent with the requirements of § 423.509 of this part.

(4) During a hearing to review the imposition of an intermediate sanction as described at § 423.750 of this part, the Part D sponsor has the burden of proving by a preponderance of the evidence that CMS' determination was inconsistent with the requirements of § 423.752 of this part.

(c) *Timing of favorable decision.* Notice of any decision favorable to the Part D sponsor appealing a determination that it is not qualified to enter into a contract with CMS must be issued by September 1 for the contract in question to be effective on January 1 of the following year.

[75 FR 19824, Apr. 15, 2010, as amended at 80 FR 7965, Feb. 12, 2015]

§ 423.651 Request for hearing.

(a) *Method and place for filing a request.* (1) A request for a hearing must be made in writing and filed by an authorized official of the contract applicant or Part D plan sponsor that was the party to the determination under the appeal.

(2) The request for the hearing must be filed in accordance with the requirements specified in the notice.

(b) *Time for filing a request.* A request for a hearing must be filed within 15 calendar days after the receipt of the notice of the contract determination or intermediate sanction.

(c) *Parties to a hearing.* The parties to a hearing must be—

(1) The parties described in § 423.650;

(2) At the discretion of the hearing officer, any interested parties who make a showing that their rights may

be prejudiced by the decision to be rendered at the hearing; and

(3) CMS.

[70 FR 4525, Jan. 28, 2005, as amended at 72 FR 68734, Dec. 5, 2007; 75 FR 19824, Apr. 15, 2010]

§ 423.652 Postponement of effective date of a contract determination when a request for a hearing is filed timely.

(a) *Hearing.* When a request for a hearing is timely filed, CMS will postpone the proposed effective date of the contract determination listed at 423.641 until a hearing decision is reached and affirmed by the Administrator following review pursuant to 423.666 in instances where a Part D sponsor or CMS requests Administrator review and the Administrator accepts the matter for review.

(b) *Exceptions:* (1) If a final decision is not reached on CMS' determination for an initial contract by September 1, CMS will not enter into a contract with the applicant for the following year.

(2) A contract terminated in accordance with § 423.509(b)(2)(i) of this part will be terminated on the date specified by CMS and will not be postponed if a hearing is requested.

[72 FR 68734, Dec. 5, 2007, as amended at 75 FR 19824, Apr. 15, 2010; 83 FR 16753, Apr. 16, 2018]

§ 423.653 Designation of hearing officer.

CMS designates a hearing officer to conduct the hearing. The hearing officer need not be an ALJ.

§ 423.654 Disqualification of hearing officer.

(a) A hearing officer may not conduct a hearing in a case in which he or she is prejudiced or partial to any party or has any interest in the matter pending for decision.

(b) A party to the hearing who objects to the designated hearing officer must notify that officer in writing at the earliest opportunity.

(c) The hearing officer must consider the objections, and may, at his or her discretion, either proceed with the hearing or withdraw.

(1) If the hearing officer withdraws, CMS designates another hearing officer to conduct the hearing.

(2) If the hearing officer does not withdraw, the objecting party may, after the hearing, present objections and request that the officer's decision be revised or a new hearing be held before another hearing officer. The objections must be submitted in writing to CMS.

§ 423.655 Time and place of hearing.

(a) The hearing officer—

(1) Fixes a time and place for the hearing, which is not to exceed 30 calendar days after the receipt of request for the hearing;

(2) Sends written notice to the parties that informs the parties of the general and specific issues to be resolved, the burden of proof, and information about the hearing procedure.

(b)(1) The hearing officer may, on his or her own motion, change the time and place of the hearing.

(2) The hearing officer may adjourn or postpone the hearing.

(c)(1) The Part D plan sponsor or CMS may request an extension by filing a written request no later than 10 calendar days prior to the scheduled hearing.

(2) When either the Part D plan sponsor or CMS requests an extension the hearing officer will provide a one-time 15-calendar day extension.

(3) Additional extensions may be granted at the discretion of the hearing officer.

[75 FR 19824, Apr. 15, 2010]

§ 423.656 Appointment of representatives.

A party may appoint as its representative at the hearing anyone not disqualified or suspended from acting as a representative before the Secretary or otherwise prohibited by law.

§ 423.657 Authority of representatives.

(a) A representative appointed and qualified in accordance with § 423.656, on behalf of the represented party—

(1) Gives or accepts any notice or request pertinent to the proceedings set forth in this subpart;

(2) Presents evidence and allegations as to facts and law in any proceedings affecting that party; and

(3) Obtains information to the same extent as the party.

(b) A notice or request sent to the representative has the same force and effect as if it is sent to the party.

§ 423.658 Conduct of hearing.

(a) The hearing is open to the parties and to the public.

(b) The hearing officer inquires fully into all the matters at issue and receives in evidence the testimony of witnesses and any documents that are relevant and material.

(c) The hearing officer provides the parties an opportunity to enter any objection to the inclusion of any document.

(d) The Part D sponsor bears the burden of going forward and must first present evidence and argument before CMS presents its evidence and argument.

[70 FR 4525, Jan. 28, 2005, as amended at 75 FR 19824, Apr. 15, 2010]

§ 423.659 Evidence.

The hearing officer rules on the admissibility of evidence and may admit evidence that is inadmissible under rules applicable to court procedures.

§ 423.660 Witnesses.

(a) The hearing officer may examine the witnesses.

(b) The parties or their representatives are permitted to examine their witnesses and cross-examine witnesses of other parties.

§ 423.661 Witnesses lists and documents.

Witness lists and documents must be identified and exchanged at least 5 calendar days prior to the scheduled hearing

[75 FR 19824, Apr. 15, 2010]

§ 423.662 Prehearing and summary judgment.

(a) *Prehearing*. The hearing officer may schedule a prehearing conference if he or she believes that a conference would more clearly define the issues.

(b) *Summary judgment*. Either party to the hearing, may ask the hearing officer to rule on a motion for summary judgment.

[72 FR 68734, Dec. 5, 2007]

§ 423.663 Record of hearing.

(a) A complete record of the proceedings at the hearing is made and transcribed and made available to all parties upon request.

(b) The record may not be closed until a hearing decision is issued.

§ 423.664 Authority of hearing officer.

In exercising his or her authority, the hearing officer must comply with the provisions of title XVIII and related provisions of the Act, the regulations issued by the Secretary, and general instructions issued by CMS in implementing the Act.

§ 423.665 Notice and effect of hearing decision.

(a) As soon as practical after the close of the hearing, the hearing officer issues a written decision that—

(1) Is based upon the evidence of record; and

(2) Contains separately numbered findings of fact and conclusions of law.

(b) The hearing officer provides a copy of the hearing decision to each party.

(c) The hearing decision is final and binding unless it is reversed or modified by the Administrator following review under § 423.666, or reopened and revised in accordance with § 423.668.

§ 423.666 Review by the Administrator.

(a) *Request for review by Administrator*. CMS or a Part D plan sponsor that has received a hearing decision may request a review by the Administrator within 15 calendar days after receipt of the hearing decision as provided under § 423.665(b) of this subpart. Both the Part D plan sponsor and CMS may provide written arguments to the Administrator for review.

(b) *Decision to review the hearing decision.* After receiving a request for review, the Administrator has the discretion to elect to review the hearing determination in accordance with paragraph (d) of this section or to decline to review the hearing decision.

(c) *Notification of Administrator determination.* The Administrator notifies both parties of his or her determination regarding review of the hearing decision within 30 calendar days after receipt of request for review. If the Administrator declines to review the hearing decision or the Administrator does not make a determination regarding review within 30 calendar days, the decision of the hearing officer is final.

(d) *Review by the Administrator.* If the Administrator elects to review the hearing decision regarding a contract determination, the Administrator shall review the hearing officer's decision and determine, based upon this decision, the hearing record, and any written arguments submitted by the Part D sponsor or CMS, whether the determination should be upheld, reversed, or modified.

(e) *Decision by the Administrator.* The Administrator issues a written decision, and furnishes the decision to the PDP sponsor requesting review.

[70 FR 4525, Jan. 28, 2005, as amended at 72 FR 68734, Dec. 5, 2007; 75 FR 19824, Apr. 15, 2010]

§ 423.667 Effect of Administrator's decision.

A decision by the Administrator under section § 423.666(c) is final and binding unless it is reopened and revised in accordance with § 423.668.

§ 423.668 Reopening of a contract determination or decision of a hearing officer or the Administrator.

(a) CMS may reopen and revise an initial determination upon its own motion.

(b) *Contract determination.* A decision of a hearing officer that is unfavorable to any party and is otherwise final may be reopened and revised by the hearing officer upon the officer's own motion within 1 year of the notice of the hearing decision. Another hearing officer designated by CMS may reopen and revise the decision if the hearing officer who issued the decision is unavailable.

(c) *Decision of Administrator.* A decision by the Administrator that is otherwise final may be reopened and revised by the Administrator upon the Administrator's own motion within 1 year of the notice of the Administrator's decision.

(d) *Notices.* (1) The notice of reopening and of any revisions following the reopening is mailed to the parties.

(2) The notice of revision specifies the reasons for revisions.

[70 FR 4525, Jan. 28, 2005, as amended at 72 FR 68734, Dec. 5, 2007; 75 FR 19824, Apr. 15, 2010]

Subpart O—Intermediate Sanctions

§ 423.750 Types of intermediate sanctions and civil money penalties.

(a) The following intermediate sanctions may be imposed and will continue in effect until CMS is satisfied that the deficiencies that are the basis for the sanction determination have been corrected and are not likely to recur:

(1) Suspension of the Part D plan sponsor's enrollment of Medicare beneficiaries.

(2) Suspension of payment to the Part D plan sponsor for Medicare beneficiaries enrolled after the date CMS notifies the organization of the intermediate sanction.

(3) Suspension of communication activities to Medicare beneficiaries by a Part D plan sponsor, as defined by CMS.

(b) CMS may impose civil money penalties as specified in 423.760.

[72 FR 68734, Dec. 5, 2007, as amended at 75 FR 19824, Apr. 15, 2010; 83 FR 16753, Apr. 16, 2018]

§ 423.752 Basis for imposing intermediate sanctions and civil money penalties.

(a) *All intermediate sanctions.* For the violations listed in this paragraph (a), CMS may impose one or more of the sanctions specified in § 423.750(a) of this subpart on any Part D plan sponsor with a contract. The Part D plan sponsor may also be subject to other remedies authorized under law.

(1) Fails substantially to provide medically necessary items and services that are required (under law or under the contract) to be provided to an individual covered under the contract, if the failure has adversely affected (or has the substantial likelihood of adversely affecting) the individual.

(2) Imposes on Part D plan enrollees premiums in excess of the monthly basic and supplemental beneficiary premiums permitted under section 1860D–1 *et seq.* of the Act and subpart F of this part.

(3) Acts to expel or refuses to re-enroll a beneficiary in violation of the provisions of this part.

(4) Engages in any practice that would reasonably be expected to have the effect of denying or discouraging enrollment (except as permitted by this part) by eligible individuals with the organization whose medical condition or history indicates a need for substantial future medical services.

(5) Misrepresents or falsifies information that it furnishes—

(i) To CMS; or

(ii) To an individual or to any other entity under the Part D drug benefit program.

(6) Employs or contracts with an individual or entity who is excluded from participation in Medicare under section 1128 or 1128A of the Act (or with an entity that employs or contracts with an excluded individual or entity) for the provision of any of the following:

(i) Health care.

(ii) Utilization review.

(iii) Medical social work.

(iv) Administrative services.

(7) Except as provided under §423.34, enrolls an individual in any plan under this part without the prior consent of the individual or the designee of the individual.

(8) Transfers an individual enrolled under this part from one plan to another without the prior consent of the individual or the designee of the individual or solely for the purpose of earning a commission.

(9) Fails to comply with communication restrictions described in subpart V of this part or applicable implementing guidance.

(10) Employs or contracts with any individual, agent, provider, supplier or entity who engages in the conduct described in paragraphs (a)(1) through (9) of this section.

(b) *Suspension of enrollment and communications.* If CMS makes a determination that could lead to a contract termination under §423.509(a), CMS may impose the intermediate sanctions at §423.750(a)(1) and (3).

(c) *Civil money penalties* (1) *CMS.* In addition to, or in place of, any intermediate sanctions, CMS may impose civil money penalties in the amounts specified in either of the following:

(i) Section 423.760(b) for any of the determinations at §423.509(a), except §423.509(a)(4)(i).

(ii) Section 423.760(c) for any of the determinations in paragraph (a) of this section except §422.752(a)(5) of this chapter.

(2) *OIG.* In addition to, or in place of any intermediate sanctions imposed by CMS, the OIG, in accordance with part 1003 of Chapter V of this title, may impose civil money penalties for the following:

(i) Violations listed at 423.752(a).

(ii) Determinations made pursuant to §422.510(a)(4)(i) of this chapter.

[70 FR 4525, Jan. 28, 2005, as amended at 72 FR 68734, Dec. 5, 2007; 75 FR 19825, Apr. 15, 2010; 79 FR 29965, May 23, 2014; 83 FR 16753, Apr. 16, 2018]

§ 423.756 Procedures for imposing intermediate sanctions and civil money penalties.

(a) *Notice of intermediate sanction and opportunity to respond*—(1) *Notice of intent.* Before imposing the intermediate sanctions, CMS—

(i) Sends a written notice to the Part D plan sponsor stating the nature and basis of the proposed intermediate sanction, and the Part D plan sponsor's right to a hearing as specified in paragraph (b) of this section; and

(ii) Sends the OIG a copy of the notice.

(2) *Opportunity to respond.* CMS allows the Part D plan sponsor 10 calendar days after receipt of the notice to provide a written rebuttal. CMS considers receipt of the notice as the day after notice is sent by fax, e-mail, or submitted for overnight mail.

(b) *Hearing.* (1) The Part D plan sponsor may request a hearing before a CMS hearing officer.

(2) A written request must be received by the designated CMS office within 15 calendar days after the receipt of the notice.

(3) A request for a hearing under § 423.650 of this part does not delay the date specified by CMS when the sanction becomes effective.

(4) The Part D plan sponsor must follow the right to a hearing procedure as specified at subpart N of this part.

(c) *Effective date and duration of sanctions*—(1) *Effective date.* The effective date of the sanction is the date specified by CMS in the notice.

(2) *Exception.* If CMS determines that the Part D sponsor's conduct poses a serious threat to an enrollee's health and safety, CMS may make the sanction effective on an earlier date that CMS specifies.

(3) *Duration of sanction.* The sanction remains in effect until CMS is satisfied that the deficiencies that are the basis for the sanction determination have been corrected and are not likely to recur.

(i) CMS may require that the Part D plan sponsor hire an independent auditor to provide CMS with additional information to determine if the deficiencies that are the basis for the sanction determination have been corrected and are not likely to recur. The independent auditor must work in accordance with CMS specifications and must be willing to attest that a complete and full independent review has been performed.

(ii) In instances where intermediate sanctions have been imposed, CMS may require a Part D plan sponsor to market or to accept enrollments or both for a limited period of time in order to assist CMS in making a determination as to whether the deficiencies that are the bases for the intermediate sanctions have been corrected and are not likely to recur.

(A) If, following this time period, CMS determines the deficiencies have not been corrected or are likely to recur, the intermediate sanctions will remain in effect until such time that CMS is assured the deficiencies have been corrected and are not likely to recur.

(B) The Part D plan sponsor does not have a right to a hearing under § 423.650(a)(4) of this subpart to challenge CMS' determination to keep the intermediate sanctions in effect.

(C) During the limited time period, sanctioned Part D plan sponsors under the benchmark that would normally participate in the annual and monthly auto enrollment process for enrollees receiving the low income subsidy will not be allowed to receive or process these types of enrollments.

(d) *Non-renewal or termination by CMS.* In addition to or as an alternative to the sanctions described in § 423.750, CMS may decline to authorize the renewal of an organization's contract in accordance with § 423.507(b), or terminate the contract in accordance with § 423.509.

(1) Decline to authorize the renewal of an organization's contract in accordance with § 423.507(b); or

(2) Terminate the contract in accordance with § 423.509.

(e) *Notice to impose civil money penalties*—(1) *CMS notice to OIG.* If CMS determines that a Part D sponsor has committed an act or failed to comply with a requirement as described in 423.752, CMS notifies the OIG of this determination. OIG may impose a civil money penalty upon a Part D sponsor as specified at 423.752(c)(2).

(2) *CMS notice of civil money penalties to Part D plan sponsors.* If CMS makes a determination to impose a CMP described in 423.752(c)(1), CMS will send a written notice of the Agency's decision to impose a civil money penalty to include—

(i) A description of the basis for the determination.

(ii) The basis for the penalty.

(iii) The amount of the penalty.

(iv) The date the penalty is due.

(v) The Part D sponsor's right to a hearing as specified under Subpart T of this part.

(vi) Information about where to file the request for hearing.

[70 FR 4525, Jan. 28, 2005, as amended at 72 FR 68735, Dec. 5, 2007; 73 FR 55764, Sept. 26, 2008; 75 FR 19825, Apr. 15, 2010; 79 FR 29965, May 23, 2014; 83 FR 16753, Apr. 16, 2018]

§ 423.758 Collection of civil money penalties imposed by CMS.

(a) When a Part D plan sponsor does not request a hearing CMS initiates collection of the civil money penalty following the expiration of the timeframe for requesting an ALJ hearing as specified in subpart T.

(b) If a Part D sponsor requests a hearing and CMS' decision to impose a civil money penalty is upheld, CMS may initiate collection of the civil money penalty once the administrative decision is final.

[72 FR 68735, Dec. 5, 2007]

§ 423.760 Determinations regarding the amount of civil money penalties and assessment imposed by CMS.

(a) *Determining the appropriate amount of any penalty.* In determining the amount of penalty imposed under § 423.752(c)(1), CMS considers the following as appropriate:

(1) The nature of the conduct.

(2) The degree of culpability of the Part D sponsor.

(3) The adverse effect to enrollees which resulted or could have resulted from the conduct of the Part D sponsor.

(4) The financial condition of the Part D sponsor.

(5) The history of prior offenses by the Part D sponsor or principals of the Part D sponsor.

(6) Such other matters as justice may require.

(b) *Amount of penalty.* CMS may impose civil money penalties in the following amounts:

(1) If the deficiency on which the determination is based has directly adversely affected (or has the substantial likelihood of adversely affecting) one or more Part D enrollees—up to $25,000 as adjusted annually under 45 CFR part 102 for each determination.

(2) If the deficiency on which the determination is based has directly adversely affected (or has the substantial likelihood of adversely affecting) one or more Part D enrollees, CMS may calculate a CMP of up to $25,000 as adjusted annually under 45 CFR part 102 for each Part D enrollee directly adversely affected (or with a substantial likelihood of being adversely affected) by a deficiency .

(3)(i) Definitions for calculating penalty amounts—

(A) *Per determination.* The penalty amounts calculated under paragraph (b)(1) of this section.

(B) *Per enrollee.* The penalty amounts calculated under paragraph (b)(2) of this section.

(C) *Standard minimum penalty.* The per enrollee or per determination penalty amount that is dependent on the type of adverse impact that occurred.

(D) *Aggravating factor(s).* Specific penalty amounts that may increase the per enrollee or per determination standard minimum penalty and are determined based on criteria under paragraph (a) of this section.

(ii) CMS sets minimum penalty amounts in accordance with paragraphs (b)(1) and (2) of this section.

(iii) CMS announces the standard minimum penalty amounts and aggravating factor amounts for per determination and per enrollee penalties on an annual basis.

(iv) CMS has the discretion to issue penalties up to the maximum amount under paragraphs (b)(1) and (2) of this section when CMS determines that an organization's non-compliance warrants a penalty that is higher than would be applied under the minimum penalty amounts set by CMS.

(4) For each week that a deficiency remains uncorrected after the week in which the Part D sponsor receives CMS' notice of the determination—up to $10,000 as adjusted annually under 45 CFR part 102.

(5) If CMS makes a determination that a Part D sponsor has terminated its contract other than in a manner described under 423.510 and that the Part D sponsor has therefore failed to substantially carry out the terms of the contract, $250 as adjusted annually under 45 CFR part 102 per Medicare enrollee from the terminated Part D sponsor or plans at the time the Part D sponsor terminated its contract, or $100,000 as adjusted annually under 45 CFR part 102, whichever is greater.

(c) *Amount of penalty imposed by CMS or OIG.* CMS or the OIG may impose civil money penalties in the following amounts for a determination made under § 423.752(a):

(1) Civil money penalties of not more than $25,000 as adjusted annually under 45 CFR part 102 for each determination made.

(2) With respect to a determination made under § 423.752(a)(4) or (a)(5)(i), not more than $100,000 as adjusted annually under 45 CFR part 102 for each such determination except with respect to a determination made under § 423.752(a)(5), an assessment of not more than the amount claimed by such plan or PDP sponsor based upon the misrepresentation or falsified information involved.

(3) Plus with respect to a determination made under § 423.752(a)(2), double the excess amount charged in violation of such paragraph (and the excess amount charged must be deducted from the penalty and returned to the individual concerned).

(4) Plus with respect to a determination made under § 423.752(a)(4), $15,000 as adjusted annually under 45 CFR part 102 for each individual not enrolled as a result of the practice involved.

[72 FR 68735, Dec. 5, 2007, as amended at 74 FR 1548, Jan. 12, 2009; 79 FR 29966, May 23, 2014; 81 FR 61562, Sept. 6, 2016; 86 FR 6121, Jan. 19, 2021; 89 FR 30841, Apr. 23, 2024]

§ 423.762 Settlement of penalties.

For civil money penalties imposed by CMS, CMS may settle civil money penalty cases at any time before a final decision is rendered.

[72 FR 68735, Dec. 5, 2007]

§ 423.764 Other applicable provisions.

The provisions of section 1128A of the Act (except paragraphs (a) and (b)) apply to civil money penalties under this subpart to the same extent that they apply to a civil money penalty or procedure under section 1128A of the Act.

[70 FR 4525, Jan. 28, 2005. Redesignated at 72 FR 68735, Dec. 5, 2007]

Subpart P—Premiums and Cost-Sharing Subsidies for Low-Income Individuals

§ 423.771 Basis and scope.

(a) *Basis.* This subpart is based on section 1860D–14 of the Act.

(b) *Scope.* This subpart sets forth the requirements and limitations for payments by and on behalf of low-income Medicare beneficiaries who enroll in a Part D plan.

§ 423.772 Definitions.

For purposes of this subpart, the following definitions apply:

Applicant means the Part D eligible individual applying for the subsidies available to subsidy eligible individuals under this subpart.

Best available evidence means evidence recognized by CMS as documentation or other information that is directly tied to State or Social Security Administration systems that confirm an individual's low-income subsidy eligibility status, and that must be accepted and used by the Part D sponsor to change low-income subsidy status.

Family size means the applicant, the spouse who is living in the same household, if any and the number of individuals who are related to the applicant or applicants, who are living in the same household and who are dependent on the applicant or the applicant's spouse for at least one-half of their financial support.

Federal poverty line (FPL) has the meaning given that term in section 673(2) of the Community Services Block Grant Act (42 USC 9902(2)), including any revision required by that section.

Full-benefit dual eligible individual means an individual who, for any month—

(1) Has coverage for the month under a prescription drug plan under Part D of title XVIII, or under an MA-PD plan under Part C of title XVIII; and

(2) Is determined eligible by the State for medical assistance for full benefits under title XIX for the month under any eligibility category covered under the State plan or comprehensive benefits under a demonstration under section 1115 of the Act. (This does not include individuals under Pharmacy Plus program demonstrations or under a section 1115 demonstration that provides pharmacy-only benefits to these individuals.). It also includes any individual who is determined by the State to be eligible for medical assistance under section 1902(a)(10)(C) of the Act (medically needy) or section 1902(f) of

the Act (States that use more restrictive eligibility criteria than are used by the SSI program) of the Act for any month if the individual was eligible for medical assistance in any part of the month.

Full subsidy means the subsidies available to full subsidy eligible individuals under § 423.780(a) and § 423.782(a).

Full subsidy eligible individuals means individuals meeting the eligibility requirements under § 423.773(b).

Income means income as described under section 1905(p)(1) of the Act without use of any more liberal disregards under section 1902(r)(2) of the Act (that is defined by section 1612 of the Act) and exempts support and maintenance furnished in kind. This definition includes the income of the applicant and spouse who is living in the same household, if any, regardless of whether the spouse is also an applicant.

Individual receiving home and community-based services means a full-benefit dual-eligible individual who is receiving services under a home and community-based program authorized for a State in accordance with one of the following:

(1) Section 1115 of the Act.

(2) Section 1915(c) or (d) of the Act.

(3) State plan amendment under section 1915(i) of the Act.

(4) Services are provided through enrollment in a Medicaid managed care organization with a contract under section 1903(m) of the Act or section 1932 of the Act.

Institutionalized individual means a full-benefit dual eligible individual who is an inpatient in a medical institution or nursing facility for which payment is made under Medicaid throughout a month, as defined under section 1902(q)(1)(B) of the Act.

Other subsidy eligible individuals means those individuals meeting the eligibility requirements under § 423.773(d).

Personal representative for purposes of this subpart means—

(1) An individual who is authorized to act on behalf of the applicant;

(2) If the applicant is incapacitated; or incompetent, someone acting responsibly on their behalf, or

(3) An individual of the applicant's choice who is requested by the applicant to act as his or her representative in the application process.

Resources means liquid resources of the applicant (and, if married, his or her spouse who is living in the same household), such as checking and savings accounts, stocks, bonds, and other resources that can be readily converted to cash within 20 days, that are not excluded from resources in section 1613 of the Act, and real estate that is not the applicant's primary residence or the land on which the primary residence is located. It exempts the value of any life insurance policy.

State means for purposes of this subpart each of the 50 States and the District of Columbia.

[70 FR 4525, Jan. 28, 2005, as amended at 73 FR 54253, Sept. 18, 2008; 74 FR 1548, Jan. 12, 2009; 76 FR 21576, Apr. 15, 2011]

§ 423.773 Requirements for eligibility.

(a) *Subsidy eligible individual.* A subsidy eligible individual is a Part D eligible individual residing in a State who is enrolled in, or seeking to enroll in a Part D plan and meets the following requirements:

(1) Has income below 150 percent of the FPL applicable to the individual's family size.

(2) Has resources at or below the resource thresholds set forth in § 423.773(b)(2) or (d)(2).

(b) *Full subsidy eligible individual.* A full subsidy eligible individual is a subsidy eligible individual who—

(1) Has income below 135 percent of the FPL applicable to the individual's family size or, with respect to a plan year beginning on or after January 1, 2024, has income below 150 percent of the FPL applicable to the individual's family size; and

(2) Has resources that do not exceed—

(i) For 2006, 3 times the amount of resources an individual may have and still be eligible for benefits under the Supplemental Security Income (SSI) program under title XVI of the Act (including the assets or resources of the individual's spouse).

(ii) For years 2007 through 2023, the amount of resources allowable for the previous year under this paragraph

(b)(2) increased by the annual percentage increase in the consumer price index (all items, U.S. city average) as of September of that previous year, rounded to the nearest multiple of $10. The nearest multiple are rounded up if it is equal to or greater than $5 and down if it is less than $5.

(iii) For plan years beginning on or after January 1, 2024, the amount of resources specified at paragraph (d)(2) of this section.

(c)(1) *Individuals treated as full subsidy eligible.* An individual must be treated as meeting the eligibility requirements for full subsidy eligible individuals under paragraph (b) of this section if the individual is a—

(i) Full-benefit dual eligible individual;

(ii) Beneficiary of SSI benefits under title XVI of the Act; or

(iii) Eligible for Medicaid as a Qualified Medicare Beneficiary (QMB), Specified Low Income Medicare Beneficiary (SLMB), or a Qualifying Individual (QI) under a State's plan.

(2) CMS notifies an individual treated as a full-subsidy eligible under this paragraph (c) that he or she does not need to apply for the subsidies under this subpart, and, at a minimum, is deemed eligible for a full subsidy as follows:

(i) For an individual deemed eligible between January 1 and June 30 of a calendar year, the individual is deemed eligible for a full subsidy for the remainder of the calendar year.

(ii) For an individual deemed eligible between July 1 and December 31 of a calendar year, the individual is deemed eligible for the remainder of the calendar year and the following calendar year.

(d) *Other low-income subsidy individuals.* Other low-income subsidy individuals are subsidy eligible individuals who, for plan years beginning before January 1, 2024—

(1) Have income less than 150 percent of the FPL applicable to the individual's family size; and

(2) Have resources that do not exceed—

(i) For 2006, $10,000 if single or $20,000 if married (including the assets or resources of the individual's spouse).

(ii) For subsequent years, the resource amount allowable for the previous year under this paragraph (d)(2), increased by the annual percentage increase in the consumer price index (all items, U.S. city average) as of September of the previous year, rounded to the nearest multiple of $10. The nearest multiple will be rounded up if it is equal to or greater than $5 and down if it is less than $5.

[70 FR 4525, Jan. 28, 2005, as amended at 75 FR 19825, Apr. 15, 2010; 88 FR 22340, Apr. 12, 2023]

§ 423.774 Eligibility determinations, redeterminations, and applications.

(a) *Determinations of whether an individual is a subsidy eligible individual.* Determinations of eligibility for subsidies under this subpart are made by the State under its State plan under title XIX of the Act if the individual applies with the Medicaid agency, or if the individual applies with the Social Security Administration (SSA), the Commissioner of Social Security in accordance with the requirements of section 1860D–14(a)(3) of the Act.

(b) *Effective date of initial eligibility determinations.* Initial eligibility determinations are effective beginning with the first day of the month in which the individual applies, but no earlier than January 1, 2006 and remain in effect for a period not to exceed 1 year.

(c) *Redeterminations and appeals of low-income subsidy eligibility*—(1) *Redeterminations and appeals of low-income subsidy eligibility determinations—eligibility determinations made by States.* Redeterminations and appeals of low-income subsidy eligibility determinations by States must be made in the same manner and frequency as the redeterminations and appeals are made under the State's plan.

(2) *Redeterminations and appeals of low-income subsidy eligibility—eligibility determinations made by Commissioner of Social Security.* Redeterminations and appeals of eligibility determinations made by the Commissioner will be made in the manner specified by the Commissioner of Social Security.

(d) *Application requirements.* (1) In order for applications for the subsidies under this subpart to be considered

complete, applicants or personal representatives applying on the individual's behalf, must—

(i) Complete all required elements of the application; (ii) Provide any statements from financial institutions, as requested, to support information in the application; and

(iii) Certify, under penalty of perjury or similar sanction for false statements, as to the accuracy of the information provided on the application form.

(2) *Multiple applications.* If the individual or his or her personal representative has previously filed an application with the State or SSA which seeks subsidy eligibility for any portion of the eligibility period covered by a subsequent application, the later application is void if the individual has received a positive subsidy determination on that earlier application from the State or SSA.

§ 423.780 Premium subsidy.

(a) *Full subsidy eligible individuals.* Full subsidy eligible individuals are entitled to a premium subsidy equal to 100 percent of the premium subsidy amount.

(b) *Premium subsidy amount.* (1) The premium subsidy amount is equal to the lesser of—

(i) Under the Part D plan selected by the beneficiary, the portion of the monthly beneficiary premium attributable to basic coverage (for enrollees in PDPs) or the portion of the MA monthly prescription drug beneficiary premium attributable to basic prescription drug coverage (for enrollees in MA–PD plans); or

(ii) The greater of the low-income benchmark premium amount (determined under paragraph (b)(2) of this section) for the PDP region in which the subsidy eligible individual resides or the lowest monthly beneficiary premium for a PDP that offers basic prescription drug coverage in the PDP region.

(2) *Calculation of the low-income benchmark premium amount.* (i) The low-income benchmark premium amount for a PDP region is a weighted average of the premium amounts described in paragraph (b)(2)(ii) of this section, with the weight for each PDP and MA–PD plan equal to a percentage, the numerator being equal to the number of Part D low-income subsidy eligible individuals enrolled in the plan in the reference month (as defined in § 422.258(c)(1) of this chapter) and the denominator equal to the total number of Part D low-income subsidy eligible individuals enrolled in all PDP and MA–PD plans (but not including PACE, private fee-for-service plans or 1876 cost plans) in a PDP region in the reference month.

(ii) *Premium amounts.* The premium amounts used to calculate the low-income benchmark premium amount are as follows:

(A) The monthly beneficiary premium for a PDP that is basic prescription drug coverage;

(B) The portion of the monthly beneficiary premium attributable to basic prescription drug coverage for a PDP that is enhanced alternative coverage; or,

(C) The MA monthly prescription drug beneficiary premium (as defined under section 1854(b)(2)(B) of the Act) for a MA–PD plan and determined before the application of the monthly rebate computed under section 1854(b)(1)(C)(i) of the Act for that plan and year involved.

(c) *Special rule for 2006 to weight the low-income benchmark premium.* For purposes of calculating the low-income benchmark premium amount for 2006, CMS assigns equal weighting to PDP sponsors (including fallback entities) and assigns MA-PD plans a weight based on prior enrollment. New MA-PD plans are assigned a zero weight. PACE, private fee-for-service plans and 1876 cost plans are not included.

(d) *Other low-income subsidy eligible individuals—sliding scale premium.* Other low-income subsidy eligible individuals are entitled to a premium subsidy for plan years beginning before January 1, 2024, based on a linear sliding scale ranging from 100 percent of the premium subsidy amount described in paragraph (b) of this section as follows:

(1) For individuals with income at or below 135 percent of the FPL applicable to their family size, the full premium subsidy amount.

(2) For individuals with income greater than 135 percent but at or

below 140 percent of the FPL applicable to the family size, a premium subsidy equal to 75 percent of the premium subsidy amount.

(3) For individual with income greater than 140 percent but at or below 145 percent of the FPL applicable to the family size a premium subsidy equal to 50 percent of the premium subsidy amount.

(4) For individuals with income greater than 145 percent but below 150 percent of FPL applicable to the family size a premium subsidy equal to 25 percent of the premium subsidy amount.

(e) *Waiver of late enrollment penalty for subsidy-eligible individuals.* Subsidy eligible individuals, as defined in § 423.773, are not subject to a late enrollment penalty, as defined in § 423.46.

(f) *Waiver of de minimis premium amounts.* CMS will permit a Part D plan to waive a de minimis amount that is above the monthly beneficiary premium defined in § 423.780(b)(2)(ii)(A) or (B) for full subsidy individuals as defined in § 423.780(a) or § 423.780(d)(1), provided waiving the de minimis amount results in a monthly beneficiary premium that is equal to the established low income benchmark as defined in § 423.780(b)(2).

[70 FR 4525, Jan. 28, 2005, as amended at 73 FR 18182, Apr. 3, 2008; 73 FR 20508, Apr. 15, 2008; 73 FR 54253, Sept. 18, 2008; 76 FR 21576, Apr. 15, 2011; 88 FR 22340, Apr. 12, 2023]

§ 423.782 Cost-sharing subsidy.

(a) *Full subsidy eligible individuals.* Full subsidy eligible individuals are entitled to the following:

(1) Elimination of the annual deductible under § 423.104(d)(1).

(2) Reduction in cost-sharing for all covered Part D drugs covered under the PDP or MA-PD plan below the out-of-pocket limit (under § 423.104), including Part D drugs covered under the PDP or MA-PD plan obtained after the initial coverage limit (under § 423.104(d)(4)), as follows:

(i) Except as provided under paragraphs (a)(2)(ii) and (a)(2)(iii) of this section, copayment amounts not to exceed the copayment amounts specified in § 423.104(d)(5)(A). This applies to both:

(A) Those full-benefit dual eligible individuals who are not institutionalized and who have income above 100 percent of the Federal poverty line applicable to the individual's family size and

(B) Those individuals who have income under 135 percent of the Federal poverty line applicable to the individual's family size who meet the resources test described at § 423.773(b)(2).

(ii) Full-benefit dual-eligible individuals who are institutionalized or who are receiving home and community-based services have no cost-sharing for Part D drugs covered under their PDP or MA–PD plans.

(iii) Full-benefit dual eligible individuals with incomes that do not exceed 100 percent of the Federal poverty line applicable to the individual's family size are subject to cost-sharing for covered Part D drugs equal to the lesser of:

(A) A copayment amount of not more than $1 for a generic drug, biological product for which an application under section 351(k) of the Public Health Service Act (42 U.S.C. 262(k)) is approved, or preferred drugs that are multiple source (as defined under section 1927(k)(7)(A)(i) of the Act) or $3 for any other drug in 2006, or for years after 2006 the amounts specified in this paragraph (a)(2)(iii)(A) for the percentage increase in the Consumer Price Index, rounded to the nearest multiple of 5 cents or 10 cents, respectively; or

(B) The copayment amount charged to other individuals under this paragraph (a)(2)(i) of this section.

(3) Elimination of all cost-sharing for covered Part D drugs covered under the PDP or MA-PD plan above the out-of-pocket limit (under § 423.104(d)(5)).

(b) *Other low-income subsidy eligible individuals.* Other low-income subsidy eligible individuals are entitled to the following:

(1) In 2006, reduction in the annual deductible to $50. This amount is increased each year beginning in 2007 by the annual percentage increase in average per capita aggregate expenditures for Part D drugs, rounded to the nearest multiple of $1.

(2) Fifteen percent coinsurance for all covered Part D drugs obtained after the annual deductible under the plan

up to the out-of-pocket limit (under § 423.104(d)(5)(iii)).

(3) For covered Part D drugs above the out-of-pocket limit (under § 423.104(d)(5)(iii)) in 2006, copayments not to exceed $2 for a generic drug, biological product for which an application under section 351(k) of the Public Health Service Act (42 U.S.C. 262(k)) is approved, or preferred drugs that are multiple source drugs (as defined under section 1927(k)(7)(A)(i) of the Act) and $5 for any other drug. For years beginning in 2007, the amounts specified in this paragraph (b)(3) for the previous years increased by the annual percentage increase in average per capita aggregate expenditures for covered Part D drugs, rounded to the nearest multiple of 5 cents.

(c) When the out-of-pocket cost for a covered Part D drug under a Part D sponsor's plan benefit package is less than the maximum allowable copayment, coinsurance or deductible amounts under paragraphs (a) and (b) of this section, the Part D sponsor may only charge the lower benefit package amount.

[70 FR 4525, Jan. 28, 2005, as amended at 74 FR 1548, Jan. 12, 2009; 76 FR 21576, Apr. 15, 2011; 83 FR 16753, Apr. 16, 2018]

§ 423.800 Administration of subsidy program.

(a) *Notification of eligibility for low-income subsidy*. CMS notifies the Part D sponsor offering the Part D plan, in which a subsidy eligible individual is enrolled, of the individual's eligibility for a subsidy under this section and the amount of the subsidy.

(b) *Reduction of premium or cost-sharing by PDP sponsor or organization*. Based on information provided by CMS under paragraph (a) of this section, or obtained under paragraph (d) of this section, the Part D sponsor offering the Part D plan in which a subsidy eligible individual is enrolled must reduce the individual's premiums and cost-sharing as applicable, and provide information to CMS on the amount of those reductions, in a manner determined by CMS. The Part D sponsor must track the application of the subsidies under this subpart to be applied to the out-of-pocket threshold.

(c) *Reimbursement for cost-sharing paid before notification of eligibility for low-income subsidy*. The Part D sponsor offering the Part D plan must reimburse subsidy eligible individuals, and organizations paying cost-sharing on behalf of such individuals, any excess premiums and cost-sharing paid by such individual or organization after the effective date of the individual's eligibility for a subsidy under this subpart.

(d) *Use of the best available evidence process to establish cost-sharing*. Part D sponsors must—

(1) Accept best available evidence as defined in § 423.772 of this part received from beneficiaries or other individuals acting directly on their behalf; and

(2) Update the subsidy eligible individual's LIS status. and respond to requests for assistance in securing acceptable evidence of subsidy eligibility from beneficiaries or other individuals acting directly on their behalf in accordance with the process(es) established by CMS, and within the reasonable timeframe(s) as determined by CMS.

(e) *Timeframe for refunds and recoveries due to retroactive adjustments to cost sharing*. Sponsors must process retroactive adjustments to cost-sharing for low-income subsidy eligible individuals and any resulting refunds and recoveries in accordance with the timeframe specified in § 423.466(a) of this part.

[70 FR 4525, Jan. 28, 2005, as amended at 74 FR 1549, Jan. 12, 2009; 75 FR 19825, Apr. 15, 2010]

Subpart Q—Guaranteeing Access to a Choice of Coverage (Fallback Prescription Drug Plans)

§ 423.851 Scope.

This subpart sets forth—the rights of beneficiaries to a choice of at least two sources of qualified prescription drug coverage; requirements and limitations on the bid submission, review and approval of fallback prescription drug plans, and the determination of enrollee premium and plan payments for these plans.

§ 423.855 Definitions.

As used in this subpart, unless specified otherwise-

Actual costs means the subset of prescription drug costs (not including administrative costs or return on investment, but including costs directly related to the dispensing of covered Part D drugs during the year) that are attributable to standard benefits only and that are incurred and actually paid by the sponsor or organization under the plan.

Actually paid has the same meaning described in § 423.308.

Eligible fallback entity or *fallback entity* means an entity that, for a particular contract period-

(1) Is a PDP sponsor that does not have to be a risk-bearing entity (or, if applying to become a fallback entity, an entity that meets all the requirements to become a Part D plan sponsor except that it does not have to be a risk-bearing entity); and

(2) Does not submit a risk bid under § 423.265 for offering a prescription drug plan for any PDP region for the first year of that contract period. An entity is treated as submitting a risk bid if the entity is acting as a subcontractor for an integral part of the drug benefit management activities of an entity that is or applies to become a non-fallback PDP sponsor. An entity is not treated as submitting a bid if it is a subcontractor of an MA organization, unless that organization is acting as or applies to become a non-fallback PDP sponsor for a prescription drug plan.

Fallback prescription drug plan means a prescription drug plan (PDP) offered by a fallback entity that—

(1) Offers only defined standard or actuarially equivalent standard prescription drug coverage as defined in § 423.100;

(2) Provides access to negotiated prices, including discounts from manufacturers; and

(3) Meets all other requirements established for prescription drug plans, except as otherwise specified by CMS in this subpart or in separate guidance.

Qualifying plan means a full-risk or limited-risk prescription drug plan, as defined in § 423.258, or an MA-PD plan described in section 1851(a)(2)(A)(i) of the Act, that provides required prescription drug coverage, as defined in § 423.100 An MA-PD plan must be open for enrollment and not operating under a capacity waiver to be counted as a qualifying plan. A PDP must not be operating under a restricted enrollment waiver, such as those that may be granted to special needs plans or employer group plans, in order to be counted as a qualifying plan in an area.

§ 423.859 Assuring access to a choice of coverage.

(a) *Choice of at least 2 qualifying plans in each area.* Each Part D eligible individual must have available a choice of enrollment in at least 2 qualifying plans (as defined in § 423.855) in the area in which the individual resides. This requirement is not satisfied if only one entity offers all the qualifying plans in the area. At least 1 of the 2 qualifying plans must be a prescription drug plan.

(b) *Fallback service area*—(1) *For coverage year.* Before the start of each coverage year CMS determines if Part D eligible individuals residing in a PDP region have access to a choice of enrollment in a minimum of 2 qualifying plans, as described in paragraph (a) of this section. If CMS determines that Part D eligible individuals in a PDP region, or some portion of the region, do not have available a choice of enrollment in a minimum of two qualified plans, CMS designates the region or portion of a region as a fallback service area. Each Part D eligible individual in a fallback service area is given the opportunity to enroll in a fallback prescription drug plan.

(2) *For mid-year changes.* If a contract with a qualifying plan is terminated in the middle of a contract year (as provided for in § 423.508, § 423.509, or § 423.510), CMS determines if Part D eligible individuals residing in the affected PDP region still have access to a choice of enrollment in a minimum of 2 qualifying plans, as described in paragraph (a) of this section. If CMS determines that Part D eligible individuals in a PDP region, or some portion of the region, no longer have available a choice of enrollment in a minimum of two qualifying plans, CMS designates the region or portion of a region as a fallback service area.

(c) *Access to coverage in the territories.* CMS may waive or modify the requirements of this part if—

(1) CMS determines that waiver or modification is necessary to secure access to qualified prescription drug coverage for Part D eligible individuals residing in a State other than the 50 States or the District of Columbia; or

(2) An entity seeking to become a prescription drug plan in an area such as a territory, other than the 50 States or the District of Columbia requests waiver or modification of any Part D requirement in order to provide qualified prescription drug coverage.

§ 423.863 Submission and approval of bids.

(a) *Submission of bids*—(1) *Solicitation of bids.* Separate from the risk bidding process under § 423.265, CMS solicits bids from eligible fallback entities for the offering in all fallback service areas in one or more PDP regions of a fallback prescription drug plan during the contract period specified in § 423.871(b).

(2) *Timing of bids.* CMS determines when to solicit bids for 2006 so that potential fallback prescription drug plans have enough time to prepare a bid. After that, bids are solicited on 3 year cycles, or annually thereafter as needed to replace contractors between contracting cycles.

(3) *Format of bid.* CMS specifies the form and manner in which fallback bids are submitted in separate guidance to bidders.

(b) *Negotiation and acceptance of bids*—(1) *General rule.* Except as provided in this section, the provisions of § 423.272 apply for the approval or disapproval of fallback prescription drug plans. CMS enters into contracts under this paragraph with eligible fallback entities for the offering of approved fallback prescription drug plans in potential fallback service areas.

(2) *Flexibility in risk assumed and application of fallback prescription drug plan.* In order to ensure access in an area in accordance with § 423.859(a), CMS may approve limited risk plans under § 423.272(c) for that area. If the access requirement is still not met after applying § 423.272(c), CMS provides for the offering of a fallback prescription drug plan in that area.

(3) *Limitation of 1 Plan for all fallback service areas in a PDP region.* All fallback service areas in any PDP region for a contract period must be served by the same fallback prescription drug plan.

(4) *Competitive procedures.* CMS uses competitive procedures (as defined in section 4(5) of the Office of Federal Procurement Policy Act (41 U.S.C. 403(5)) to enter into a contract under this paragraph. The provisions of section 1874A(d) of the Act apply to a contract under this section in the same manner as they apply to a contract under that section.

(5) *Timing of contracts.* CMS approves a fallback prescription drug plan for a PDP region in a manner so that, if there are any fallback service areas in the region for a year, the fallback prescription drug plan is offered at the same time as prescription drug plans are otherwise offered. In the event of mid-year changes and as required by § 423.859(b)(2), CMS approves a fallback prescription drug plan for a PDP region in a manner so that the fallback prescription drug plan is offered within 90 days of notice.

(6) *No national fallback prescription drug plan.* CMS may not enter into a contract with a single fallback entity for the offering of fallback prescription drug plans throughout the United States.

§ 423.867 Rules regarding premiums.

(a) *Monthly beneficiary premium.* Except as provided in § 423.286(d)(3) (relating to late enrollment penalty) and subject to subpart P (relating to low-income assistance), the monthly beneficiary premium under a fallback prescription drug plan must be uniform for all fallback service areas in a PDP region. It must equal 25.5 percent of CMS's estimate of the average monthly per capita actuarial cost, including administrative expenses, of providing coverage in the PDP region based on similar expenses of prescription drug plans that are not fallback prescription drug plans.

(b) *Special rule for collection of premiums in fallback prescription drug plans.* In the case of a fallback prescription

drug plan, the provisions of § 423.293 (b) concerning payments of the late enrollment penalty to the PDP sponsor do not apply and the monthly beneficiary premium is collected in the manner specified in § 422.262(f)(1) of this chapter, or paid directly to the fallback entity by the beneficiary if there are either no benefits, or insufficient benefits available to be collected in the manner specified under § 422.262(f)(1) of this chapter. The amount of any premiums collected by the fallback entity is deducted from management fees due from CMS.

§ 423.871 Contract terms and conditions.

(a) *General.* Except as may be appropriate to carry out the requirements of this section, the terms and conditions of contracts with eligible fallback entities offering fallback prescription drug plans are the same as the terms and conditions of contracts at §§ 423.504 and 423.505 for Part D plans.

(b) *Period of contract.* A contract with a fallback entity for fallback service areas for a PDP region is in effect for a period of 3 years. However, a fallback prescription drug plan may be offered for any year within the contract period for a particular area only if the area is a fallback service area for that year.

(c) *Entity not permitted to market or brand fallback prescription drug plans.* Notwithstanding any other provisions of this part, an eligible fallback entity with a contract under this part may not engage in any marketing or branding of a fallback prescription drug plan.

(d) *Performance measures.* CMS issues guidance establishing performance measures for fallback prescription drug plans based on the following:

(1) *Types of performance measures.* Performance measures include at least measures for each of the following:

(i) *Costs.* The entity contains costs to the Medicare Prescription Drug Account and to Part D eligible individuals enrolled in a fallback prescription drug plan offered by the entity through mechanisms such as generic substitution and price discounts.

(ii) *Quality programs.* The entity provides the enrollees in its fallback prescription drug plan with quality programs that avoid adverse drug reactions, monitor for appropriate utilization, and reduce medical errors.

(iii) *Customer service.* The entity provides timely and accurate delivery of services and pharmacy and beneficiary support services.

(iv) *Benefit administration and claims adjudication.* The entity provides efficient and effective benefit administration and claims adjudication.

(2) *Development of performance measures.* CMS establishes detailed performance measures for use in evaluating fallback entity performance and determination of certain management fees based on criteria from historical performance, application of acceptable statistical measures of variation to fallback entity and PDP sponsor (other than fallback entities) experience nationwide during a base period, or changing program emphases or requirements.

(e) *Payment terms.* A contract approved with a fallback entity includes terms for payment for—

(1) The actual costs of covered Part D drugs provided to Part D eligible individuals enrolled in a fallback prescription drug plan offered by the entity; and

(2) Management fees that consist of administrative costs and return on investment and are tied to the performance measures established by CMS for the management, administration, and delivery of the benefits under the contract as provided under paragraph (d) of this section.

(f) *Requirement for the submission of information.* Each contract for a fallback prescription drug plan requires an eligible fallback entity offering a fallback prescription drug plan to provide CMS with the information CMS determines is necessary to carry out the payment provisions under subpart G or under this subpart, or as required by law. Information disclosed to determine Medicare payment or reimbursement to the fallback entity may be used by the officers, employees and contractors of the Department of Health and Human Services only for the purposes of, and to the extent necessary in, determining such payment or reimbursement. This restriction does not limit CMS or OIG

authority to conduct audits and evaluations necessary to ensure accurate and correct payment and to otherwise oversee Medicare reimbursement

(g) *Amendment to reflect changes in service area.* The contract may be amended by CMS at any time as needed to reflect the exact regions or counties where the fallback plan are required to operate within the contracted service area(s).

§ 423.875 Payment to fallback plans.

The amount payable for a fallback prescription drug plan is the amount determined under the contract for the plan in accordance with § 423.871(e).

Subpart R—Payments to Sponsors of Retiree Prescription Drug Plans

§ 423.880 Basis and scope.

(a) *Basis.* This subpart is based on section 1860D–22 of the Act, as amended by section 101 of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA).

(b) *Scope.* This section implements the statutory requirement that a subsidy payment be made to sponsors of qualified retiree prescription drug plans.

§ 423.882 Definitions.

For the purposes of this subpart, the following definitions apply:

Actually paid means that the costs must be actually incurred by the qualified retiree prescription drug plan and must be net of any direct or indirect remuneration (including discounts, charge backs or rebates, cash discounts, free goods contingent on a purchase agreement, up-front payments, coupons, goods in kind, free or reduced-price services, grants, or other price concessions or similar benefits offered to some or all purchasers) from any source that would serve to decrease the costs incurred under the qualified retiree prescription drug plan.

Administrative costs means costs incurred by a qualified retiree prescription drug plan that are not drug costs incurred to purchase or reimburse the purchase of Part D drugs.

Allowable retiree costs means the subset of gross covered retiree plan-related prescription drug costs actually paid by the sponsor of the qualified retiree prescription drug plan or by (or on behalf of) a qualifying covered retiree under the plan.

Benefit option means a particular benefit design, category of benefits, or cost-sharing arrangement offered within a group health plan.

Employment-based retiree health coverage means coverage of health care costs under a group health plan based on an individual's status as a retired participant in the plan, or as the spouse or dependent of a retired participant. The term includes coverage provided by voluntary insurance coverage, or coverage as a result of a statutory or contractual obligation.

Gross covered retiree plan-related prescription drug costs, or *gross retiree costs*, means those Part D drug costs incurred under a qualified retiree prescription drug plan, excluding administrative costs, but including dispensing fees, during the coverage year. They equal the sum of the following:

(1) The share of prices paid by the qualified retiree prescription drug plan that is received as reimbursement by the pharmacy or by an intermediary contracting organization, and reimbursement paid to indemnify a qualifying covered retiree when the reimbursement is associated with a qualifying covered retiree obtaining Part D drugs under the qualified retiree prescription drug plan.

(2) All amounts paid under the qualified retiree prescription drug plan by or on behalf of a qualifying covered retiree (such as the deductible, coinsurance, or cost sharing) in order to obtain Part D drugs that are covered under the qualified retiree prescription drug plan.

Group health plans include plans as defined in section 607(1) of ERISA, 29 U.S.C. § 1167(1). They also include the following plans:

(1) A Federal or State governmental plan, which is a plan providing medical care that is established or maintained for its employees by the Government of the United States, by the government of any State or political subdivision of a State (including a county or local government), or by any agency or instrumentality or any of the foregoing, including a health benefits plan offered

under chapter 89 of Title 5, United States Code (the Federal Employee Health Benefit Plan (FEHBP)).

(2) A collectively bargained plan, which is a plan providing medical care that is established or maintained under or by one or more collective bargaining agreements.

(3) A church plan, which is a plan providing medical care that is established and maintained for its employees or their beneficiaries by a church or by a convention or association of churches that is exempt from tax under section 501 of the Internal Revenue Code of 1986 (26 U.S.C. 501).

(4) An account-based medical plan such as a Health Reimbursement Arrangement (HRA) as defined in Internal Revenue Service Notice 2002–45, 2002–28 I.R.B. 93, a health Flexible Spending Arrangement (FSA) as defined in Internal Revenue Code (Code) section 106(c)(2), a health savings account (HSA) as defined in Code section 223, or an Archer MSA as defined in Code section 220, to the extent they are subject to ERISA as employee welfare benefit plans providing medical care (or would be subject to ERISA but for the exclusion in ERISA section 4(b), 29 U.S.C.§. §1003(b), for governmental plans or church plans).

Part D drug is defined in §423.100 of this part.

Part D eligible individual is defined in §423.4 of this part.

Qualified retiree prescription drug plan means employment-based retiree health coverage that meets the requirements set forth in §423.884 of this chapter for a Part D eligible individual who is a retired participant or the spouse or dependent of a retired participant under the coverage.

Qualifying covered retiree means a Part D eligible individual who is: a participant or the spouse or dependent of a participant; covered under employment-based retiree health coverage that qualifies as a qualified retiree prescription drug plan; and not enrolled in a Part D plan. For this purpose, the determination of whether an individual is covered under employment-based retiree health coverage is made by the sponsor in accordance with the rules of its plan. For purposes of this subpart, however, an individual is presumed not to be covered under employment-based retiree health coverage if, under the Medicare Secondary Payer rules in §411.104 of this chapter and related CMS guidance, the person is considered to be receiving coverage by reason of current employment status. The presumption applies whether or not the Medicare Secondary Payer rules actually apply to the sponsor. For this purpose, a sponsor also may treat a person receiving coverage under its qualified retiree prescription drug plan as the dependent of a qualifying covered retiree in accordance with the rules of its plan, regardless of whether that person constitutes the qualifying covered retiree's dependent for Federal or State tax purposes.

Retiree drug subsidy amount, or subsidy payment, means the subsidy amount paid to sponsors of qualified retiree prescription drug coverage under §423.886(a).

Standard prescription drug coverage is defined in §423.100 of this part.

Sponsor is a plan sponsor as defined in section 3(16)(B) of the Employee Retirement Income Security Act of 1974 (ERISA), 29 U.S.C. 1002(16)(B), except that, in the case of a plan maintained jointly by one employer and an employee organization and for which the employer is the primary source of financing, the term means the employer.

Sponsor agreement means an agreement by the sponsor to comply with the provisions of this subpart.

[70 FR 4525, Jan. 28, 2005, as amended at 74 FR 1549, Jan. 12, 2009; 77 FR 1883, Jan. 12, 2012]

§423.884 Requirements for qualified retiree prescription drug plans.

(a) *General.* Employment-based retiree health coverage is considered to be a qualified retiree prescription drug plan if all of the following requirements are satisfied:

(1) An actuarial attestation is submitted in accordance with paragraph (d) of this section. The rules for submitting attestations as part of subsidy applications are described in paragraph (c) of this section.

(2) Part D eligible individuals covered under the plan are provided with creditable coverage notices in accordance with §423.56.

(3) Records are maintained and made available for audit in accordance with paragraph (f) of this section and § 423.888(d).

(b) *Disclosure of information.* The sponsor must have a written agreement with its health insurance issuer (as defined in 45 CFR 160.103), or group health plan (as applicable) regarding disclosure of information to CMS, and the issuer or plan must disclose to CMS, on behalf of the sponsor, the information necessary for the sponsor to comply with this subpart.

(c) *Application*—(1) *Submitting an application.* The sponsor (or its designee) must submit an application for the subsidy to CMS that is signed by an authorized representative of the sponsor. The application must be provided in a form and manner specified by CMS.

(2) *Required information.* In connection with each application the sponsor (either directly or through its designee) must submit the following:

(i) Employer Tax ID Number (if applicable).

(ii) Sponsor name and address.

(iii) Contact name and email address.

(iv) Actuarial attestation that satisfies the standards specified in paragraph (d) of this section and any other supporting documentation required by CMS for each qualified retiree prescription drug plan for which the sponsor seeks subsidy payments.

(v) A list of all individuals the sponsor believes (using information reasonably available to the sponsor when it submits the application) are qualifying covered retirees enrolled in each prescription drug plan (including spouses and dependents, if Medicare-eligible), along with the information about each person listed below in this paragraph:

(A) Full name.

(B) Health Insurance Claim (HIC) number or Social Security number.

(C) Date of birth.

(D) Gender.

(E) Relationship to the retired employee.

(vi) A sponsor may satisfy paragraph (c)(2)(v) of this section by entering into a voluntary data sharing agreement (VDSA) with CMS (or any other arrangement CMS may make available).

(vii) A signed sponsor agreement.

(viii) Any other information specified by CMS.

(3) *Terms and conditions.* To receive a subsidy payment, the sponsor (through the signed sponsor agreement or as otherwise specified by CMS) must specifically accept and agree to:

(i) Comply with the terms and conditions of eligibility for a subsidy payment set forth in this regulation and in any related CMS guidance;

(ii) Acknowledge that at the same time CMS releases Part C and Part D summary payment data in accordance with §§ 422.504(n) and 423.505(o) CMS will also release Part D retiree drug subsidy payment data for the most recently reconciled year including the name of the eligible sponsor, the total gross aggregate dollar amount of the CMS subsidy, and the number of eligible retirees;

(iii) Acknowledge that the information in the application is being provided to obtain Federal funds; and

(iv) Require that all subcontractors, including plan administrators, acknowledge that information provided in connection with the subcontract is used for purposes of obtaining Federal funds.

(4) *Signature by sponsor.* An authorized representative of the requesting sponsor must sign the completed application and certify that the information contained in the application is true and accurate to the best of the sponsor's knowledge and belief.

(5) *Timing*—(i) *General rule.* An application for a given plan year must be submitted prior to the beginning of the plan year by a date specified by CMS in published guidance, unless a request for an extension has been filed and approved under procedures set forth in such guidance.

(ii) *Transition rule.* For plan years that end in 2006, an application must be submitted by September 30, 2005 unless a request for an extension has been filed and approved under procedures established by CMS.

(6) *Updates.* The sponsor (or the designee) must provide updates to CMS in a manner specified by CMS of the information required in paragraph (c)(2) of this section on a monthly basis or at a frequency specified by CMS.

(7) *Data match.* Once the full application for the subsidy payment is submitted, CMS—

(i) Matches the names and identifying information for the individuals submitted as qualifying covered retirees with a CMS database(s) to determine which retirees are Part D eligible individuals who are not enrolled in a Part D plan.

(ii) Provides information concerning the results of the search in paragraph (c)(7)(i) of this paragraph (such as names and other identifying information, if necessary) to the sponsor (or to a designee).

(d) *Actuarial attestation—general.* The sponsor of the plan must provide to CMS an attestation in a form and manner specified by CMS that the actuarial value of the retiree prescription drug coverage under the plan is at least equal to the actuarial value of the defined standard prescription coverage (as defined at § 423.100), not taking into account the value of any discount or coverage provided during the coverage gap (as defined at § 423.100). The attestation must meet all of the following standards:

(1) Contents of the attestation include the following assurances:

(i) The actuarial gross value of the retiree prescription drug coverage under the plan for the plan year is at least equal to the actuarial gross value of the defined standard prescription drug coverage under Part D for the plan year in question, not taking into account the value of any discount or coverage provided during the coverage gap.

(ii) The actuarial net value of the retiree prescription drug coverage under the plan for that plan year is at least equal to the actuarial net value of the defined standard prescription drug coverage under Part D for that plan year in question, not taking into account the value of any discount or coverage provided during the coverage gap.

(iii) The actuarial values must be determined using the methodology in paragraph (d)(5) of this section.

(2) The attestation must be made by a qualified actuary who is a member of the American Academy of Actuaries. Applicants may use qualified outside actuaries, including (but not limited to) actuaries employed by the plan administrator or an insurer providing benefits under the plan. If an applicant uses an outside actuary, the attestation can be submitted directly by the outside actuary or by the plan sponsor.

(3) The attestation must be signed by a qualified actuary and must state that the attestation is true and accurate to the best of the attester's knowledge and belief.

(4) The attestation must contain an acknowledgement that the information being provided in the attestation is being used to obtain Federal funds.

(5) *Methodology*—(i) *Basis of the attestation.* The attestation must be based on generally accepted actuarial principles and any actuarial guidelines established by CMS in this section or in future guidance. To the extent CMS has not provided guidance on a specific aspect of the actuarial equivalence standard under this section, an actuary providing the attestation may rely on any reasonable interpretation of this section and section 1860D–22(a) of the Act consistent with generally accepted actuarial principles in determining actuarial values.

(ii) *Specific rules for determining the actuarial value of the sponsor's retiree prescription drug coverage.* (A) The gross value of coverage under the sponsor's retiree prescription drug plan must be determined using the actual claims experience and demographic data for Part D eligible individuals who are participants and beneficiaries in the sponsor's plan, provided that sponsors without creditable data due to their size or other factors, may use normative databases as specified by CMS. Sponsors may use other actuarial approaches specified by CMS as an alternative to the actuarial valuation specified by this paragraph (d)(5)(ii)(A).

(B) The net value of coverage provided under the sponsor's retiree prescription drug plan must be determined by reducing the gross value of such coverage as determined under paragraph (d)(5)(ii)(A) of this section by the expected premiums paid by Part D eligible individuals who are plan participants or their spouses and dependents.

For sponsors of plans that charge a single, integrated premium or contribution to their retirees for both prescription drug coverage and other types of medical coverage, the attestation must allocate a portion of the premium/contribution to prescription drug coverage under the sponsor's plan, under any method determined by the sponsor or its actuary.

(iii) *Specific rules for calculating the actuarial value of defined standard prescription drug coverage under Part D.* (A) The gross value of defined standard prescription drug coverage under Part D must be determined using the actual claims experience and demographic data for Part D eligible individuals in the sponsor's plan, provided that sponsors without credible data due to their size or other factors may use normative databases as specified by CMS. Sponsors may use other actuarial approaches specified by CMS as an alternative to the actuarial valuation specified by this paragraph (d)(5)(iii)(A).

(B) To calculate the net value of defined standard prescription drug coverage under Part D, the gross value of defined standard prescription drug coverage under Part D as determined by paragraph (d)(5)(iii)(A) of this section is reduced by the following amounts:

(*1*) The monthly beneficiary premiums (as defined in § 423.286) expected to be paid for standard prescription drug coverage; and

(*2*) An amount calculated to reflect the impact on the value of defined standard prescription drug coverage of supplemental coverage actually provided by the sponsor. Sponsors may use other actuarial approaches specified by CMS as an alternative to the actuarial valuation specified in this paragraph (d)(5)(iii)(B)(*2*).

(C) The valuation of defined standard prescription drug coverage for a given plan year is based on the initial coverage limit cost-sharing and out-of-pocket threshold for defined standard prescription drug coverage under Part D in effect at the start of such plan year, not taking into account the value of any discount or coverage provided during the coverage gap.

(D) Example: If a sponsor's retiree prescription drug plan operates under a plan year that ends March 30, the sponsor has a choice of basing the attestation for the year April 1, 2007 through March 30, 2008 on either the initial coverage limit, cost-sharing amounts, and out-of-pocket threshold amounts that apply to defined standard prescription drug coverage under Part D in CY 2007, or the amounts announced for CY 2008. However, in order to use the amounts applicable in CY 2007, the sponsor must submit the attestation within 60 days after the publication of the Part D coverage limits for CY 2008. If the attestation is submitted more than 60 days after the 2008 coverage limits have been published, the CY 2008 coverage limits would apply.

(iv) Employment-based retiree health coverage with two or more benefit options. For the assurance required under paragraph (d)(1)(i) of this section, the assurance must be provided separately for each benefit option for which the sponsor requests a subsidy under this subpart. For the assurance required under paragraph (d)(1)(ii) of this section, the assurance may be provided either separately for each benefit option for which the sponsor provided assurances under paragraph (d)(1)(i) of this section, or in the aggregate for all benefit options (or for a subset of the benefit options).

(6) *Timing*—(i) *Annual submission.* The attestation must be provided annually at the time the sponsor's subsidy application is submitted, or at such other times as specified by CMS in further guidance.

(ii) Submission following material change. The attestation must be provided no later than 90 days before the implementation of a material change to the drug coverage of the sponsor's retiree prescription drug plan. For purposes of this clause, the term ''material change'' means the addition of a benefit option that does not impact the actuarial value of the retiree prescription drug coverage under the sponsor's plan such that it no longer meets the standards set forth in paragraph (d)(1)(i) or (ii) of this section.

(7) Notice of failure to continue to satisfy the actuarial equivalence standards. A sponsor must notify CMS, in a form and manner specified by CMS, no later than 90 days before the implementation of a change to the

drug coverage that impacts the actuarial value of the retiree prescription drug coverage under the sponsor's plan such that it no longer meets the standards set forth in paragraph (d)(1)(i) or (ii) of this section.

(e) *Disclosure of creditable prescription drug coverage status.* The sponsor must disclose to all of its retirees and their spouses and dependents eligible to participate in its plan who are Part D eligible individuals whether the coverage is creditable prescription drug coverage under § 423.56 in accordance with the notification requirements under that section.

(f) *Access to records for audit.* The sponsor (and where applicable, its designee) must meet the requirements of § 423.888(d). Failure to comply with § 423.888(d) may result in nonpayment or recoupment of all or part of a subsidy payment.

[70 FR 4525, Jan. 28, 2005, as amended at 73 FR 20508, Apr. 15, 2008; 76 FR 21576, Apr. 15, 2011]

§ 423.886 Retiree drug subsidy amounts.

(a) *Amount of subsidy payment.* (1) For each qualifying covered retiree enrolled with the sponsor of a qualified retiree prescription drug plan in a plan year, the sponsor receives a subsidy payment in the amount of 28 percent of the allowable retiree costs (as defined in § 423.882) in the plan year for such retiree attributable to gross retiree costs between the cost threshold and the cost limit as defined in paragraph (b) of this section. The subsidy payment is calculated by first determining gross retiree costs between the cost threshold and cost limit, and then determining allowable retiree costs attributable to the gross retiree costs. For this purpose and where otherwise relevant in this subpart, plan year is the calendar, policy, or fiscal year on which the records of a plan are kept.

(2) *Transition provision.* For a qualified retiree prescription drug plan that has a plan year which begins in calendar year 2005 and ends in calendar year 2006, the subsidy for the plan year must be determined in the following manner. Claims incurred in all months of the plan year (including claims incurred in 2005) are taken into account in determining which claims fall within the cost threshold and cost limit for the plan year. The subsidy amount is determined based only on costs incurred on and after January 1, 2006.

(b) *Cost threshold and cost limit.* The following cost threshold and cost limits apply—

(1) Subject to paragraph (b)(3) of this section, the cost threshold under this section is equal to $250 for plan years that end in 2006.

(2) Subject to paragraph (b)(3) of this section, the cost limit under this section is equal to $5,000 for plan years that end in 2006.

(3) The cost threshold and cost limit specified in paragraphs (b)(1) and (b)(2) of this section, for plan years that end in years after 2006, are adjusted in the same manner as the annual Part D deductible and the annual Part D out-of-pocket threshold are adjusted annually under § 423.104(d)(1)(ii) and (d)(5)(iii)(B), respectively.

§ 423.888 Payment methods, including provision of necessary information.

(a) *Basis.* The provisions of § 423.301 through § 423.343, including requirements to provide information necessary to ensure accurate subsidy payments, govern payment under § 423.886 except to the extent the provisions in this section specify otherwise.

(b) *General payment rules.* Payment under § 423.886 is conditioned on provision of accurate information. The information must be submitted, in a form and manner and at the times provided in this paragraph and under other guidance specified by CMS, by the sponsor or its designee.

(1) *Timing.* Payment can be made on a monthly, quarterly or annual basis, as elected by the plansponsor under guidance specified by CMS, unless CMS determines that the options must be restricted because of operational limitations.

(i) *Monthly or quarterly payments.* If the plan sponsor elects for payment on a monthly or quarterly basis, it must provide information described in paragraph (b)(2)(i) of this section on the same monthly or quarterly basis, or at such time as CMS specifies.

(ii) *Annual payments.* If the sponsor elects an annual payment, it must submit to CMS actual rebate and other price concession data within 15 months after the end of the plan year.

(2) *Submission of cost data*—(i) *Monthly or quarterly payments.* If the plan sponsor elects to receive payment on a monthly or quarterly basis, it must submit to CMS, in a manner specified by CMS, the gross covered retiree plan-related prescription drug costs (as defined in § 423.882) incurred for its qualifying covered retirees during the payment period for which it is claiming a subsidy payment and any other data CMS may require. Except as otherwise provided by CMS in future guidance, the sponsor must also submit, using historical data and generally accepted actuarial principles, an estimate of the extent to which its expected allowable retiree costs differs from the gross covered retiree plan-related prescription drug costs, based on expected rebates and other price concessions for the upcoming plan year. The estimate must be used to reduce the periodic payments for the plan year. Final allocation of price concession data must occur after the end of the year under the reconciliation provisions of paragraph (b)(4) of this section

(ii) *Annual payments.* If the plan sponsor elects a one-time final annual payment, it must submit, in a manner specified by CMS, within 15 months, or within any other longer time limit specified by CMS, after the end of the plan year, the total gross covered retiree plan-related prescription drug costs (as defined in § 423.882) for the plan year for which it is claiming a subsidy payment, actual rebate and other price concession data described in paragraph (b)(1)(ii) of this section, and any other data CMS may require. The alternative is that the sponsor can elect an interim annual payment, in which case it must submit the following to CMS, at a time and in a manner specified by CMS: the gross covered retiree plan-related prescription drug costs (as defined in § 423.882) incurred for all of its qualifying covered retirees during the payment period for which it is claiming a subsidy payment; an estimate (using historical data and generally accepted actuarial principles) of the difference between such gross costs and allowable costs (based on expected rebates and other price concessions for the upcoming plan year); and any other data CMS may require.

(3) *Payment by CMS.* CMS makes payment after the sponsor's submission of the cost data at a time and in a manner to be specified by CMS.

(4) *Reconciliation.* (i) Sponsors who elect either monthly, quarterly or an interim annual payment must submit to CMS, within 15 months, or within any other longer time limit specified by CMS, after the end of its plan year, the total gross covered retiree plan-related prescription drug costs (as defined in § 423.882), in a manner specified by CMS; actual rebate and other price concession data for the plan year in question; and any other data CMS may require.

(ii) Upon receiving this data, CMS adjusts the payments made for the plan year in question in a manner to be specified by CMS.

(5) *Special rule for insured plans*—(i) *Interim payments.* Sponsors of group health plans that provide benefits through health insurance coverage (as defined in 45 CFR 144.103) and that choose either monthly payments, quarterly payments or an interim annual payment in paragraphs (b)(1) and (b)(2) of this section, may elect to determine gross covered plan-related retiree prescription drug costs for purposes of the monthly, quarterly or interim annual payments based on a portion of the premium costs paid by the sponsor (or by the qualifying covered retirees) for coverage of the covered retirees under the group health plan. Premium costs that are determined, using generally accepted actuarial principles, may be attributable to the gross covered plan-related retiree prescription drug costs incurred by the health insurance issuer (as defined in 45 CFR 144.103) for the sponsor's qualifying covered retirees, except that administrative costs and risk charges must be subtracted from the premium.

(ii) *Final payments.* At the end of the plan year, actual gross retiree plan-related prescription drug costs incurred by the insurer (or the retiree), and the allowable costs attributable to the gross costs, are determined for each of

the sponsor's qualifying covered retirees and submitted for reconciliation after the end of the plan year as specified in paragraph (b)(4)of this section. The data for the reconciliation can be submitted directly to CMS by the insurer in a manner to be specified by CMS. Upon receiving this data, CMS adjusts the payments made for the relevant plan year in a manner to be specified by CMS.

(c) *Use of information provided.* Officers, employees and contractors of the Department of Health and Human Services, including the Office of Inspector General (OIG), may use information collected under this section only for the purposes of, and to the extent necessary in, carrying out this subpart including, but not limited to, determination of payments and payment-related oversight and program integrity activities, or as otherwise required by law. This restriction does not limit OIG authority to conduct audits and evaluations necessary for carrying out these regulations.

(d) *Maintenance of records.* (1) The sponsor of the qualified retiree prescription drug plan (or a designee), as applicable, must maintain, and furnish to CMS or the OIG upon request, the records enumerated in paragraph (d)(3) of this section. The records must be maintained for 6 years after the expiration of the plan year in which the costs were incurred for the purposes of audits and other oversight activities conducted by CMS to assure the accuracy of the actuarial attestation and the accuracy of payments.

(2) CMS or the OIG may extend the 6-year retention requirement for the records enumerated in paragraph (d)(3) of this section in the event of an ongoing investigation, litigation, or negotiation involving civil, administrative or criminal liability. In addition, the sponsor of the qualified retiree prescription drug plan (or a designee), as applicable, must maintain the records enumerated in paragraph (d)(3) of this section longer than 6 years if it knows or should know that the records are the subject of an ongoing investigation, litigation or negotiation involving civil, administrative or criminal liability.

(3) The records that must be retained are:

(i) Reports and working documents of the actuaries who wrote the attestation submitted in accordance with § 423.884(a).

(ii) All documentation of costs incurred and other relevant information utilized for calculating the amount of the subsidy payment made in accordance with § 423.886, including the underlying claims data.

(iii) Any other records specified by CMS.

(4) CMS may issue additional guidance addressing recordkeeping requirements, including (but not limited to) the use of electronic media.

[70 FR 4525, Jan. 28, 2005, as amended at 74 FR 1549, Jan. 12, 2009]

§ 423.890 Appeals.

(a) *Informal written reconsideration—*(1) *Initial determinations.* A sponsor is entitled to an informal written reconsideration of an adverse initial determination. An initial determination is a determination regarding the following:

(i) The amount of the subsidy payment.

(ii) The actuarial equivalence of the sponsor's retiree prescription drug plan.

(iii) If an enrollee in a retiree prescription drug plan is a qualifying covered retiree; or

(iv) Any other similar determination (as determined by CMS) that affects eligibility for, or the amount of, a subsidy payment.

(2) *Effect of an initial determination regarding the retiree drug subsidy.* An initial determination is final and binding unless reconsidered in accordance with this paragraph (a) of this section.

(3) *Manner and timing for request.* A request for reconsideration must be made in writing and filed with CMS within 15 days of the date on the notice of adverse determination.

(4) *Content of request.* The request for reconsideration must specify the findings or issues with which the sponsor disagrees and the reasons for the disagreements. The request for reconsideration may include additional documentary evidence the sponsor wishes CMS to consider.

(5) *Conduct of informal written reconsideration.* In conducting the reconsideration, CMS reviews the subsidy determination, the evidence and findings upon which it was based, and any other written evidence submitted by the sponsor or by CMS before notice of the reconsidered determination is made.

(6) *Decision of the informal written reconsideration.* CMS informs the sponsor of the decision orally or through electronic mail. CMS sends a written decision to the sponsor on the sponsor's request.

(7) *Effect of CMS informal written reconsideration.* A reconsideration decision, whether delivered orally or in writing, is final and binding unless a request for hearing is filed in accordance with paragraph (b) of this section, or it is revised in accordance paragraph (d) of this section.

(b) *Right to informal hearing.* A sponsor dissatisfied with the CMS reconsideration decision is entitled to an informal hearing as provided in this section.

(1) *Manner and timing for request.* A request for a hearing must be made in writing and filed with CMS within 15 days of the date the sponsor receives the CMS reconsideration decision.

(2) *Content of request.* The request for informal hearing must include a copy of the CMS reconsideration decision (if any) and must specify the findings or issues in the decision with which the sponsor disagrees and the reasons for the disagreements.

(3) *Informal hearing procedures.* (i)CMS provides written notice of the time and place of the informal hearing at least 10 days before the scheduled date.

(ii) The hearing is conducted by a CMS hearing officer who neither receives testimony nor accepts any new evidence that was not presented with the reconsideration request. The CMS hearing officer is limited to the review of the record that was before CMS when CMS made both its initial and reconsideration determinations.

(iii) If CMS did not issue a written reconsideration decision, the hearing officer may request, but not require, a written statement from CMS or its contractors explaining CMS' determination, or CMS or its contractors may, on their own, submit the written statement to the hearing officer. Failure of CMS to submit a written statement does not result in any adverse findings against CMS and may not in any way be taken into account by the hearing officer in reaching a decision.

(4) *Decision of the CMS hearing officer.* The CMS hearing officer decides the case and sends a written decision to the sponsor, explaining the basis for the decision.

(5) *Effect of hearing officer decision.* The hearing officer decision is final and binding, unless the decision is reversed or modified by the Administrator in accordance with paragraph (c) of this section.

(c) *Review by the Administrator.* (1) A sponsor that has received a hearing officer decision upholding a CMS initial or reconsidered determination may request review by the Administrator within 15 days of receipt of the hearing officer's decision.

(2) The Administrator may review the hearing officer's decision, any written documents submitted to CMS or to the hearing officer, as well as any other information included in the record of the hearing officer's decision and determine whether to uphold, reverse or modify the hearing officer's decision.

(3) The Administrator's determination is final and binding.

(d) *Reopening*—(1) *Ability to reopen.* CMS may reopen and revise an initial or reconsidered determination upon its own motion or upon the request of a sponsor:

(i) Within 1 year of the date of the notice of determination for any reason.

(ii) Within 4 years for good cause.

(iii) At any time when the underlying decision was obtained through fraud or similar fault.

(2) *Notice of reopening.* (i) Notice of reopening and any revisions following the reopening are mailed to the sponsor.

(ii) Notice of reopening specifies the reasons for revision.

(3) *Effect of reopening.* The revision of an initial or reconsidered determination is final and binding unless-

(i) The sponsor requests reconsideration in accordance with paragraph (a) of this section;

(ii) A timely request for a hearing is filed under paragraph (b) of this section;

(iii) The determination is reviewed by the Administrator in accordance with paragraph (c) of this section; or

(iv) The determination is reopened and revised in accordance with paragraph (d) of this section.

(4) *Good cause.* For purposes of this section, CMS finds good cause if—

(i) New and material evidence exists that was not readily available at the time the initial determination was made;

(ii) A clerical error in the computation of payments was made; or

(iii) The evidence that was considered in making the determination clearly shows on its face that an error was made.

(5) For purposes of this section, CMS does not find good cause if the only reason for reopening is a change of legal interpretation or administrative ruling upon which the initial determination was made.

(6) A decision by CMS not to reopen an initial or reconsidered determination is final and binding and cannot be appealed.

§ 423.892 Change of ownership.

(a) *Change of ownership.* Any of the following constitutes a change of ownership:

(1) *Partnership.* The removal, addition, or substitution of a partner, unless the partners expressly agree otherwise as permitted by applicable State law.

(2) *Asset sale.* Transfer of all or substantially all of the assets of the sponsor to another party.

(3) *Corporation.* The merger of the sponsor's corporation into another corporation or the consolidation of the sponsor's organization with one or more other corporations, resulting in a new corporate body.

(b) *Change of ownership, exception.* Transfer of corporate stock or the merger of another corporation into the sponsor's corporation, with the sponsor surviving, does not ordinarily constitute change of ownership.

(c) *Advance notice requirement.* A sponsor that has a sponsor agreement in effect under this part and is considering or negotiating a change in ownership must notify CMS at least 60 days before the anticipated effective date of the change.

(d) *Assignment of agreement.* When there is a change of ownership as specified in paragraph (a) of this section, and this results in a transfer of the liability for prescription drug costs, the existing sponsor agreement is automatically assigned to the new owner.

(e) *Conditions that apply to assigned agreements.* The new owner to whom a sponsor agreement is assigned is subject to all applicable statutes and regulations and to the terms and conditions of the sponsor agreement.

§ 423.894 Construction.

Nothing in this part must be interpreted as prohibiting or restricting:

(a) A Part D eligible individual who is covered under employment-based retiree health coverage, including a qualified retiree prescription drug plan, from enrolling in a Part D plan;

(b) A sponsor or other person from paying all or any part of the monthly beneficiary premium (as defined in § 423.286) for a Part D plan on behalf of a retiree (or his or her spouse or dependents);

(c) A sponsor from providing coverage to Part D eligible individuals under employment-based retiree health coverage that is—

(1) Supplemental to the benefits provided under a Part D plan; or

(2) Of higher actuarial value than the actuarial value of standard prescription drug coverage (as defined in § 423.104(d)); or

(d) Sponsors from providing for flexibility in the benefit design and pharmacy network for their qualified retiree prescription drug coverage, without regard to the requirements applicable to Part D plans under § 423.104, as long as the requirements under § 423.884 are met.

Subpart S—Special Rules for States-Eligibility Determinations for Subsidies and General Payment Provisions

§ 423.900 Basis and scope.

(a) *Basis.* This subpart is based on sections 1935(a) through (d) of the Act as amended by section 103 of the MMA.

(b) *Scope.* This subpart specifies State agency obligations for the Part D prescription drug benefit.

§ 423.902 Definitions.

The following definitions apply to this subpart:

Actuarial value of capitated prescription drug benefits is the estimated actuarial value of prescription drug benefits provided under a comprehensive Medicaid managed care plan per full-benefit dual eligible individual for 2003, as determined using data as the Secretary determines appropriate. This value will be established using data determined by the Secretary to be the best available among the following options:

(1) State rate setting documentation for drug costs to the full dual eligible population;

(2) State encounter and enrollment record databases including cost data; and

(3) State managed care plan-specific financial cost data; and

(4) Other appropriate data.

Applicable growth factor for each of 2004, 2005, and 2006, is the average annual percent change (to that year from the previous year) of the per capita amount of prescription drug expenditures (as determined based on the most recent National Total Drug National Health Expenditure projections for the years involved). The growth factor for 2007 and succeeding years will equal the annual percentage increase in average per capita aggregate expenditures for covered Part D drugs in the United States for Part D eligible individuals for the 12-month period ending in July of the previous year, as described in § 423.104(d)(5)(iv). CMS provides further detail regarding the sources of data to be used and how the annual percentage increase will be determined via operational guidance to States.

Base year Medicaid per capita expenditures are equal to the weighted average of:

(1) The gross base year (calendar year 2003) per capita Medicaid expenditures for prescription drugs, reduced by the rebate adjustment factor; and

(2) The estimated actuarial value of prescription drug benefits provided under a comprehensive capitated Medicaid managed care plan per full-benefit dual eligible for 2003. The per capita payments for full-benefit dual eligibles with comprehensive managed care and non-managed care are weighted by the respective average monthly full dual eligible enrollment populations reported through the Medicaid Statistical Information System (MSIS).

Full-benefit dual eligible individual means an individual who, for any month-

(1) Has coverage for the month under a prescription drug plan under Part D of title XVIII, or under an MA-PD plan under Part C of title XVIII; and

(2) Is determined eligible by the State for medical assistance for full benefits under title XIX for the month under any eligibility category covered under the State plan or comprehensive benefits under a demonstration under section 1115 of the Act. (This does not include individuals under Pharmacy Plus demonstrations or under a section 1115 of the Act demonstration that provides pharmacy only benefits to these individuals.) It also includes any individual who is determined by the State to be eligible for medical assistance under section 1902(a)(10)(C) of the Act (medically needy) or section 1902(f) of the Act (States that use more restrictive eligibility criteria than are used by the SSI program) of the Act for any month if the individual was eligible for medical assistance in any part of the month. For the 2003 baseline calculations, the full-benefit dual eligibles are those individuals reported in MSIS as having Medicaid drug benefit coverage and Medicare Part A or Part B coverage. Dual eligibility status will be established by CMS using an algorithm that incorporates the quarterly MSIS dual eligibility code for the prescription fill date and the dual eligibility code for the prior quarter.

Gross base year Medicaid per capita expenditures are equal to the expenditures, including dispensing fees, made by the State and reported in MSIS during calendar year 2003 for covered outpatient drugs, excluding drugs or classes of drugs, or their medical uses, which may be excluded from coverage or otherwise restricted under section 1860D–2 of the Act, other than smoking cessation agents determined per full-benefit dual eligible individual for the individuals not receiving medical assistance for the drugs through a comprehensive Medicaid managed care plan. This amount is determined based on MSIS drug claims paid during the four quarters of calendar year 2003 and the corresponding dual eligibility enrollment status of the beneficiary. MSIS drug claims having National Drug Codes determined by CMS to be in the Part D excluded drug class, and claims having a program type code indicating Indian Health Service or Family Planning will be excluded from the calculation.

Noncovered drugs are those drugs specifically excluded from the definition of Part D drug, which may be excluded from coverage or otherwise restricted under Medicaid under sections 1927(d)(2) or (d)(3) of the Act, except for smoking cessation agents.

Phased-down State contribution factor for a month in 2006 is 90 percent; in 2007 is 88⅓ percent; in 2008 is 86⅔ percent; in 2009 is 85 percent; in 2010 is 83⅓ percent; in 2011 is 81⅔ percent; in 2012 is 80 percent; in 2013 is 78⅓ percent; in 2014 is 76⅔ percent; or after December 2014, is 75 percent.

Phased-down State contribution payment refers to the States' monthly payment made to the Federal government beginning in 2006 to defray a portion of the Medicare drug expenditures for full-benefit dual eligible individuals whose Medicaid drug coverage is assumed by Medicare Part D. The contribution is calculated as 1/12th of the base year (2003) Medicaid per capita expenditures for prescription drugs (that is, covered Part D drugs) for full-benefit dual eligible individuals,

(1) Multiplied by the State medical assistance percentage;

(2) Increased for each year (beginning with 2004 up to and including the year involved) by the applicable growth factor;

(3) Multiplied by the number of the State's full-benefit dual eligible individuals for the given month; and

(4) Multiplied by the phased-down State contribution factor.

Rebate adjustment factor takes into account drug rebates and, for a State, is equal to the ratio of the four quarters of calendar year 2003 of aggregate rebate payments received by the State under section 1927 of the Act to the gross expenditures for covered outpatient drugs.

State medical assistance percentage means the proportion equal to 100 percent minus the State's Federal medical assistance percentage, applicable to the State for the fiscal year in which the month occurs.

[70 FR 4525, Jan. 28, 2005, as amended at 73 FR 20509, Apr. 15, 2008]

§ 423.904 Eligibility determinations for low-income subsidies.

(a) *General rule.* The State agency must make eligibility determinations and redeterminations for low-income premium and cost-sharing subsidies in accordance with subpart P of part 423.

(b) *Notification to CMS.* The State agency must inform CMS of cases where eligibility is established or redetermined, in a manner determined by CMS.

(c) *Screening for eligibility for Medicare cost-sharing and enrollment under the State plan.* States must—

(1) Screen individuals who apply for subsidies under this part for eligibility for Medicaid programs that provide assistance with Medicare cost-sharing specified in section 1905(p)(3) of the Act.

(2) Offer enrollment for the programs under the State plan (or under a waiver of the plan) for those meeting the eligibility requirements.

(d) *Application form and process*—(1) *Assistance with application.* No later than July 1, 2005, States must make available—

(i) Low-income subsidy application forms;

(ii) Information on the nature of, and eligibility requirements for, the subsidies under this section; and

(iii) Assistance with completion of low-income subsidy application forms.

(2) *Completion of application.* The State must require an individual or personal representative applying for the low-income subsidy to—

(i) Complete all required elements of the application and provide documents, as necessary, consistent with paragraph (d)(3) of this section; and

(ii) Certify, under penalty of perjury or similar sanction for false statements, as to the accuracy of the information provided on the application form.

(3) *The application process and States.* (i) States may require submission of statements from financial institutions for an application for low-income subsidies to be considered complete; and

(ii) May require that information submitted on the application be subject to verification in a manner the State determines to be most cost-effective and efficient.

(4) *Other information.* States must provide CMS with other information as specified by CMS that may be needed to carry out the requirements of the Part D prescription drug benefit.

§ 423.906 General payment provisions.

(a) *Regular Federal matching.* Regular Federal matching applies to the eligibility determination and notification activities specified in § 423.904(a) and (b).

(b) *Medicare as primary payer.* Medicare is the primary payer for covered drugs for Part D eligible individuals. Medical assistance is not available to full-benefit dual eligible individuals, including those not enrolled in a Part D plan, for—

(1) Part D drugs; or

(2) Any cost-sharing obligations under Part D relating to Part D drugs.

(3) The effective date of paragraphs (b)(1) and (b)(2) of this section is January 1, 2006.

(c) *Noncovered drugs.* States may elect to provide coverage for outpatient drugs other than Part D drugs in the same manner as provided for non-full benefit dual eligible individuals or through an arrangement with a prescription drug plan or a MA-PD plan.

[70 FR 4525, Jan. 28, 2005, as amended at 73 FR 20509, Apr. 15, 2008]

§ 423.907 Treatment of territories.

(a) *General rules.* (1) Low-income Part D eligible individuals who reside in the territories are not eligible to receive premium and cost-sharing subsidies under subpart P of this part.

(2) A territory may submit a plan to the Secretary under which medical assistance is to be provided to low-income individuals for the provision of covered Part D drugs.

(3) Territories with plans approved by the Secretary will receive increased grants under section 1935(e)(3) of the Act as described in paragraph (c) of this section.

(b) *Plan requirements.* Plans submitted to the Secretary must include the following:

(1) A description of the medical assistance to be provided.

(2) The low-income population (income less than 150 percent of the Federal poverty level) to receive medical assistance.

(3) An assurance that no more than 10 percent of the amount of the increased grant will be used for administrative expenses.

(c) *Increased grant amounts.* The amount of the grant provided under section 1108 (f) of the Act as increased by section 1108 (g) of the Act for each territory with an approved plan for a year is the amount in paragraph (d) of this section multiplied by the ratio of—

(1) The number of individuals who are entitled to benefits under Part A or enrolled under Part B and who reside in the territory (as determined by the Secretary based on the most recent available data for the beginning of the year); and

(2) The sum of the number of individuals in all territories in paragraph (c)(1) of this section with approved plans.

(d) *Total grant amount.* The total grant amount is—

(1) For the last three quarters of fiscal year 2006, $28,125,000;

(2) For fiscal year 2007, $37,500,000; and

(3) For each subsequent year, the amount for the prior fiscal year increased by the annual percentage increase described in § 423.104(d)(5)(iv).

§ 423.908 Phased-down State contribution to drug benefit costs assumed by Medicare.

This subpart sets forth the requirements for State contributions for Part D drug benefits based on full-benefit dual eligible individual drug expenditures.

§ 423.910 Requirements.

(a) *General rule.* Each of the 50 States and the District of Columbia is required to provide for payment to CMS a phased-down contribution to defray a portion of the Medicare drug expenditures for individuals whose projected Medicaid drug coverage is assumed by Medicare Part D.

(b) *State contribution payment—*

(1) *Calculation of payment.* The State contribution payment is calculated by CMS on a monthly basis, as indicated in the following chart. For States that do not meet state enrollment reporting requirement described in paragraph (d) of this section, the State contribution payment is calculated using a methodology determined by CMS.

ILLUSTRATIVE CALCULATION OF STATE PHASED-DOWN MONTHLY CONTRIBUTION FOR 2006

	Item	Illustrative Value	Source
(i)	Gross per capita Medicaid expenditures for prescription drugs for 2003 for full-benefit dual eligibles not receiving drug coverage through a comprehensive Medicaid managed care plan, excluding drugs not covered by Part D.	$2,000	CY MSIS data
(ii)	Aggregate State rebate receipts in calendar year 2003	$100,000,000	CMS–64
(iii)	Gross State Medicaid expenditures for prescription drugs in calendar year 2003.	$500,000,000	CMS–64
(iv) ...	Rebate adjustment factor	0.2000	(2) ÷ (3)
(v)	Adjusted 2003 gross per capita Medicaid expenditures for prescription drugs for full-benefit dual eligibles not in comprehensive managed care plans.	$1,600	(1) × [1 − (4)]
(vi) ...	Estimated actuarial value of prescription drug benefits under comprehensive capitated managed care plans for full-benefit dual eligibles for 2003.	$1,500	To be Determined
(vii) ...	Average number of full-benefit dual eligibles in 2003 who did not receive covered outpatient drugs through comprehensive Medicaid managed care plans.	90,000	CY MSIS data
(viii) ..	Average number of full-benefit dual eligibles in 2003 who received covered outpatient drugs through comprehensive Medicaid managed care plans.	10,000	CY MSIS data
(ix) ...	Base year State Medicaid per capita expenditures for covered Part D drugs for full-benefit dual eligible individuals (weighted average of (5) and (6)).	$1,590	[(7) × (5) + (8) × (6)] ÷ [(7) + (8)]
(x)	100 minus Federal Medical Assistance Percentage (FMAP) applicable to month of State contribution (as a proportion).	0.4000	FEDERAL REGISTER
(xi) ...	Applicable growth factor (cumulative increase from 2003 through 2006).	50.0%	NHE projections
(xii) ...	Number of full-benefit dual eligibles for the month	120,000	State submitted data
(xiii) ..	Phased-down State reduction factor for the month	0.9000	specified in statute
(xiv) ..	Phased-down State contribution for the month	$8,586,000	1 / 12 × (9) × (10) × [1 + (11)] × (12) × (13)

(2) *Method of payment.* Payments for the phased down State contribution begins in January 2006, and are made on a monthly basis for each subsequent month. State payment must be made in a manner specified by CMS that is similar to the manner in which State payments are made under the State Buy-in Program except that all payments must be deposited into the Medicare Prescription Drug Account in the Federal Supplementary Medical Insurance Trust Fund. The policy on collection of the Phased-down State contribution payment is the same as the policy that governs collection of Part A and Part B Medicare premiums for State Buy-in.

(c) *State Medicaid Statistical Information System (MSIS) Reporting.* Effective with calendar year (CY) 2003 and all subsequent MSIS data submittals,

States are required to provide accurate and complete coding to identify the numbers and types of Medicaid and Medicare dual eligibles. Calendar year 2003 submittals must be complete and must be accepted, based on CMS' data quality review, by December 31, 2004.

(d) *State monthly enrollment reporting.*—

(1) States must submit an electronic file as specified in paragraph (d)(2) of this section, identifying each full-benefit dual eligible individual enrolled in the State for each month. This file must include specified information including identifying information, a dual eligible type code, available income data and institutional status. The file includes data on enrollment for the current month, plus retroactive changes in enrollment characteristics for prior months. This file will be used by CMS to establish the monthly enrollment for those individuals with Part D drug coverage who are also determined by the State to be eligible for full Medicaid benefits subject to the phased down State contribution payment. This file is due to CMS no later than the last day of the reporting month. For States that do not submit an acceptable file by the end of the month, the phased down State contribution for that month is based on data deemed appropriate by CMS.

(2)(i) For the period prior to April 1, 2022, States must submit the file at least monthly and may submit updates to that file on a more frequent basis.

(ii) For the period beginning April 1, 2022, States must submit the file at least monthly and must submit updates to that file on a daily basis.

(e) *Data match.* CMS performs those periodic data matches as may be necessary to identify and compute the number of full-benefit dual eligible individuals needed to establish the State contribution payment.

(f) *Rebate adjustment factor.* CMS establishes the rebate adjustment factor using total drug expenditures made and drug rebates received during calendar year 2003 as reported on CMS 64 Medicaid expenditure reports for the four quarters of calendar year 2003 that were received by CMS on or before March 31, 2004. Rebates include rebates received under the national rebate agreement and under a State supplemental rebate program, as reported on CMS–64 expenditure reports for the four quarters of calendar year 2003.

(g) *Annual per capita drug expenditures.* CMS notifies each State no later than October 15 before each calendar year, beginning October 15, 2005, of their annual per capita drug payment expenditure amount for the next year.

[70 FR 4525, Jan. 28, 2005, as amended at 73 FR 20509, Apr. 15, 2008; 85 FR 25634, May 1, 2020]

Subpart T—Appeal Procedures for Civil Money Penalties

SOURCE: 72 FR 68736, Dec. 5, 2007, unless otherwise noted.

§ 423.1000 Basis and scope.

(a) *Statutory basis.* (1) Section 1128A(c)(2) of the Act provides that the Secretary may not collect a civil money penalty until the affected party has had notice and opportunity for a hearing.

(2) Section 1857 (g) of the Act provides that, for Part D sponsors found to be out of compliance with the requirements in part 423, specified remedies may be imposed instead of, or in addition to, termination of the Part D sponsor's contract. Section 1857(g)(4) of the Act makes certain provisions of section 1128A of the Act applicable to civil money penalties imposed on Part D sponsors.

(3) Section 1860D–14A(e)(2) of the Act specifies that the Secretary must impose a civil money penalty on a manufacturer that fails to provide applicable beneficiaries discounts for applicable drugs of the manufacturer in accordance with its Discount Program Agreement. Section 1860D–14A(e)(2)(B) of the Act makes certain provisions of section 1128A of the Act applicable to such civil money penalties imposed on manufacturers.

(b) [Reserved]

[72 FR 68736, Dec. 5, 2007, as amended 77 FR 22171, Apr. 12, 2012]

§ 423.1002 Definitions.

As used in this subpart—

Affected party means any Part D sponsor or manufacturer (as defined in

§ 423.2305) impacted by an initial determination or, if applicable, by a subsequent determination or decision issued under this part, and ''party'' means the affected party or CMS, as appropriate.

ALJ stands for Administrative Law Judge.

Departmental Appeals Board or Board means a Board established in the Office of the Secretary to provide impartial review of disputed decisions made by the operating components of the Department.

Part D sponsor has the meaning given the term in 423.4.

[72 FR 68736, Dec. 5, 2007, as amended 77 FR 22171, Apr. 12, 2012]

§ 423.1004 Scope and applicability.

(a) *Scope.* This subpart sets forth procedures for reviewing initial determinations that CMS makes with respect to the matters specified in paragraph (b) of this section.

(b) *Initial determinations by CMS.* CMS makes initial determinations with respect to the imposition of civil money penalties in accordance with part 423, subpart O.

§ 423.1006 Appeal rights.

(a) *Appeal rights of Part D sponsors.* (1) Any Part D sponsor dissatisfied with an initial determination as specified in 423.1004, has a right to a hearing before an ALJ in accordance with this subpart and may request Departmental Appeals Board review of the ALJ decision.

(2) Part D sponsors may request judicial review of the Departmental Appeals Board's decision that imposes a CMP.

(b) [Reserved]

§ 423.1008 Appointment of representatives.

(a) An affected party may appoint as its representative anyone not disqualified or suspended from acting as a representative in proceedings before the Secretary or otherwise prohibited by law.

(b) If the representative appointed is not an attorney, the party must file written notice of the appointment with the ALJ or the Departmental Appeals Board.

(c) If the representative appointed is an attorney, the attorney's statement that he or she has the authority to represent the party is sufficient.

§ 423.1010 Authority of representatives.

(a) A representative appointed and qualified in accordance with 423.1008 may, on behalf of the represented party—

(1) Give and accept any notice or request pertinent to the proceedings set forth in this part;

(2) Present evidence and allegations as to facts and law in any proceedings affecting that party to the same extent as the party; and

(3) Obtain information to the same extent as the party.

(b) A notice or request may be sent to the affected party, to the party's representative, or to both. A notice or request sent to the representative has the same force and effect as if it had been sent to the party.

§ 423.1012 Fees for services of representatives.

Fees for any services performed on behalf of an affected party by an attorney appointed and qualified in accordance with 423.1008 are not subject to the provisions of section 206 of Title II of the Act, which authorizes the Secretary to specify or limit those fees.

§ 423.1014 Charge for transcripts.

A party that requests a transcript of prehearing or hearing proceedings or Board review must pay the actual or estimated cost of preparing the transcript unless, for good cause shown by that party, the payment is waived by the ALJ or the Departmental Appeals Board, as appropriate.

§ 423.1016 Filing of briefs with the Administrative Law Judge or Departmental Appeals Board, and opportunity for rebuttal.

(a) *Filing of briefs and related documents.* If a party files a brief or related document such as a written argument, contention, suggested finding of fact, conclusion of law, or any other written statement, it must submit an original and 1 copy to the ALJ or the Departmental Appeals Board, as appropriate. The material may be filed by mail or in person and must include a statement

certifying that a copy has been furnished to the other party.

(b) *Opportunity for rebuttal.* (1) The other party will have 20 calendar days from the date of mailing or in person filing to submit any rebuttal statement or additional evidence. If a party submits a rebuttal statement or additional evidence, it must file an original and 1 copy with the ALJ or the Board and furnish a copy to the other party.

(2) The ALJ or the Board will grant an opportunity to reply to the rebuttal statement only if the party shows good cause.

[72 FR 68736, Dec. 5, 2007, as amended at 79 FR 29966, May 23, 2014]

§ 423.1018 Notice and effect of initial determinations.

(a) *Notice of initial determination*—(1) *General rule.* CMS, as required under 422.756(f)(2), mails notice of an initial determination to the affected party, setting forth the basis or reasons for the determination, the effect of the determination, the party's right to a hearing, and information about where to file the request for a hearing.

(b) *Effect of initial determination.* An initial determination is binding unless—

(1) The affected party requests a hearing; or

(2) CMS revises its decision.

§ 423.1020 Request for hearing.

(a) *Manner and timing of request.* (1) A Part D sponsor is entitled to a hearing as specified in 423.1006 and may file a request with the Departmental Appeals Board office specified in the initial determination.

(2) The Part D sponsor or its legal representative or other authorized official must file the request, in writing, to the appropriate Departmental Appeals Board office, with a copy to CMS, within 60 calendar days after receipt of the notice of initial determination, to request a hearing before an ALJ to appeal any determination by CMS to impose a civil money penalty.

(b) *Content of request for hearing.* The request for hearing must—

(1) Identify the specific issues, and the findings of fact and conclusions of law with which the affected party disagrees; and

(2) Specify the basis for each contention that a CMS finding or conclusion of law is incorrect.

[72 FR 68736, Dec. 5, 2007, as amended at 79 FR 29966, May 23, 2014]

§ 423.1022 Parties to the hearing.

The parties to the hearing are the affected party and CMS, as appropriate.

§ 423.1024 Designation of hearing official.

(a) The Chair of the Departmental Appeals Board, or his or her delegate, designates an ALJ or a member or members of the Departmental Appeals Board to conduct the hearing.

(b) If appropriate, the Chair or the delegate may substitute another ALJ or another member or other members of the Departmental Appeals Board to conduct the hearing.

(c) As used in this part, ''ALJ'' includes a member or members of the Departmental Appeals Board who are designated to conduct a hearing.

§ 423.1026 Disqualification of Administrative Law Judge.

(a) An ALJ may not conduct a hearing in a case in which he or she is prejudiced or partial to the affected party or has any interest in the matter pending for decision.

(b) A party that objects to the ALJ designated to conduct the hearing must give notice of its objections at the earliest opportunity.

(c) The ALJ will consider the objections and decide whether to withdraw or proceed with the hearing.

(1) If the ALJ withdraws, another ALJ will be designated to conduct the hearing.

(2) If the ALJ does not withdraw, the objecting party may, after the hearing, present its objections to the Departmental Appeals Board as reasons for changing, modifying, or reversing the ALJ's decision or providing a new hearing before another ALJ.

§ 423.1028 Prehearing conference.

(a) At any time before the hearing, the ALJ may call a prehearing conference for the purpose of delineating the issues in controversy, identifying

the evidence and witnesses to be presented at the hearing, and obtaining stipulations accordingly.

(b) On the request of either party or on his or her own motion, the ALJ may adjourn the prehearing conference and reconvene at a later date.

§ 423.1030 Notice of prehearing conference.

(a) *Timing of notice.* The ALJ will fix a time and place for the prehearing conference and mail written notice to the parties at least 10 calendar days before the scheduled date.

(b) *Content of notice.* The notice will inform the parties of the purpose of the conference and specify what issues are sought to be resolved, agreed to, or excluded.

(c) *Additional issues.* Issues other than those set forth in the notice of determination or the request for hearing may be considered at the prehearing conference if—

(1) Either party gives timely notice to that effect to the ALJ and the other party; or

(2) The ALJ raises the issues in the notice of prehearing conference or at the conference.

§ 423.1032 Conduct of prehearing conference.

(a) The prehearing conference is open to the affected party or its representative, to the CMS representatives and their technical advisors, and to any other persons whose presence the ALJ considers necessary or proper.

(b) The ALJ may accept the agreement of the parties as to the following:

(1) Facts that are not in controversy.

(2) Questions that have been resolved favorably to the affected party after the determination in dispute.

(3) Remaining issues to be resolved.

(c) The ALJ may request the parties to indicate the following:

(1) The witnesses that will be present to testify at the hearing.

(2) The qualifications of those witnesses.

(3) The nature of other evidence to be submitted.

§ 423.1034 Record, order, and effect of prehearing conference.

(a) *Record of prehearing conference.* (1) A record is made of all agreements and stipulations entered into at the prehearing conference.

(2) The record may be transcribed at the request of either party or the ALJ.

(b) *Order and opportunity to object.* (1) The ALJ issues an order setting forth the results of the prehearing conference, including the agreements made by the parties as to facts not in controversy, the matters to be considered at the hearing, and the issues to be resolved.

(2) Copies of the order are sent to all parties and the parties have 10 calendar days to file objections to the order.

(3) After the 10 calendar days have elapsed, the ALJ settles the order.

(c) *Effect of prehearing conference.* The agreements and stipulations entered into at the prehearing conference are binding on all parties, unless a party presents facts that, in the opinion of the ALJ, would make an agreement unreasonable or inequitable.

§ 423.1036 Time and place of hearing.

(a) The ALJ fixes a time and place for the hearing and gives the parties written notice at least 10 calendar days before the scheduled date.

(b) The notice informs the parties of the general and specific issues to be resolved at the hearing.

§ 423.1038 Change in time and place of hearing.

(a) The ALJ may change the time and place for the hearing either on his or her own initiative or at the request of a party for good cause shown, or may adjourn or postpone the hearing.

(b) The ALJ may reopen the hearing for receipt of new evidence at any time before mailing the notice of hearing decision.

(c) The ALJ gives the parties reasonable notice of any change in time or place or any adjournment or reopening of the hearing.

§ 423.1040 Joint hearings.

When two or more affected parties have requested hearings and the same or substantially similar matters are at issue, the ALJ may, if all parties agree,

fix a single time and place for the prehearing conference or hearing and conduct all proceedings jointly. If joint hearings are held, a single record of the proceedings is made and a separate decision issued with respect to each affected party.

§ 423.1042 Hearing on new issues.

(a) *Basic rules.* (1) Within the time limits specified in paragraph (b) of this section, the ALJ may, at the request of either party, or on his or her own motion, provide a hearing on new issues that impinge on the rights of the affected party.

(2) The ALJ may consider new issues even if CMS has not made initial determinations on them, and even if they arose after the request for hearing was filed or after a prehearing conference.

(3) The ALJ may give notice of hearing on new issues at any time after the hearing request is filed and before the hearing record is closed.

(b) *Notice and conduct of hearing on new issues.* (1) Unless the affected party waives its right to appear and present evidence, notice of the time and place of hearing on any new issue will be given to the parties in accordance with 423.1036.

(2) After giving notice, the ALJ will, except as provided in paragraph (c) of this section, proceed to hearing on new issues in the same manner as on an issue raised in the request for hearing.

(c) *Remand to CMS.* At the request of either party, or on his or her own motion, in lieu of a hearing under paragraph (b) of this section, the ALJ may remand the case to CMS for consideration of the new issue and, if appropriate, a determination. If necessary, the ALJ may direct CMS to return the case to the ALJ for further proceedings.

§ 423.1044 Subpoenas.

(a) *Basis for issuance.* The ALJ, upon his or her own motion or at the request of a party, may issue subpoenas if they are reasonably necessary for the full presentation of a case.

(b) *Timing of request by a party.* The party must file a written request for a subpoena with the ALJ at least 5 calendar days before the date set for the hearing.

(c) *Content of request.* The request must:

(1) Identify the witnesses or documents to be produced;

(2) Describe their addresses or location with sufficient particularity to permit them to be found; and

(3) Specify the pertinent facts the party expects to establish by the witnesses or documents, and indicate why those facts could not be established without use of a subpoena.

(d) *Method of issuance.* Subpoenas are issued in the name of the Secretary.

§ 423.1046 Conduct of hearing.

(a) *Participants in the hearing.* The hearing is open to the parties and their representatives and technical advisors, and to any other persons whose presence the ALJ considers necessary or proper.

(b) *Hearing procedures.* (1) The ALJ inquires fully into all of the matters at issue, and receives in evidence the testimony of witnesses and any documents that are relevant and material.

(2) If the ALJ believes that there is relevant and material evidence available which has not been presented at the hearing, he may, at any time before mailing of notice of the decision, reopen the hearing to receive that evidence.

(3) The ALJ decides the order in which the evidence and the arguments of the parties are presented and the conduct of the hearing.

(4) CMS has the burden of coming forward with evidence related to disputed findings that is sufficient (together with any undisputed findings and legal authority) to establish a prima facie case that CMS has a legally sufficient basis for its determination.

(5) The affected party has the burden of coming forward with evidence sufficient to establish the elements of any affirmative argument or defense which it offers.

(6) The affected party bears the ultimate burden of persuasion. To prevail, the affected party must prove by a preponderance of the evidence on the record as a whole that there is no basis for the determination.

(c) *Review of the penalty.* When an ALJ finds that the basis for imposing a

civil money penalty exists, as specified in 423.752, the ALJ may not—

(1) Set a penalty of zero or reduce a penalty to zero, or

(2) Review the exercise of discretion by CMS to impose a civil money penalty.

§ 423.1048 Evidence.

Evidence may be received at the hearing even though inadmissible under the rules of evidence applicable to court procedure. The ALJ rules on the admissibility of evidence.

§ 423.1050 Witnesses.

Witnesses at the hearing testify under oath or affirmation. The representative of each party is permitted to examine his or her own witnesses subject to interrogation by the representative of the other party. The ALJ may ask any questions that he or she deems necessary. The ALJ rules upon any objection made by either party as to the propriety of any question.

§ 423.1052 Oral and written summation.

The parties to a hearing are allowed a reasonable time to present oral summation and to file briefs or other written statements of proposed findings of fact and conclusions of law. Copies of any briefs or other written statements must be sent in accordance with 423.1016.

§ 423.1054 Record of hearing.

A complete record of the proceedings at the hearing is made and transcribed in all cases.

§ 423.1056 Waiver of right to appear and present evidence.

(a) *Waiver procedures.* (1) If an affected party wishes to waive its right to appear and present evidence at the hearing, it must file a written waiver with the ALJ.

(2) If the affected party wishes to withdraw a waiver, it may do so, for good cause, at any time before the ALJ mails notice of the hearing decision.

(b) *Effect of waiver.* If the affected party waives the right to appear and present evidence, the ALJ need not conduct an oral hearing except in one of the following circumstances:

(1) The ALJ believes that the testimony of the affected party or its representatives or other witnesses is necessary to clarify the facts at issue.

(2) CMS shows good cause for requiring the presentation of oral evidence.

(c) *Dismissal for failure to appear.* If, despite the waiver, the ALJ sends notice of hearing and the affected party fails to appear, or to show good cause for the failure, the ALJ will dismiss the appeal in accordance with 423.1058.

(d) *Hearing without oral testimony.* When there is no oral testimony, the ALJ will—

(1) Make a record of the relevant written evidence that was considered in making the determination being appealed, and of any additional evidence submitted by the parties;

(2) Furnish to each party copies of the additional evidence submitted by the other party; and

(3) Give both parties a reasonable opportunity for rebuttal.

(e) *Handling of briefs and related statements.* If the parties submit briefs or other written statements of evidence or proposed findings of facts or conclusions of law, those documents will be handled in accordance with 423.1016.

§ 423.1058 Dismissal of request for hearing.

(a) The ALJ may, at any time before mailing the notice of the decision, dismiss a hearing request if a party withdraws its request for a hearing or the affected party asks that its request be dismissed.

(b) An affected party may request a dismissal by filing a written notice with the ALJ.

§ 423.1060 Dismissal for abandonment.

(a) The ALJ may dismiss a request for hearing if it is abandoned by the party that requested it.

(b) The ALJ may consider a request for hearing to be abandoned if the party or its representative—

(1) Fails to appear at the prehearing conference or hearing without having previously shown good cause for not appearing; and

(2) Fails to respond, within 10 calendar days after the ALJ sends a ''show

cause'' notice, with a showing of good cause.

§ 423.1062 Dismissal for cause.

On his or her own motion, or on the motion of a party to the hearing, the ALJ may dismiss a hearing request either entirely or as to any stated issue, under any of the following circumstances:

(a) *Res judicata.* There has been a previous determination or decision with respect to the rights of the same affected party on the same facts and law pertinent to the same issue or issues which has become final either by judicial affirmance or, without judicial consideration, because the affected party did not timely request reconsideration, hearing, or review, or commence a civil action with respect to that determination or decision.

(b) *No right to hearing.* The party requesting a hearing is not a proper party or does not otherwise have a right to a hearing.

(c) *Hearing request not timely filed.* The affected party did not file a hearing request timely and the time for filing has not been extended.

§ 423.1064 Notice and effect of dismissal and right to request review.

(a) Notice of the ALJ's dismissal action is mailed to the parties. The notice advises the affected party of its right to request that the dismissal be vacated as provided in 423.1066.

(b) The dismissal of a request for hearing is binding unless it is vacated by the ALJ or the Departmental Appeals Board.

§ 423.1066 Vacating a dismissal of request for hearing.

An ALJ may vacate any dismissal of a request for hearing if a party files a request to that effect within 60 calendar days from receipt of the notice of dismissal and shows good cause for vacating the dismissal.

§ 423.1068 Administrative Law Judge's decision.

(a) *Timing, basis and content.* As soon as practical after the close of the hearing, the ALJ issues a written decision in the case. The decision is based on the evidence of record and contains separate numbered findings of fact and conclusions of law.

(b) *Notice and effect.* A copy of the decision is mailed to the parties and is binding on them unless—

(1) A party requests review by the Departmental Appeals Board within the time period specified in 423.1076, and the Board reviews the case;

(2) The Departmental Appeals Board denies the request for review and the party seeks judicial review by filing an action in a United States District Court or, in the case of a civil money penalty, in a United States Court of Appeals;

(3) The decision is revised by an ALJ or the Department Appeals Board; or

(4) The decision is a recommended decision directed to the Board.

§ 423.1070 Removal of hearing to Departmental Appeals Board.

(a) At any time before the ALJ receives oral testimony, the Board may remove to itself any pending request for a hearing.

(b) Notice of removal is mailed to each party.

(c) The Board conducts the hearing in accordance with the rules that apply to ALJ hearings under this subpart.

§ 423.1072 Remand by the Administrative Law Judge.

(a) If CMS requests remand, and the affected party concurs in writing or on the record, the ALJ may remand any case properly before him or her to CMS for a determination satisfactory to the affected party.

(b) The ALJ may remand at any time before notice of hearing decision is mailed.

§ 423.1074 Right to request Departmental Appeals Board review of Administrative Law Judge's decision or dismissal.

Either of the parties has a right to request Departmental Appeals Board review of the ALJ's decision or dismissal order, and the parties are so informed in the notice of the ALJ's action.

§ 423.1076 Request for Departmental Appeals Board review.

(a) *Manner and time of filing.* (1) Any party that is dissatisfied with an ALJ's

decision or dismissal of a hearing request, may file a written request for review by the Departmental Appeals Board.

(2) The requesting party or its representative or other authorized official must file the request with the DAB within 60 calendar days from receipt of the notice of decision or dismissal, unless the Board, for good cause shown by the requesting party, extends the time for filing.

(b) *Content of request for review.* A request for review of an ALJ decision or dismissal must specify the issues, the findings of fact or conclusions of law with which the party disagrees, and the basis for contending that the findings and conclusions are incorrect.

§ 423.1078 Departmental Appeals Board action on request for review.

(a) *Request by CMS.* The Departmental Appeals Board may dismiss, deny, or grant a request made by CMS for review of an ALJ decision or dismissal.

(b) *Request by the affected party.* The Board may deny or grant the affected party's request for review or may dismiss the request for one of the following reasons:

(1) The affected party requests dismissal of its request for review.

(2) The affected party did not file timely or show good cause for late filing.

(3) The affected party does not have a right to review.

(4) A previous determination or decision, based on the same facts and law, and regarding the same issue, has become final through judicial affirmance or because the affected party failed to timely request reconsideration, hearing, Board review, or judicial review, as appropriate.

(c) *Effect of dismissal.* The dismissal of a request for Departmental Appeals Board review is binding and not subject to further review.

(d) *Review panel.* If the Board grants a request for review of the ALJ's decision, the review will be conducted by a panel of three members of the Board, designated by the Chair or Deputy Chair.

§ 423.1080 Procedures before the Departmental Appeals Board on review.

The parties are given, upon request, a reasonable opportunity to file briefs or other written statements as to fact and law, and to appear before the Departmental Appeals Board to present evidence or oral arguments. Copies of any brief or other written statement must be sent in accordance with 423.1016.

§ 423.1082 Evidence admissible on review.

(a) The Departmental Appeals Board may admit evidence into the record in addition to the evidence introduced at the ALJ hearing, (or the documents considered by the ALJ if the hearing was waived), if the Board considers that the additional evidence is relevant and material to an issue before it.

(b) If it appears to the Board that additional relevant evidence is available, the Board will require that it be produced.

(c) Before additional evidence is admitted into the record—

(1) Notice is mailed to the parties (unless they have waived notice) stating that evidence will be received regarding specified issues; and

(2) The parties are given a reasonable time to comment and to present other evidence pertinent to the specified issues.

(d) If additional evidence is presented orally to the Board, a transcript is prepared and made available to any party upon request.

§ 423.1084 Decision or remand by the Departmental Appeals Board.

(a) When the Departmental Appeals Board reviews an ALJ's decision or order of dismissal, or receives a case remanded by a court, the Board may either issue a decision or remand the case to an ALJ for a hearing and decision or a recommended decision for final decision by the Board.

(b) In a remanded case, the ALJ initiates additional proceedings and takes other actions as directed by the Board in its order of remand, and may take other action not inconsistent with that order.

(c) Upon completion of all action called for by the remand order and any

other consistent action, the ALJ promptly makes a decision or, as specified by the Board, certifies the case to the Board with a recommended decision.

(d) The parties have 20 calendar days from the date of a notice of a recommended decision to submit to the Board any exception, objection, or comment on the findings of fact, conclusions of law, and recommended decision.

(e) After the 20-calendar day period, the Board issues its decision adopting, modifying or rejecting the ALJ's recommended decision.

(f) If the Board does not remand the case to an ALJ, the following rules apply:

(1) The Board's decision—

(i) Is based upon the evidence in the hearing record and any further evidence that the Board receives during its review;

(ii) Is in writing and contains separate numbered findings of fact and conclusions of law; and

(iii) May modify, affirm, or reverse the ALJ's decision.

(2) A copy of the Board's decision is mailed to each party.

§ 423.1086 Effect of Departmental Appeals Board Decision.

(a) *General rule.* The Board's decision is binding unless—

(1) The affected party has a right to judicial review and timely files a civil action in a United States District Court or, in the case of a civil money penalty, in a United States Court of Appeals; or

(2) The Board reopens and revises its decision in accordance with 423.1092.

(b) *Right to judicial review.* Section 423.1006 specifies the circumstances under which an affected party has a right to seek judicial review.

(c) *Special rules: Civil money penalty.* Finality of Board's decision. When CMS imposes a civil money penalty, notice of the Board's decision (or denial of review) is the final administrative action that initiates the 60-calendar day period for seeking judicial review.

§ 423.1088 Extension of time for seeking judicial review.

(a) Any affected party that is dissatisfied with an Departmental Appeals Board decision and is entitled to judicial review must commence civil action within 60 calendar days from receipt of the notice of the Board's decision, unless the Board extends the time in accordance with paragraph (c) of this section.

(b) The request for extension must be filed in writing with the Board before the 60-calendar day period ends.

(c) For good cause shown, the Board may extend the time for commencing civil action.

§ 423.1090 Basis, timing, and authority for reopening an Administrative Law Judge or Board decision.

(a) *Basis and timing for reopening.* An ALJ of Departmental Appeals Board decision may be reopened, within 60 calendar days from the date of the notice of decision, upon the motion of the ALJ or the Board or upon the petition of either party to the hearing.

(b) *Authority to reopen.* (1) A decision of the Departmental Appeals Board may be reopened only by the Departmental Appeals Board.

(2) A decision of an ALJ may be reopened by that ALJ, by another ALJ if that one is not available, or by the Departmental Appeals Board. For purposes of this paragraph, an ALJ is considered to be unavailable if the ALJ has died, terminated employment, or been transferred to another duty station, is on leave of absence, or is unable to conduct a hearing because of illness.

§ 423.1092 Revision of reopened decision.

(a) Revision based on new evidence. If a reopened decision is to be revised on the basis of new evidence that was not included in the record of that decision, the ALJ or the Departmental Appeals Board—

(1) Notifies the parties of the proposed revision; and

(2) Unless the parties waive their right to hearing or appearance—

(i) Grants a hearing in the case of an ALJ revision; and

(ii) Grants opportunity to appear in the case of a Board revision.

(b) *Basis for revised decision and right to review.* (1) If a revised decision is necessary, the ALJ or the Departmental Appeals Board, as appropriate, renders it on the basis of the entire record.

(2) If the decision is revised by an ALJ, the Departmental Appeals Board may review that revised decision at the request of either party or on its own motion.

§ 423.1094 Notice and effect of revised decision.

(a) *Notice.* The notice mailed to the parties states the basis or reason for the revised decision and informs them of their right to Departmental Appeals Board review of an ALJ revised decision, or to judicial review of a Board reviewed decision.

(b) *Effect*—(1) *ALJ revised decision.* An ALJ revised decision is binding unless it is reviewed by the Departmental Appeals Board.

(2) *Departmental Appeals Board revised decision.* A Board revised decision is binding unless a party files a civil action in a district court of the United States within the time frames specified in 423.1088.

[72 FR 68726, Dec. 5, 2007, as amended at 85 FR 72909, Nov. 16, 2020]

Subpart U—Reopening, ALJ Hearings and ALJ and Attorney Adjudicator Decisions, Council Review, and Judicial Review

SOURCE: 74 FR 65363, Dec. 9, 2009, unless otherwise noted.

§ 423.1968 Scope.

This subpart sets forth the requirements relating to the following:

(a) Part D sponsors, the Part D IRE, ALJs and attorney adjudicators, and the Council with respect to reopenings.

(b) ALJs with respect to hearings and decisions or decisions of attorney adjudicators if no hearing is conducted.

(c) The Council with respect to review of Part D appeals.

(d) Part D enrollees' rights with respect to reopenings, ALJ hearings and ALJ or attorney adjudicator reviews, Council reviews, and judicial review by a Federal District Court.

[82 FR 5125, Jan. 17, 2017]

§§ 423.1970–423.1976 [Reserved]

§ 423.1978 Reopening determinations and decisions.

(a) A coverage determination or redetermination made by a Part D plan sponsor, a reconsideration made by the independent review entity specified in § 423.600, or the decision of an ALJ or attorney adjudicator or the Council that is otherwise binding may be reopened and revised by the entity that made the determination or decision as provided in § 423.1980 through § 423.1986.

(b) The filing of a request for reopening does not relieve the Part D plan sponsor of its obligation to make payment or provide benefits as specified in § 423.636 or § 423.638 of this chapter.

(c) Once an entity issues a revised determination or decision, the revisions made by the decision may be appealed.

(d) A decision not to reopen by the Part D plan sponsor or any other entity is not subject to review.

[74 FR 65363, Dec. 9, 2009, as amended at 82 FR 5126, Jan. 17, 2017]

§ 423.1980 Reopening of coverage determinations, redeterminations, reconsiderations, decisions, and reviews.

(a) *General rules.* (1) A reopening is a remedial action taken to change a binding determination or decision, even though the binding determination or decision may have been correct at the time it was made based on the evidence of record. Consistent with § 423.1978(a), that action may be taken by—

(i) A Part D plan sponsor to revise the coverage determination or redetermination;

(ii) An IRE to revise the reconsideration;

(iii) An ALJ or attorney adjudicator to revise his or her decision; or

(iv) The Council to revise the ALJ or attorney adjudicator decision, or its review decision.

(2) When an enrollee has filed a valid request for an appeal of a coverage determination, redetermination, reconsideration, ALJ or attorney adjudicator decision, or Council review, no adjudicator has jurisdiction to reopen an issue that is under appeal until all appeal rights for that issue are exhausted. Once the appeal rights for the issue have been exhausted, the Part D plan sponsor, IRE, ALJ or attorney adjudicator, or Council may reopen as set forth in this section.

(3) Consistent with §423.1978(b), the filing of a request for reopening does not relieve the Part D plan sponsor of its obligation to make payment or provide benefits as specified in §423.636 or §423.638.

(4) Consistent with §423.1978(d), the Part D plan sponsor's, IRE's, ALJ's or attorney adjudicator's, or Council's decision on whether to reopen is binding and not subject to appeal.

(5) A determination under the Medicare secondary payer provisions of section 1862(b) of the Act that Medicare has an MSP recovery claim for drug claims that were already reimbursed by the Part D plan sponsor is not a reopening.

(b) *Timeframes and requirements for reopening coverage determinations and redeterminations initiated by a Part D plan sponsor.* A Part D plan sponsor may reopen its coverage determination or redetermination on its own motion:

(1) Within 1 year from the date of the coverage determination or redetermination for any reason.

(2) Within 4 years from the date of the coverage determination or redetermination for good cause as defined in §423.1986.

(3) At any time if there exists reliable evidence as defined in §405.902 of this chapter that the coverage determination was procured by fraud or similar fault as defined in §405.902.

(c) *Timeframe and requirements for reopening coverage determinations and redeterminations requested by an enrollee.* (1) An enrollee may request that a Part D plan sponsor reopen its coverage determination or redetermination within 1 year from the date of the coverage determination or redetermination for any reason.

(2) An enrollee may request that a Part D plan sponsor reopen its coverage determination or redetermination within 4 years from the date of the coverage determination or redetermination for good cause in accordance with §423.1986.

(d) *Time frame and requirements for reopening reconsiderations, decisions and reviews initiated by an IRE, ALJ or attorney adjudicator, or the Council.* (1) An IRE may reopen its reconsideration on its own motion within 180 calendar days from the date of the reconsideration for good cause in accordance with §423.1986. If the IRE's reconsideration was procured by fraud or similar fault, then the IRE may reopen at any time.

(2) An ALJ or attorney adjudicator may reopen his or her decision, or the Council may reopen an ALJ or attorney adjudicator decision on its own motion within 180 calendar days from the date of the decision for good cause in accordance with §423.1986. If the decision was procured by fraud or similar fault, then the ALJ or attorney adjudicator may reopen his or her decision, or the Council may reopen an ALJ or attorney adjudicator decision at any time.

(3) The Council may reopen its review decision on its own motion within 180 calendar days from the date of the review decision for good cause in accordance with §423.1986. If the Council's decision was procured by fraud or similar fault, then the Council may reopen at any time.

(e) *Time frames and requirements for reopening reconsiderations, decisions, and reviews requested by an enrollee or a Part D plan sponsor.* (1) An enrollee who received a reconsideration or a Part D plan sponsor may request that an IRE reopen its reconsideration decision within 180 calendar days from the date of the reconsideration for good cause in accordance with §423.1986.

(2) An enrollee who received an ALJ's or attorney adjudicator's decision or a Part D plan sponsor may request that an ALJ or attorney adjudicator reopen his or her decision, or the Council reopen an ALJ or attorney adjudicator decision, within 180 calendar days from the date of the decision for good cause in accordance with §423.1986.

(3) An enrollee who received a Council decision or a Part D plan sponsor may request that the Council reopen its decision within 180 calendar days from the date of the review decision for good cause in accordance with § 423.1986.

[74 FR 65363, Dec. 9, 2009, as amended at 82 FR 5126, Jan. 17, 2017]

§ 423.1982 Notice of a revised determination or decision.

(a) *When adjudicators initiate reopenings.* When any determination or decision is reopened and revised as provided in § 423.1980:

(1) The Part D plan sponsor, IRE, ALJ or attorney adjudicator, or the Council must mail its revised determination or decision to the enrollee at his or her last known address.

(2) The IRE, ALJ or attorney adjudicator, or the Council must mail its revised determination or decision to the Part D plan sponsor.

(3) An adverse revised determination or decision must state the rationale and basis for the reopening and revision and any right to appeal.

(b) *Reopenings initiated at the request of an enrollee or a Part D plan sponsor.* (1) The Part D plan sponsor, IRE, ALJ or attorney adjudicator, or the Council must mail its revised determination or decision to the enrollee at his or her last known address.

(2) The IRE, ALJ or attorney adjudicator or the Council must mail its revised determination or decision to the Part D plan sponsor.

(3) An adverse revised determination or decision must state the rationale and basis for the reopening and revision and any right to appeal.

[74 FR 65363, Dec. 9, 2009, as amended at 82 FR 5126, Jan. 17, 2017]

§ 423.1984 Effect of a revised determination or decision.

(a) *Coverage determinations.* The revision of a coverage determination is binding unless an enrollee submits a request for a redetermination that is accepted and processed in accordance with § 423.580 through § 423.590.

(b) *Redeterminations.* The revision of a redetermination is binding unless an enrollee submits a request for an IRE reconsideration that is accepted and processed in accordance with § 423.600 through § 423.604.

(c) *Reconsiderations.* The revision of a reconsideration is binding unless an enrollee submits a request for an ALJ hearing that is accepted and processed in accordance with §§ 423.2000 through 423.2063.

(d) *ALJ or attorney adjudicator decisions.* The revision of an ALJ or attorney adjudicator decision is binding unless an enrollee submits a request for a Council review that is accepted and processed as specified in §§ 423.2100 through 423.2130.

(e) *Council review.* The revision of a Council determination or decision is binding unless an enrollee files a civil action in which a Federal District Court accepts jurisdiction and issues a decision.

(f) *Appeal of only the portion of the determination or decision revised by the reopening.* Only the portion of the coverage determination, redetermination, reconsideration, or hearing decision revised by the reopening may be subsequently appealed.

(g) *Effect of a revised determination or decision.* Consistent with § 423.1978(c), a revised determination or decision is binding unless it is appealed or otherwise reopened.

[74 FR 65363, Dec. 9, 2009, as amended at 82 FR 5127, Jan. 17, 2017; 84 FR 19872, May 7, 2019]

§ 423.1986 Good cause for reopening.

(a) *Establishing good cause.* Good cause may be established when—

(1) There is new and material evidence that—

(i) Was not available or known at the time of the determination or decision; and

(ii) May result in a different conclusion; or

(2) The evidence that was considered in making the determination or decision clearly shows on its face that an obvious error was made at the time of the determination or decision.

(b) *Change in substantive law or interpretative policy.* (1) *General rule.* A change of legal interpretation or policy by CMS in a regulation, CMS ruling, or CMS general instruction, whether made in response to judicial precedent

or otherwise, is not a basis for reopening a determination or hearing decision regarding appeals under this section.

(2) An adjudicator may reopen a determination or decision to apply the current law or CMS or the Part D plan sponsor policy rather than the law or CMS or the Part D plan sponsor policy at the time the coverage determination is made in situations where the enrollee has not yet received the drug and the current law or CMS or the Part D plan sponsor policy may affect whether the drug should be received.

(c) *Third party payer error.* A request to reopen a claim based upon a third party payer's error in making a primary payment determination when Medicare processed the claim in accordance with the information in its system of records or on the claim form does not constitute good cause for reopening.

§ 423.1990 Expedited access to judicial review.

(a) *Process for expedited access to judicial review.* (1) For purposes of this section, a ''review entity'' means an entity of up to three reviewers who are ALJs or members of the Departmental Appeals Board, as determined by the Secretary.

(2) In order to obtain expedited access to judicial review (EAJR), a review entity must certify that the Council does not have the authority to decide the question of law or regulation relevant to the matters in dispute and that there is no material issue of fact in dispute.

(3) An enrollee may make a request for EAJR only once with respect to a question of law or regulation for a specific matter in dispute in an appeal.

(b) *Conditions for making the expedited appeals request.* (1) An enrollee may request EAJR in place of an ALJ hearing or Council review if the following conditions are met:

(i) An IRE has made a reconsideration determination and the enrollee has filed a request for an ALJ hearing in accordance with § 423.2002 and a decision, dismissal order, or remand order of the ALJ or an attorney adjudicator has not been issued; or

(ii) An ALJ or attorney adjudicator has made a decision and the enrollee has filed a request for Council review in accordance with § 423.2102 and a final decision, dismissal order, or remand order of the Council has not been issued.

(2) The requestor is an enrollee.

(3) The amount remaining in controversy meets the threshold requirements specified in § 423.2006.

(4) If there is more than one enrollee to the hearing or Council review, each enrollee concurs, in writing, with the request for the EAJR.

(5) There are no material issues of fact in dispute.

(c) *Content of the request for EAJR.* The request for EAJR must—

(1) Allege that there are no material issues of fact in dispute and identify the facts that the enrollee considers material and that are not disputed; and

(2) Assert that the only factor precluding a decision favorable to the enrollee is—

(i) A statutory provision that is unconstitutional, or a provision of a regulation that is invalid and specify the statutory provision that the enrollee considers unconstitutional or the provision of a regulation that the enrollee considers invalid; or

(ii) A CMS Ruling that the enrollee considers invalid.

(3) Include a copy of the IRE reconsideration and of any ALJ or attorney adjudicator decision that the enrollee has received;

(4) If the IRE reconsideration or ALJ or attorney adjudicator decision was based on facts that the enrollee is disputing, state why the enrollee considers those facts to be immaterial; and

(5) If the IRE reconsideration or ALJ or attorney adjudicator decision was based on a provision of a law, regulation, or CMS Ruling in addition to the one the enrollee considers unconstitutional or invalid, a statement as to why further administrative review of how that provision applies to the facts is not necessary.

(d) *Place and time for an EAJR request.* (1) *Method and place for filing request.* The enrollee may—

(i) If a request for ALJ hearing or Council review is not pending, file a written EAJR request with the HHS Departmental Appeals Board, with his

or her request for an ALJ hearing or Council review; or

(ii) If an appeal is already pending for an ALJ hearing or otherwise before OMHA or the Council, file a written EAJR request with the HHS Departmental Appeals Board.

(2) Time of filing request. The enrollee may file a request for EAJR—

(i) If the enrollee has requested a hearing, at any time before receipt of the notice of the ALJ's or attorney adjudicator's decision; or

(ii) If the enrollee has requested Council review, at any time before receipt of notice of the Council's decision.

(e) *Determination on EAJR request.* (1) The review entity described in paragraph (a) of this section will determine whether the request for EAJR meets all of the requirements of paragraphs (b), (c), and (d) of this section.

(2) Within 60 calendar days after the date the review entity receives a request and accompanying documents and materials meeting the conditions in paragraphs (b), (c), and (d) of this section, the review entity will issue either a certification in accordance with paragraph (f) of this section or a denial of the request.

(3) A determination by the review entity either certifying that the requirements for EAJR are met pursuant to paragraph (f) of this section or denying the request is not subject to review by the Secretary.

(4) If the review entity fails to make a determination within the timeframe specified in paragraph (e)(2) of this section, then the enrollee may bring a civil action in Federal District Court within 60 calendar days of the end of the timeframe.

(f) *Certification by the review entity.* If an enrollee meets the requirements for the EAJR, the review entity certifies in writing that—

(1) The material facts involved in the appeal are not in dispute;

(2) Except as indicated in paragraph (f)(3) of this section, the Secretary's interpretation of the law is not in dispute;

(3) The sole issue(s) in dispute is the constitutionality of a statutory provision, or the validity of a provision of a regulation or CMS Ruling;

(4) But for the provision challenged, the enrollee would receive a favorable decision on the ultimate issue; and

(5) The certification by the review entity is the Secretary's final action for purposes of seeking expedited judicial review.

(g) *Effect of certification by the review entity.* If an EAJR request results in a certification described in paragraph (f) of this section:

(1) The enrollee that requested the EAJR is considered to have waived any right to completion of the remaining steps of the administrative appeals process regarding the matter certified.

(2) The enrollee has 60 calendar days, beginning on the date of the review entity's certification within which to bring a civil action in Federal District Court.

(3) The enrollee must satisfy the requirements for venue under section 205(g) of the Act, as well as the requirements for filing a civil action in a Federal District Court under § 423.2136.

(h) *Rejection of EAJR.* (1) If a request for EAJR does not meet all the conditions set out in paragraphs (b), (c), and (d) of this section, or if the review entity does not certify a request for EAJR, the review entity advises the enrollee in writing that the request has been denied, and forwards the request to OMHA or the Council, which will treat it as a request for hearing or for Council review, as appropriate.

(2) Whenever a review entity forwards a rejected EAJR request to OMHA or the Council, the appeal is considered timely filed and, if an adjudication time frame applies to the appeal, the adjudication time frame begins on the day the request is received by OMHA or the Council from the review entity.

[74 FR 65363, Dec. 9, 2009, as amended at 82 FR 5127, Jan. 17, 2017; 84 FR 19872, May 7, 2019]

§ 423.2000 Hearing before an ALJ and decision by an ALJ or attorney adjudicator: General rule.

(a) If an enrollee is dissatisfied with an IRE's reconsideration, the enrollee may request a hearing before an ALJ.

(b) A hearing before an ALJ may be conducted in-person, by video-teleconference, or by telephone. At the

hearing, the enrollee may submit evidence subject to the restrictions in § 423.2018, examine the evidence used in making the determination under review, and present and/or question witnesses.

(c) In some circumstances, the Part D plan sponsor, CMS, or the IRE may participate in the proceedings on a request for an ALJ hearing as specified in § 423.2010.

(d) The ALJ or attorney adjudicator conducts a de novo review and issues a decision based on the administrative record, including, for an ALJ, any hearing record.

(e) If an enrollee waives his or her right to appear at the hearing in person or by telephone or video-teleconference, the ALJ or an attorney adjudicator may make a decision based on the evidence that is in the file and any new evidence that is submitted for consideration.

(f) The ALJ may require the enrollee to participate in a hearing if it is necessary to decide the case. If the ALJ determines that it is necessary to obtain testimony from a person other than the enrollee, he or she may hold a hearing to obtain that testimony, even if the enrollee has waived the right to appear. In that event, however, the ALJ will give the enrollee the opportunity to appear when the testimony is given, but may hold the hearing even if the enrollee decides not to appear.

(g) An ALJ or attorney adjudicator may also issue a decision on the record on his or her own initiative if the evidence in the administrative record supports a fully favorable finding.

[74 FR 65363, Dec. 9, 2009, as amended at 82 FR 5127, Jan. 17, 2017]

§ 423.2002 Right to an ALJ hearing.

(a) An enrollee who is dissatisfied with the IRE reconsideration determination has a right to a hearing before an ALJ if—

(1) The enrollee files a written request for an ALJ hearing within 60 calendar days after receipt of the written notice of the IRE's reconsideration; and

(2) The enrollee meets the amount in controversy requirements of § 423.2006.

(b) An enrollee may request that the hearing before an ALJ be expedited if:

(1) The appeal involves an issue specified in § 423.566(b) but does not include solely a request for payment of Part D drugs already furnished;

(2) The enrollee submits a written or oral request for an expedited ALJ hearing within 60 calendar days of the date of the written notice of an IRE reconsideration determination. The request can only be submitted after the enrollee receives the written IRE reconsideration notice. The request should also explain why applying the standard timeframe may seriously jeopardize the life or health of the enrollee; and

(3) The enrollee meets the amount in controversy requirements of § 423.2006.

(c) OMHA must document all oral requests for expedited hearings in writing and maintain the documentation in the case files.

(d) For purposes of this section, the date of receipt of the reconsideration is presumed to be 5 calendar days after the date of the written reconsideration, unless there is evidence to the contrary.

(e) For purposes of meeting the 60 calendar day filing deadline, the request is considered as filed on the date it is received by the office specified in the IRE's reconsideration.

[74 FR 65363, Dec. 9, 2009, as amended at 82 FR 5127, Jan. 17, 2017; 84 FR 19872, May 7, 2019]

§ 423.2004 Right to a review of IRE notice of dismissal.

(a) An enrollee has a right to have an IRE's dismissal of a request for reconsideration reviewed by an ALJ or attorney adjudicator if—

(1) The enrollee files a written request for review within 60 calendar days after receipt of the notice of the IRE's dismissal.

(2) The enrollee meets the amount in controversy requirements of § 423.2006.

(3) For purposes of this section, the date of receipt of the IRE's dismissal is presumed to be 5 calendar days after the date of the written dismissal notice, unless there is evidence to the contrary.

(4) For purposes of meeting the 60 calendar day filing deadline, the request is considered as filed on the date it is received by the office specified in the IRE's dismissal.

(b) If the ALJ or attorney adjudicator determines that the IRE's dismissal was in error, he or she vacates the dismissal and remands the case to the IRE for a reconsideration in accordance with § 423.2056.

(c) If the ALJ or attorney adjudicator affirms the IRE's dismissal of a reconsideration request, he or she issues a notice of decision affirming the IRE's dismissal in accordance with § 423.2046(b).

(d) The ALJ or attorney adjudicator may dismiss the request for review of an IRE's dismissal in accordance with § 423.2052(b).

[74 FR 65363, Dec. 9, 2009, as amended at 82 FR 5127, Jan. 17, 2017; 84 FR 19872, May 7, 2019]

§ 423.2006 Amount in controversy required for an ALJ hearing and judicial review.

(a) *ALJ review.* To be entitled to a hearing before an ALJ, an enrollee must meet the amount in controversy requirements of this section.

(1) For ALJ hearing requests, the required amount remaining in controversy must be $100, increased by the percentage increase in the medical care component of the Consumer Price Index for All Urban Consumers (U.S. city average) as measured from July 2003 to the July preceding the current year involved.

(2) If the figure in paragraph (a)(1) of this section is not a multiple of $10, it is rounded to the nearest multiple of $10. The Secretary will publish changes to the amount in controversy requirement in the FEDERAL REGISTER when necessary.

(b) *Judicial review.* To be entitled to judicial review, the enrollee must meet the amount in controversy requirements of this subpart at the time it requests judicial review. For review requests, the required amount remaining in controversy must be $1,000 or more, adjusted as specified in paragraphs (a)(1) and (2) of this section.

(c) *Calculating the amount remaining in controversy.* (1) The amount remaining in controversy is computed as the projected value described in paragraph (c)(2) or (3) of this section, reduced by any cost sharing amounts, including deductible, coinsurance, or copayment amounts that may be collected from the enrollee for the Part D drug(s).

(2) If the basis for the appeal is the refusal by the Part D plan sponsor to provide drug benefits, the projected value of those benefits is used to compute the amount remaining in controversy. The projected value of a Part D drug or drugs must include any costs the enrollee could incur based on the number of refills prescribed for the drug(s) in dispute during the plan year.

(3) If the basis for the appeal is an at-risk determination made under a drug management program in accordance with § 423.153(f), the projected value of the drugs subject to the drug management program is used to compute the amount remaining in controversy. The projected value of the drugs subject to the drug management program shall include the value of any refills prescribed for the drug(s) in dispute during the plan year.

(d) *Aggregating appeals to meet the amount in controversy*—(1) *Enrollee.* Two or more appeals may be aggregated by an enrollee to meet the amount in controversy for an ALJ hearing if—

(i) The appeals have previously been reconsidered by an IRE;

(ii) The enrollee requests aggregation at the same time the requests for hearing are filed, and the request for aggregation and requests for hearing are filed within 60 calendar days after receipt of the notice of reconsideration for each of the reconsiderations being appealed, unless the deadline to file one or more of the requests for hearing has been extended in accordance with § 423.2014(d); and

(iii) The appeals the enrollee seeks to aggregate involve the delivery of prescription drugs to a single enrollee, as determined by an ALJ or attorney adjudicator. Only an ALJ may determine the appeals the enrollee seeks to aggregate do not involve the delivery of prescription drugs to a single enrollee.

(2) *Multiple enrollees.* Two or more appeals may be aggregated by multiple enrollees to meet the amount in controversy for an ALJ hearing if—

(i) The appeals have previously been reconsidered by an IRE;

(ii) The enrollees request aggregation at the same time the requests for hearing are filed, and the request for aggregation and requests for hearing are filed within 60 calendar days after receipt of the notice of reconsideration for each of the reconsiderations being appealed, unless the deadline to file one or more of the requests for hearing has been extended in accordance with § 423.2014(d); and

(iii) The appeals the enrollees seek to aggregate involve the same prescription drugs, as determined by an ALJ or attorney adjudicator. Only an ALJ may determine the appeals the enrollees seek to aggregate do not involve the same prescription drugs.

[84 FR 19872, May 7, 2019, as amended at 86 FR 6121, Jan. 19, 2021]

§ 423.2008 Parties to the proceedings on a request for an ALJ hearing.

The enrollee (or the enrollee's representative) who filed the request for hearing is the only party to the proceedings on a request for an ALJ hearing.

[82 FR 5127, Jan. 17, 2017]

§ 423.2010 When CMS, the IRE, or Part D plan sponsors may participate in the proceedings on a request for an ALJ hearing.

(a) *When CMS, the IRE, or the Part D plan sponsor may participate.* (1) CMS, the IRE, and/or the Part D plan sponsor may request to participate in the proceedings on a request for an ALJ hearing upon filing a request to participate in accordance with paragraph (b) of this section.

(2) An ALJ may request, but may not require, CMS, the IRE, and/or the Part D plan sponsor to participate in any proceedings before the ALJ, including the oral hearing, if any. The ALJ cannot draw any adverse inferences if CMS, the IRE, and/or the Part D plan sponsor decide not to participate in any proceedings before an ALJ, including the hearing.

(b) *How a request to participate is made*—(1) *No notice of hearing.* If CMS, the IRE, and/or the Part D plan sponsor requests participation before it receives a notice of hearing, or when no notice is required, it must send written notice of its request to participate to the assigned ALJ or attorney adjudicator, or a designee of the Chief ALJ if the request is not yet assigned to an ALJ or attorney adjudicator, and the enrollee, except that the request may be made orally if a request for an expedited hearing was filed and OMHA will notify the enrollee of the request to participate.

(2) *Notice of hearing.* If CMS, the IRE, and/or the Part D plan sponsor requests participation after the IRE and Part D plan sponsor receive a notice of hearing, it must send written notice of its request to participate to the ALJ and the enrollee, except that the request to participate may be made orally for an expedited hearing and OMHA will notify the enrollee of the request to participate.

(3) *Timing of request.* CMS, the IRE, and/or the Part D plan sponsor must send its request to participate—

(i) If a standard request for hearing was filed, if no hearing is scheduled, within 30 calendar days after notification that a standard request for hearing was filed;

(ii) If an expedited hearing is requested, but no hearing has been scheduled, within 2 calendar days after notification that a request for an expedited hearing was filed;

(iii) If a non-expedited hearing is scheduled, within 5 calendar days after receiving the notice of hearing; or

(iv) If an expedited hearing is scheduled, within 1 calendar day after receiving the notice of hearing. Requests may be made orally or submitted by facsimile to the hearing office.

(c) *The ALJ's or attorney adjudicator's decision on a request to participate.* The assigned ALJ or attorney adjudicator has discretion not to allow CMS, the IRE, and/or the Part D plan sponsor to participate. The ALJ or attorney adjudicator must notify the entity requesting participation, the Part D plan sponsor, if applicable, and the enrollee of his or her decision on the request to participate within the following time frames—

(1) If no hearing is scheduled, at least 20 calendar days before the ALJ or attorney adjudicator issues a decision, dismissal, or remand;

(2) If a non-expedited hearing is scheduled, within 5 calendar days of receipt of a request to participate; or

(3) If an expedited hearing is scheduled, within 1 calendar of receipt of a request to participate.

(d) *Roles and responsibilities of CMS, the IRE, and/or the Part D plan sponsor as a participant.* (1) Participation may include filing position papers and/or providing testimony to clarify factual or policy issues in a case, but it does not include calling witnesses or cross-examining the witnesses of an enrollee.

(2) When CMS, the IRE, and/or the Part D plan sponsor participates in an ALJ hearing, CMS, the IRE, and/or the Part D plan sponsor may not be called as a witness during the hearing and is not subject to examination or cross-examination by the enrollee, but the enrollee may provide testimony to rebut factual or policy statements made by a participant and the ALJ may question the participant about its testimony.

(3) CMS, IRE, and/or Part D plan sponsor position papers and written testimony are subject to the following:

(i) Unless the ALJ or attorney adjudicator grants additional time to submit a position paper or written testimony, a position paper and written testimony must be submitted—

(A) Within 14 calendar days for a standard appeal, or 1 calendar day for an expedited appeal, after receipt of the ALJ's or attorney adjudicator's decision on a request to participate if no hearing has been scheduled; or

(B) No later than 5 calendar days prior to the hearing if a non-expedited hearing is scheduled, or 1 calendar day prior to the hearing if an expedited hearing is scheduled.

(ii) A copy of any position paper and written testimony that CMS, the IRE, or the Part D plan sponsor submits to OMHA must be sent within the same time frames specified in paragraph (d)(3)(i)(A) and (B) of this section to the enrollee.

(iii) If CMS, the IRE, and/or the Part D plan sponsor fails to send a copy of its position paper or written testimony to the enrollee or fails to submit its position paper or written testimony within the time frames described in this section, the position paper or written testimony will not be considered in deciding the appeal.

(e) *Invalid requests to participate.* (1) An ALJ or attorney adjudicator may determine that a CMS, IRE, and/or Part D plan sponsor request to participate is invalid under this section if the request to participate was not timely filed or the request to participate was not sent to the enrollee.

(2) If the request to participate is determined to be invalid, the written notice of an invalid request to participate must be sent to the entity that made the request to participate and the enrollee.

(i) If no hearing is scheduled or the request to participate was made after the hearing occurred, the written notice of an invalid request to participate must be sent no later than the date the notice of decision, dismissal, or remand is mailed.

(ii) If a non-expedited hearing is scheduled, the written notice of an invalid request to participate must be sent prior to the hearing. If the notice would be sent fewer than 5 calendar days before the hearing is scheduled to occur, oral notice must be provided to the entity that submitted the request, and the written notice must be sent as soon as possible after the oral notice is provided.

(iii) If an expedited hearing is scheduled, oral notice of an invalid request to participate must be provided to the entity that submitted the request, and the written notice must be sent as soon as possible after the oral notice is provided.

[82 FR 5127, Jan. 17, 2017, as amended at 84 FR 19873, May 7, 2019]

§ 423.2014 Request for an ALJ hearing or a review of an IRE dismissal.

(a) *Content of the request.* (1) The request for an ALJ hearing or a review of an IRE dismissal must be made in writing, except as set forth in paragraph (b) of this section. The request, including any oral request, must include all of the following—

(i) The name, address, telephone number, and Medicare number of the enrollee.

(ii) The name, address, and telephone number of the representative, as defined at § 423.560, if any.

(iii) The Medicare appeal number, if any, assigned to the IRE reconsideration or dismissal being appealed.

(iv) The prescription drug in dispute.

(v) The plan name.

(vi) The reasons the enrollee disagrees with the IRE's reconsideration or dismissal being appealed.

(2) The enrollee must submit a statement of any additional evidence to be submitted and the date it will be submitted.

(3) The enrollee must submit a statement that the enrollee is requesting an expedited hearing, if applicable.

(b) *Request for expedited hearing.* If an enrollee is requesting that the hearing be expedited, the enrollee may make the request for an ALJ hearing orally, but only after receipt of the written IRE reconsideration notice. OMHA must document all oral requests in writing and maintain the documentation in the case files. A prescribing physician or other prescriber may provide oral or written support for an enrollee's request for expedited review.

(c) *Complete request required.* (1) A request must contain the information in paragraph (a)(1) of this section to the extent the information is applicable, to be considered complete. If a request is not complete, the enrollee will be provided with an opportunity to complete the request, and if an adjudication time frame applies it does not begin until the request is complete. If the enrollee fails to provide the information necessary to complete the request within the time frame provided, the enrollee's request for hearing or review will be dismissed.

(2) If supporting materials submitted with a request clearly provide information required for a complete request, the materials will be considered in determining whether the request is complete.

(d) *When and where to file.* The request for an ALJ hearing after an IRE reconsideration or request for review of an IRE dismissal must be filed:

(1) Within 60 calendar days from the date the enrollee receives written notice of the IRE's reconsideration or dismissal being appealed.

(2) With the office specified in the IRE's reconsideration or dismissal.

(i) If the request for hearing is timely filed with an office other than the office specified in the IRE's reconsideration, the request is not treated as untimely, and any applicable time frame specified in § 423.2016 for deciding the appeal begins on the date the office specified in the IRE's reconsideration or dismissal receives the request for hearing.

(ii) If the request for hearing is filed with an office, other than the office specified in the IRE's reconsideration or dismissal, OMHA must notify the enrollee of the date the request was received in the correct office and the commencement of any applicable adjudication timeframe.

(e) *Extension of time to request a hearing or review.* (1) If the request for hearing or review is not filed within 60 calendar days of receipt of the written IRE's reconsideration or dismissal, an enrollee may request an extension for good cause.

(2) Any request for an extension of time must be in writing or, for expedited reviews, in writing or oral. OMHA must document all oral requests in writing and maintain the documentation in the case file.

(3) The request must be filed with the office specified in the notice of reconsideration or dismissal, must give the reasons why the request for a hearing or review was not filed within the stated time period, and must be filed with the request for hearing or request for review of an IRE dismissal, or upon notice that the request may be dismissed because it was not timely filed.

(4) An ALJ or attorney adjudicator may find there is good cause for missing the deadline to file a request for an ALJ hearing or request for review of an IRE dismissal, or there is no good cause for missing the deadline to file a request for a review of an IRE dismissal, but only an ALJ may find there is no good cause for missing the deadline to file a request for an ALJ hearing. If good cause is found for missing the deadline, the time period for filing the request for hearing or request for review of an IRE dismissal will be extended. To determine whether good cause for late filing exists, the ALJ or

attorney adjudicator uses the standards set forth in § 405.942(b)(2) and (3) of this chapter.

(5) If a request for hearing is not timely filed, any applicable adjudication period in § 423.2016 begins the date the ALJ or attorney adjudicator grants the request to extend the filing deadline.

(6) A determination granting a request to extend the filing deadline is not subject to further review.

[82 FR 5128, Jan. 17, 2017, as amended at 84 FR 19873, May 7, 2019; 86 FR 6121, Jan. 19, 2021]

§ 423.2016 Timeframes for deciding an appeal of an IRE reconsideration.

(a) *Standard appeals.* (1) When a request for an ALJ hearing is filed after an IRE has issued a written reconsideration, an ALJ or attorney adjudicator issues a decision, dismissal order, or remand, as appropriate, no later than the end of the 90 calendar day period beginning on the date the request for hearing is received by the office specified in the IRE's notice of reconsideration, unless the 90 calendar day period has been extended as provided in this subpart.

(2) The adjudication period specified in paragraph (a)(1) of this section begins on the date that a timely filed request for hearing is received by the office specified in the IRE's reconsideration, or, if it is not timely filed, the date that the ALJ or attorney adjudicator grants any extension to the filing deadline.

(3) If the Council remands a case and the case was subject to an adjudication time frame under paragraph (a)(1) of this section, the remanded appeal will be subject to the same adjudication time frame beginning on the date that OMHA receives the Council remand.

(b) *Expedited appeals*—(1) *Standard for expedited appeal.* An ALJ or attorney adjudicator issues an expedited decision if the appeal involves an issue specified in § 423.566(b), but is not solely a request for payment of Part D drugs already furnished, and the enrollee's prescribing physician or other prescriber indicates, or an ALJ or attorney adjudicator determines that applying the standard timeframe for making a decision may seriously jeopardize the enrollee's life, health or ability to regain maximum function. An ALJ or attorney adjudicator may consider this standard as met if a lower level adjudicator has granted a request for an expedited decision.

(2) *Grant of a request.* If an ALJ or attorney adjudicator grants a request for expedited hearing, an ALJ or attorney adjudicator must—

(i) Make the decision to grant an expedited appeal within 5 calendar days of receipt of the request for an expedited hearing;

(ii) Give the enrollee prompt oral notice of this decision; and

(iii) Subsequently send to the enrollee at his or her last known address and to the Part D plan sponsor written notice of the decision. This notice may be provided within the written notice of hearing.

(3) *Denial of a request.* If an ALJ or attorney adjudicator denies a request for expedited hearing, an ALJ or attorney adjudicator must—

(i) Make this decision within 5 calendar days of receipt of the request for expedited hearing;

(ii) Give the enrollee prompt oral notice of the denial that informs the enrollee of the denial and explains that an ALJ or attorney adjudicator will process the enrollee's request using the 90 calendar day timeframe for non-expedited appeals; and

(iii) Subsequently send to the enrollee at his or her last known address and to the Part D plan sponsor an equivalent written notice of the decision within 3 calendar days after the oral notice.

(4) *Decision not appealable.* A decision on a request for expedited hearing may not be appealed.

(5) *Time frame for adjudication.* (i) If an ALJ or attorney adjudicator accepts a request for expedited hearing, an ALJ or attorney adjudicator issues a written decision, dismissal order, or remand as expeditiously as the enrollee's health condition requires, but no later than the end of the 10 calendar day period beginning on the date the request for hearing is received by the office specified in the IRE's written notice of reconsideration, unless the 10 calendar day period has been extended as provided in this subpart.

(ii) The adjudication period specified in paragraph (b)(5)(i) of this section begins on the date that a timely provided request for hearing is received by the office specified in the IRE's reconsideration, or, if it is not timely provided, the date that an ALJ or attorney adjudicator grants any extension to the filing deadline.

(6) *Time frame for Council remands.* If the Council remands a case and the case was subject to an adjudication time frame under paragraph (b)(5) of this section, the remanded appeal will be subject to the same adjudication timeframe beginning on the date that OMHA receives the Council remand, if the standards for an expedited appeal continue to be met. If the standards for an expedited appeal are no longer met, the appeal will be subject to the adjudication time frame for a standard appeal.

(c) *Waivers and extensions of adjudication period.* (1) At any time during the adjudication process, the enrollee may waive the adjudication period specified in paragraphs (a)(1) and (b)(5) of this section. The waiver may be for a specific period of time agreed upon by the ALJ or attorney adjudicator and the enrollee.

(2) The adjudication periods specified in paragraphs (a)(1) and (b)(5) of this section are extended as otherwise specified in this subpart, and for the following events—

(i) The duration of a stay of action on adjudicating the matters at issue ordered by a court or tribunal of competent jurisdiction;

(ii) The duration of a stay of proceedings granted by an ALJ or attorney adjudicator on a motion by an enrollee.

[82 FR 5129, Jan. 17, 2017, as amended at 84 FR 19873, May 7, 2019]

§ 423.2018 Submitting evidence.

(a) *All appeals.* An enrollee must submit any written or other evidence that he or she wishes to have considered.

(1) An ALJ or attorney adjudicator will not consider any evidence submitted regarding a change in condition of an enrollee after the appealed coverage determination or at-risk determination was made.

(2) An ALJ or attorney adjudicator will remand a case to the Part D IRE where an enrollee wishes evidence on his or her change in condition after the coverage determination or at-risk determination to be considered.

(b) *Non-expedited appeals.* (1) Except as provided in this paragraph, a represented enrollee must submit all written or other evidence he or she wishes to have considered with the request for hearing, by the date specified in the request for hearing in accordance with § 423.2014(a)(2), or, if a hearing is scheduled, within 10 calendar days of receiving the notice of hearing.

(2) If a represented enrollee submits written or other evidence later than 10 calendar days after receiving the notice of hearing, any applicable adjudication period specified in § 423.2016 is extended by the number of calendar days in the period between 10 calendar days after receipt of the notice of hearing and the day the evidence is received.

(3) The requirements of paragraph (b) of this section do not apply to unrepresented enrollees.

(c) *Expedited appeals.* (1) Except as provided in this section, an enrollee must submit all written or other evidence he or she wishes to have considered with the request for hearing, by the date specified in the request for hearing pursuant to § 423.2014(a)(2), or, if an expedited hearing is scheduled, within 2 calendar days of receiving the notice of the expedited hearing.

(2) If an enrollee submits written or other evidence later than 2 calendar days after receiving the notice of expedited hearing, any applicable adjudication period specified in § 423.2016 is extended by the number of calendar days in the period between 2 calendar days after receipt of the notice of expedited hearing and the day the evidence is received.

(d) *When this section does not apply.* The requirements of paragraphs (b) and (c) of this section do not apply to oral testimony given at a hearing.

[82 FR 5130, Jan. 17, 2017, as amended at 83 FR 16754, Apr. 16, 2018]

§ 423.2020 Time and place for a hearing before an ALJ.

(a) *General.* The ALJ sets the time and place for the hearing, and may change the time and place, if necessary.

(b) *Determining how appearances are made.* (1) *Appearances by unrepresented enrollees.* The ALJ will direct that the appearance of an unrepresented enrollee who filed a request for hearing be conducted by video-teleconferencing if the ALJ finds that video-teleconferencing technology is available to conduct the appearance, unless the ALJ finds good cause for an in-person appearance.

(i) The ALJ may also offer to conduct a hearing by telephone if the request for hearing or administrative record suggests that a telephone hearing may be more convenient for the unrepresented enrollee.

(ii) The ALJ, with the concurrence of the Chief ALJ or designee, may find good cause that an in-person hearing should be conducted if—

(A) The video-teleconferencing or telephone technology is not available; or

(B) Special or extraordinary circumstances exist.

(2) *Appearances by represented enrollees.* The ALJ will direct that the appearance of an individual, other than an unrepresented enrollee who filed a request for hearing, be conducted by telephone, unless the ALJ finds good cause for an appearance by other means.

(i) The ALJ may find good cause for an appearance by video-teleconferencing if he or she determines that video-teleconferencing is necessary to examine the facts or issues involved in the appeal.

(ii) The ALJ, with the concurrence of the Chief ALJ or designee, may find good cause that an in-person hearing should be conducted if—

(A) The video-teleconferencing and telephone technology are not available; or

(B) Special or extraordinary circumstances exist.

(c) *Notice of hearing.* (1) A notice of hearing is sent to the enrollee, the Part D plan sponsor that issued the coverage determination or at-risk determination, and the IRE that issued the reconsideration, advising them of the proposed time and place of the hearing.

(2) The notice of hearing will require the enrollee to reply to the notice by:

(i) Acknowledging whether they plan to attend the hearing at the time and place proposed in the notice of hearing, or whether they object to the proposed time and/or place of the hearing;

(ii) If the representative is an entity or organization, specifying who from the entity or organization plans to attend the hearing, if anyone, and in what capacity, in addition to the individual who filed the request for hearing; and

(iii) Listing the witnesses who will be providing testimony at the hearing.

(3) The notice of hearing will require CMS, the IRE, or the Part D plan sponsor that requests to attend the hearing as a participant to reply to the notice by:

(i) Acknowledging whether it plans to attend the hearing at the time and place proposed in the notice of hearing; and

(ii) Specifying who from the entity plans to attend the hearing,

(d) *An enrollee's right to waive a hearing.* An enrollee may also waive the right to a hearing and request a decision based on the written evidence in the record in accordance with § 423.2038(b).

(1) As specified in § 423.2000, an ALJ may require the enrollee to attend a hearing if it is necessary to decide the case.

(2) If an ALJ determines that it is necessary to obtain testimony from a person other than the enrollee, he or she may still hold a hearing to obtain that testimony, even if the enrollee has waived the right to appear. In those cases, the ALJ would give the enrollee the opportunity to appear when the testimony is given but may hold the hearing even if the enrollee decides not to appear.

(e) *An enrollee's objection to time and place of hearing.* (1) If an enrollee objects to the time and place of the hearing, the enrollee must notify the ALJ at the earliest possible opportunity before the time set for the hearing.

(2) The enrollee must state the reason for the objection and state the time and place he or she wants the hearing to be held.

(3) The objection must be in writing except for an expedited hearing when the objection may be provided orally, and except that the enrollee may orally request that a non-expedited hearing be rescheduled in an emergency circumstance the day prior to or day of the hearing. The ALJ must document all oral objections to the time and place of a hearing in writing and maintain the documentation in the case files.

(4) The ALJ may change the time or place of the hearing if the enrollee has good cause.

(5) If the enrollee's objection to the place of the hearing includes a request for an in-person or video-teleconferencing hearing, the objection and request are considered in paragraph (i) of this section.

(f) *Good cause for changing the time or place.* The ALJ can find good cause for changing the time or place of the scheduled hearing and reschedule the hearing if the information available to the ALJ supports the enrollee's contention that—

(1) The enrollee or his or her representative is unable to attend or to travel to the scheduled hearing because of a serious physical or mental condition, incapacitating injury, or death in the family; or

(2) Severe weather conditions make it impossible to travel to the hearing; or

(3) Good cause exists as set forth in paragraph (g) of this section.

(g) *Good cause in other circumstances.* (1) In determining whether good cause exists in circumstances other than those set forth in paragraph (f) of this section, the ALJ considers the enrollee's reason for requesting the change, the facts supporting the request, and the impact of the change on the efficient administration of the hearing process.

(2) Factors evaluated to determine the impact of the change include, but are not limited to, the effect on processing other scheduled hearings, potential delays in rescheduling the hearing, and whether any prior changes were granted the enrollee.

(3) Examples of other circumstances an enrollee might give for requesting a change in the time or place of the hearing include, but are not limited to, the following:

(i) The enrollee has attempted to obtain a representative but needs additional time.

(ii) The enrollee's representative was appointed within 10 calendar days of the scheduled hearing for non-expedited hearings (or 2 calendar days for expedited hearings) and needs additional time to prepare for the hearing.

(iii) The enrollee's representative has a prior commitment to be in court or at another administrative hearing on the date scheduled for the hearing.

(iv) A witness who will testify to facts material to an enrollee's case is unavailable to attend the scheduled hearing and the evidence cannot be otherwise obtained.

(v) Transportation is not readily available for an enrollee to travel to the hearing.

(vi) The enrollee is unrepresented, and is unable to respond to the notice of hearing because of any physical, mental, educational, or linguistic limitations (including any lack of facility with the English language).

(vii) The enrollee or enrollee's representative has a prior commitment that cannot be changed without significant expense.

(viii) The enrollee or enrollee's representative asserts he or she did not receive the notice of hearing and is unable to appear at the scheduled time and place.

(h) *Effect of rescheduling hearing.* If a hearing is postponed at the request of the enrollee for any of the above reasons, the time between the originally scheduled hearing date and the new hearing date is not counted toward the adjudication period specified in § 423.2016.

(i) *An enrollee's request for an in-person or video-teleconferencing hearing.* (1) If an unrepresented enrollee objects to a video-teleconferencing hearing or to the ALJ's offer to conduct a hearing by telephone, or a represented enrollee

who filed the request for hearing objects to a telephone or video-teleconferencing hearing, the enrollee or the enrollee's representative must notify the ALJ at the earliest possible opportunity before the time set for the hearing and request a video-teleconferencing or an in-person hearing.

(2) The enrollee must state the reason for the objection and state the time and/or place he or she wants an in-person or video-teleconferencing hearing to be held.

(3) The request must be in writing except for an expedited hearing for which the request may be provided orally. The ALJ must document all oral objections to an expedited video-teleconferencing or telephone hearing in writing and maintain the documentation in the case files.

(4) When an enrollee's request for an in-person or video-teleconferencing hearing is granted and an adjudication time frame applies in accordance with § 423.2016, the ALJ issues a decision, dismissal, or remand to the IRE within the adjudication time frame specified in § 423.2016 (including any applicable extensions provided in this subpart), unless the enrollee requesting the hearing agrees to waive such adjudication timeframe in writing.

(5) The ALJ may grant the request, with the concurrence of the Chief ALJ or designee if the request was for an in-person hearing, upon a finding of good cause and will reschedule the hearing for a time and place when the enrollee may appear in person or by video-teleconference before the ALJ. Good cause is not required for a request for video-teleconferencing hearing made by an unrepresented enrollee who filed the request for hearing and objects to an ALJ's offer to conduct a hearing by telephone.

(j) *Amended notice of hearing.* If the ALJ changes or will change the time and/or place of the hearing, an amended notice of hearing must be sent to the enrollee and CMS, the IRE, and/or the Part D plan sponsor in accordance with § 423.2022(a)(2).

[74 FR 65363, Dec. 9, 2009, as amended at 82 FR 5130, Jan. 17, 2017; 83 FR 16754, Apr. 16, 2018; 84 FR 19873, May 7, 2019]

§ 423.2022 Notice of a hearing before an ALJ.

(a) *Issuing the notice.* (1) After the ALJ sets the time and place of the hearing, the notice of the hearing will be mailed or otherwise transmitted in accordance with OMHA procedures to the enrollee and other potential participants, as provided in § 423.2020(c) at their last known addresses, or given by personal service, except to an enrollee or other potential participant who indicates in writing that he or she does not wish to receive this notice.

(2) The notice is mailed, transmitted, or served at least 20 calendar days before the hearing, except for expedited hearings where written notice is mailed, transmitted, or served at least 3 calendar days before the hearing, unless the enrollee or other potential participant agrees in writing to the notice being mailed, transmitted, or served fewer than 20 calendar days before the non-expedited hearing or 3 calendar days before the expedited hearing. For expedited hearings, the ALJ may orally provide notice of the hearing to the enrollee and other potential participants but oral notice must be followed by an equivalent written notice within 1 calendar day of the oral notice.

(b) *Notice information.* (1) The notice of hearing contains—

(i) A statement that the issues before the ALJ include all of the issues brought out in the coverage determination or at-risk determination, redetermination, or reconsideration that were not decided entirely in the enrollee's favor and that were specified in the request for hearing; and

(ii) A statement of any specific new issues the ALJ will consider in accordance with § 423.2032.

(2) The notice will inform the enrollee that he or she may designate a person to represent him or her during the proceedings.

(3) The notice must include an explanation of the procedures for requesting a change in the time or place of the hearing, a reminder that the ALJ may dismiss the hearing request if the enrollee fails to appear at the scheduled hearing without good cause, and other information about the scheduling and conduct of the hearing.

(4) The enrollee will also be told if his or her appearance or that of any other witness is scheduled by video-teleconferencing, telephone, or in person. If the ALJ has scheduled the enrollee to appear at the hearing by video-teleconferencing, the notice of hearing will advise that the scheduled place for the hearing is a video-teleconferencing site and explain what it means to appear at the hearing by video-teleconferencing.

(5) The notice advises the enrollee that if he or she objects to appearing by video-teleconferencing or telephone, and wishes instead to have his or her hearing at a time and place where he or she may appear in person before the ALJ, he or she must follow the procedures set forth at § 423.2020(i) for notifying the ALJ of his or her objections and for requesting an in-person hearing.

(c) *Acknowledging the notice of hearing.* (1) If the enrollee or his or her representative does not acknowledge receipt of the notice of hearing, OMHA attempts to contact the enrollee for an explanation.

(2) If the enrollee states that he or she did not receive the notice of hearing, a copy of the notice is sent to him or her by certified mail or other means requested by the enrollee and in accordance with OMHA procedures.

(3) The enrollee may request that the ALJ reschedule the hearing in accordance with § 423.2020(e).

[82 FR 5131, Jan. 17, 2017, as amended at 83 FR 16754, Apr. 16, 2018]

§ 423.2024 Objections to the issues.

(a) If an enrollee objects to the issues described in the notice of hearing, he or she must notify the ALJ in writing at the earliest possible opportunity before the time set for the hearing, and no later than 5 calendar days before the hearing, except for expedited hearings in which the enrollee must submit written or oral notice of objection no later than 2 calendar days before the hearing. OMHA must document all oral objections in writing and maintain the documentation in the case files.

(b) The enrollee must provide the reasons for his or her objections.

(c) The ALJ makes a decision on the objections either in writing, at a prehearing conference, or at the hearing.

[74 FR 65363, Dec. 9, 2009, as amended at 82 FR 5132, Jan. 17, 2017]

§ 423.2026 Disqualification of the ALJ or attorney adjudicator.

(a) An ALJ or attorney adjudicator may not adjudicate an appeal if he or she is prejudiced or partial to the enrollee or has any interest in the matter pending for decision.

(b) If an enrollee objects to the ALJ or attorney adjudicator assigned to adjudicate the appeal, the enrollee must notify the ALJ within 10 calendar days of the date of the notice of hearing if a non-expedited hearing is scheduled, except for expedited hearings in which the enrollee must submit written or oral notice no later than 2 calendar days after the date of the notice of hearing, or the ALJ or attorney adjudicator at any time before a decision, dismissal order, or remand order is issued if no hearing is scheduled. The ALJ or attorney adjudicator must document all oral objections in writing and maintain the documentation in the case files. The ALJ or attorney adjudicator considers the enrollee's objections and decides whether to proceed with the appeal or withdraw.

(c) If the ALJ or attorney adjudicator withdraws, another ALJ or attorney adjudicator will be assigned to adjudicate the appeal. If the ALJ or attorney adjudicator does not withdraw, the enrollee may, after the ALJ or attorney adjudicator has issued an action in the case, present his or her objections to the Council in accordance with § 423.2100 through § 423.2130. The Council will then consider whether the decision or dismissal should be revised or, if applicable, a new hearing held before another ALJ.

(d) If the enrollee objects to the ALJ or attorney adjudicator and the ALJ or attorney adjudicator subsequently withdraws from the appeal, any adjudication period that applies to the appeal in accordance with § 423.2016 is extended by 14 calendar days for a standard appeal, or 2 calendar days for an expedited appeal.

[82 FR 5132, Jan. 17, 2017]

§ 423.2030 ALJ hearing procedures.

(a) *General rule.* A hearing is open to the enrollee and to other persons the ALJ considers necessary and proper.

(b) *At the hearing.* (1) The ALJ fully examines the issues, questions the enrollee and other witnesses, and may accept evidence that is material to the issues consistent with § 423.2018.

(2) The ALJ may limit testimony and argument at the hearing that are not relevant to an issue before the ALJ, that are repetitive of evidence or testimony already in the record, or that relate to an issue that has been sufficiently developed or on which the ALJ has already ruled. The ALJ may, but is not required to, provide the enrollee or representative with an opportunity to submit additional written statements and affidavits on the matter in lieu of testimony and/or argument at the hearing. The written statements and affidavits must be submitted within the time frame designated by the ALJ.

(3) If the ALJ determines that the enrollee or enrollee's representative is uncooperative, disruptive to the hearing, or abusive during the course of the hearing after the ALJ has warned the enrollee or representative to stop such behavior, the ALJ may excuse the enrollee or representative from the hearing and continue with the hearing to provide the participants with an opportunity to offer testimony and/or argument. If an enrollee or representative was excused from the hearing, the ALJ will provide the enrollee or representative with an opportunity to submit written statements and affidavits in lieu of testimony and/or argument at the hearing, and the enrollee or representative may request a recording of the hearing in accordance with § 423.2042 and respond in writing to any statements made by participants and/or testimony of the witnesses at the hearing. The written statements and affidavits must be submitted within the time frame designated by the ALJ.

(c) *Missing evidence.* The ALJ may also stop the hearing temporarily and continue it at a later date if he or she believes that there is material evidence missing at the hearing.

(d) *Effect of new evidence on adjudication period.* If an enrollee, other than an unrepresented enrollee in a standard appeal, submits evidence pursuant to paragraph (b) or (c) of this section, and an adjudication period applies to the appeal, the adjudication period specified in § 423.2016 is extended in accordance with § 423.2018(b) or (c), as applicable.

(e) *Continued hearing.* (1) A hearing may be continued to a later date. Notice of the continued hearing must be sent in accordance with § 423.2022, except that a waiver of notice of the hearing may be made in writing or on the record, and the notice is sent to the enrollee and participants who attended the hearing, and any additional potential participants the ALJ determines are appropriate.

(2) If the enrollee requests the continuance and an adjudication time frame applies to the appeal in accordance with § 423.2016, the adjudication period is extended by the period between the initial hearing date and the continued hearing date.

(f) *Supplemental hearing.* (1) The ALJ may conduct a supplemental hearing at any time before he or she mails a notice of the decision in order to receive new and material evidence, obtain additional testimony, or address a procedural matter. The ALJ determines whether a supplemental hearing is necessary and if one is held, the scope of the hearing, including when evidence is presented and what issues are discussed. Notice of the supplemental hearing must be sent in accordance with § 423.2022, except that the notice is sent to the enrollee and participants who attended the hearing, and any additional potential participants the ALJ determines are appropriate.

(2) If the enrollee requests the supplemental hearing and an adjudication period applies to the appeal in accordance with § 423.2016, the adjudication period is extended by the period between the initial hearing date and the supplemental hearing date.

[82 FR 5132, Jan. 17, 2017]

§ 423.2032 Issues before an ALJ or attorney adjudicator.

(a) *General rule.* The issues before the ALJ or attorney adjudicator include all the issues for the appealed matter specified in the request for hearing that were brought out in the coverage

determination or at-risk determination, redetermination, or reconsideration that were not decided entirely in an enrollee's favor.

(b) *New issues*—(1) *When a new issue may be considered.* A new issue may include issues resulting from the participation of CMS, the IRE, or the Part D plan sponsor at the OMHA level of adjudication and from any evidence and position papers submitted by CMS, the IRE, or the Part D plan sponsor for the first time to the ALJ. The ALJ or the enrollee may raise a new issue; however, the ALJ may only consider a new issue relating to a determination or appealed matter specified in the request for hearing, including a favorable portion of a determination or appealed matter specified in the request for hearing, if its resolution could have a material impact on the appealed matter and—

(i) There is new and material evidence that was not available or known at the time of the determination and that may result in a different conclusion; or

(ii) The evidence that was considered in making the determination clearly shows on its face that an obvious error was made at the time of the determination.

(2) *Notice of the new issue.* The ALJ may consider a new issue at the hearing if he or she notifies the enrollee about the new issue before the start of the hearing.

(3) *Opportunity to submit evidence.* If notice of the new issue is sent after the notice of hearing, the enrollee will have at least 10 calendar days in standard appeals or 2 calendar days in expedited appeals after receiving notice of the new issue to submit evidence regarding the issue, and without affecting any applicable adjudication period. If a hearing is conducted before the time to submit evidence regarding the issue expires, the record will remain open until the opportunity to submit evidence expires.

(c) *Adding coverage determinations to a pending appeal.* A coverage determination on a drug that was not specified in a request for hearing may only be added to a pending appeal if the coverage determination was adjudicated in the same reconsideration that is appealed, and the period to request an ALJ hearing for that reconsideration has not expired, or an ALJ or attorney adjudicator extends the time to request an ALJ hearing on the reconsideration in accordance with § 423.2014(e).

[82 FR 5132, Jan. 17, 2017, as amended at 83 FR 16754, Apr. 16, 2018; 84 FR 19873, May 7, 2019]

§ 423.2034 Requesting information from the IRE.

(a) If an ALJ or attorney adjudicator believes that the written record is missing information that is essential to resolving the issues on appeal and that information can be provided only by CMS, the IRE, and/or the Part D plan sponsor, the information may be requested from the IRE that conducted the reconsideration or its successor.

(1) Official copies of redeterminations and reconsiderations that were conducted on the appealed issues, and official copies of dismissals of a request for redetermination or reconsideration, can be provided only by CMS, the IRE, and/or the Part D plan sponsor. Prior to issuing a request for information to the IRE, OMHA will confirm whether an electronic copy of the missing redetermination, reconsideration, or dismissal is available in the official system of record, and if so will accept the electronic copy as an official copy.

(2) ''Can be provided only by CMS, the IRE, and/or the Part D plan sponsor'' means the information is not publicly available, is not in the possession of the enrollee, and cannot be requested and obtained by the enrollee. Information that is publicly available is information that is available to the general public via the Internet or in a printed publication. Information that is publicly available includes, but is not limited to, information available on a CMS, IRE or Part D Plan sponsor Web site or information in an official CMS or HHS publication.

(b) The ALJ or attorney adjudicator retains jurisdiction of the case, and the case remains pending at OMHA.

(c) The IRE has 15 calendar days for standard appeals, or 2 calendar days for expedited appeals, after receiving the request for information to furnish the information or otherwise respond to the information request directly or

through CMS or the Part D plan sponsor.

(d) If an adjudication period applies to the appeal in accordance with § 423.2016, the adjudication period is extended by the period between the date of the request for information and the date the IRE responds to the request or 20 calendar days after the date of the request for standard appeals, or 3 calendar days after the date of the request for expedited appeals, whichever occurs first.

[82 FR 5133, Jan. 17, 2017, as amended at 84 FR 19873, May 7, 2019]

§ 423.2036 Description of an ALJ hearing process.

(a) *The right to appear and present evidence.* (1) An enrollee has the right to appear at the hearing before the ALJ to present evidence and to state his or her position. An enrollee may appear by video-teleconferencing, telephone, or in person as determined under § 423.2020.

(2) An enrollee may also make his or her appearance by means of a representative, who may make his or her appearance by video-teleconferencing, telephone, or in person, as determined under § 423.2020.

(3) Witness testimony may be given and CMS, IRE, and Part D plan sponsor participation may also be accomplished by video-teleconferencing, telephone, or in person, as determined under § 423.2020.

(b) *Waiver of the right to appear.* (1) An enrollee may submit to OMHA a written statement indicating that he or she does not wish to appear at the hearing.

(i) For expedited hearings, an enrollee may indicate in writing or orally that he or she does not wish to appear at the hearing.

(ii) The OMHA hearing office must document all oral waivers in writing and maintain the documentation in the case files.

(2) The enrollee may subsequently withdraw his or her waiver in writing at any time before the notice of the hearing decision is issued; however, by withdrawing the waiver the enrollee agrees to an extension of the adjudication period as specified in § 423.2016, that may be necessary to schedule and hold the hearing.

(3) Even if the enrollee waives his or her right to appear at a hearing, the ALJ may require him or her to attend an oral hearing if the ALJ believes that a personal appearance and testimony by the enrollee is necessary to decide the case.

(c) *Presenting written statements and oral arguments.* An enrollee or an enrollee's representative, as defined at § 423.560, may appear before the ALJ to state the enrollee's case, to present a written summary of the case, or to enter written statements about the facts and law material to the case in the record.

(d) *Witnesses at a hearing.* Witnesses may appear at a hearing. They testify under oath or affirmation, unless the ALJ finds an important reason to excuse them from taking an oath or affirmation. The ALJ may ask the witnesses any questions relevant to the issues and allow the enrollee or his or her representative, as defined at § 423.560, to do so.

(e) *What evidence is admissible at a hearing.* The ALJ may receive evidence at the hearing even though the evidence is not admissible in court under the rules of evidence used by the court. However, the ALJ may not consider evidence on any change in condition of an enrollee after a coverage determination or at-risk determination. If the enrollee wishes for the evidence to be considered, the ALJ must remand the case to the Part D IRE as set forth in § 423.2056(e).

(f)(1) *Subpoenas.* When it is reasonably necessary for the full presentation of a case, an ALJ may, on his or her own initiative, issue subpoenas for the appearance and testimony of witnesses and for the enrollee and/or the Part D plan sponsor to make books, records, correspondence, papers, or other documents that are material to an issue at the hearing available for inspection and copying. An ALJ may not issue a subpoena to CMS, or the IRE to compel an appearance, testimony, or the production of evidence, or to the Part D plan sponsor to compel an appearance or testimony.

(2) *Reviewability of an ALJ Subpoena.* A subpoena issued by an ALJ is not subject to immediate review by the Council. The subpoena may be reviewed

solely during the Council's review specified in § 423.2102 and § 423.2110.

(3) *Exception.* To the extent a subpoena compels disclosure of a matter which an objection based on privilege, or other protection from disclosure such as case preparation, confidentiality, or undue burden, was made before an ALJ, the Council may review immediately the ruling of the ALJ on the objections to the subpoena or that portion of the subpoena as applicable.

(i) Upon notice to the ALJ that the enrollee or a non-party, as applicable, intends to seek Council review of the ALJ's ruling on the subpoena, the ALJ must stay all proceedings affected by the subpoena.

(ii) The proceedings are stayed for 15 calendar days or until the Council issues a written decision that affirms, reverses, or modifies the ALJ's subpoena, whichever comes first.

(iii) If the Council does not take action within the 15 calendar days, then the stay is lifted and the enrollee or non-party must comply with the ALJ's subpoena.

(4) *Enforcement.* (i) If the ALJ determines that an enrollee or person other than the enrollee subject to a subpoena issued under this section has refused to comply with the subpoena, the ALJ may request that the Secretary seek enforcement of the subpoena in accordance with section 205(e) of the Act, 42 U.S.C. 405(e).

(ii) After submitting the enforcement request, the time period for the ALJ to issue a decision, dismissal or remand a case in response to a request for hearing is stayed for 15 calendar days or until the Secretary makes a decision with respect to the enforcement request, whichever occurs first.

(iii) Any enforcement request by an ALJ must consist of a written notice to the Secretary describing in detail the ALJ's findings of noncompliance and his or her specific request for enforcement, and providing a copy of the subpoena and evidence of its receipt by certified mail by the enrollee or person other than the enrollee subject to the subpoena.

(iv) The ALJ must promptly mail a copy of the notice and related documents to the individual or entity subject to the subpoena, to the enrollee, and to any other affected person.

[74 FR 65363, Dec. 9, 2009, as amended at 82 FR 5133, Jan. 17, 2017; 83 FR 16754, Apr. 16, 2018; 84 FR 19873, May 7, 2019; 86 FR 6121, Jan. 19, 2021]

§ 423.2038 Deciding a case without a hearing before an ALJ.

(a) *Decision fully favorable.* If the evidence in the administrative record supports a finding fully in favor of the enrollee(s) on every issue, the ALJ or attorney adjudicator may issue a decision without giving the enrollee(s) prior notice and without an ALJ conducting a hearing. The notice of the decision informs the enrollee(s) that he or she has the right to a hearing and a right to examine the evidence on which the decision is based.

(b) *Enrollee does not wish to appear.* (1) The ALJ or attorney adjudicator may decide a case on the record and without an ALJ conducting a hearing if—

(i) The enrollee indicates in writing or, for expedited hearings orally or in writing, that he or she does not wish to appear before an ALJ at a hearing, including a hearing conducted by telephone or video-teleconferencing, if available. OMHA must document all oral requests not to appear at a hearing in writing and maintain the documentation in the case files; or

(ii) The enrollee lives outside the United States and does not inform OMHA that he or she wants to appear at a hearing before an ALJ.

(2) When a hearing is not held, the decision of the ALJ or attorney adjudicator must refer to the evidence in the record on which the decision was based.

(c) *Stipulated decision.* If CMS, the IRE, and/or the Part D plan sponsor submits a written statement or makes an oral statement at a hearing indicating the drug should be covered or payment may be made, or an enrollee's at-risk determination should be reversed, and the written or oral statement agrees to the amount of payment the parties believe should be made if the amount of payment is an issue before the ALJ or attorney adjudicator, an ALJ or attorney adjudicator may issue a stipulated decision finding in favor of the enrollee on the basis of the

statement, and without making findings of fact, conclusions of law, or further explaining the reasons for the decision.

[82 FR 5133, Jan. 17, 2017, as amended at 83 FR 16754, Apr. 16, 2018]

§ 423.2040 Prehearing and posthearing conferences.

(a) The ALJ may decide on his or her own, or at the request of the enrollee to the hearing, to hold a prehearing or posthearing conference to facilitate the hearing or the hearing decision.

(b) For non-expedited hearings, the ALJ informs the enrollee, and CMS, the IRE, and/or the Part D plan sponsor if the ALJ has granted their request(s) to be a participant to the hearing at the time the notice of conference is sent, of the time, place, and purpose of the conference at least 7 calendar days before the conference date, unless the enrollee indicates in writing that he or she does not wish to receive a written notice of the conference.

(c) For expedited hearings, the ALJ informs the enrollee, and CMS, the IRE, and/or the Part D plan sponsor if the ALJ has granted their request(s) to be a participant to the hearing, of the time, place, and purpose of the conference at least 2 calendar days before the conference date, unless the enrollee indicates orally or in writing that he or she does not wish to receive a written notice of the conference.

(d) All oral requests not to receive written notice of the conference must be documented in writing and the documentation must be made part of the administrative record.

(e) At the conference—

(1) The ALJ or an OMHA attorney designated by the ALJ conducts the conference, but only the ALJ conducting a conference may consider matters in addition to those stated in the conference notice, if the enrollee consents to consideration of the additional matters in writing.

(2) An audio recording of the conference is made.

(f) The ALJ issues an order to the enrollee and all participants who attended the conference stating all agreements and actions resulting from the conference. If the enrollee does not object within 10 calendar days of receiving the order for non-expedited hearings or 1 calendar day for expedited hearings, or any additional time granted by the ALJ, the agreements and actions become part of the administrative record and are binding on the enrollee.

[82 FR 5133, Jan. 17, 2017]

§ 423.2042 The administrative record.

(a) *Creating the record.* (1) OMHA makes a complete record of the evidence and administrative proceedings on the appealed matter, including any prehearing and posthearing conference and hearing proceedings that were conducted.

(2) The record will include marked as exhibits, the appealed determinations and documents and other evidence used in making the appealed determinations and the ALJ's or attorney adjudicator's decision, including, but not limited to, medical records, written statements, certificates, reports, affidavits, and any other evidence the ALJ or attorney adjudicator admits. The record will also include any evidence excluded or not considered by the ALJ or attorney adjudicator, including but not limited to duplicative evidence submitted by the enrollee.

(3) An enrollee may request and receive a copy of the record prior to or at the hearing, or, if a hearing is not held, at any time before the notice of decision is issued.

(4) If a request for review is filed, the complete record, including any prehearing and posthearing conference and hearing recordings, is forwarded to the Council.

(5) A typed transcription of the hearing is prepared if an enrollee seeks judicial review of the case in a Federal district court within the stated time period and all other jurisdictional criteria are met, unless, upon the Secretary's motion prior to the filing of an answer, the court remands the case.

(b) *Requesting and receiving copies of the record.* (1) While an appeal is pending at OMHA, an enrollee may request and receive a copy of all or part of the record from OMHA, including any index of the administrative record, documentary evidence, and a copy of

the audio recording of the oral proceedings. The enrollee may be asked to pay the costs of providing these items.

(2) If an enrollee requests a copy of all or part of the record from OMHA or the ALJ or attorney adjudicator and an opportunity to comment on the record, any adjudication period that applies in accordance with § 423.2016 is extended by the time beginning with the receipt of the request through the expiration of the time granted for the enrollee's response.

(3) If the enrollee requests a copy of all or part of the record and the record, including any audio recordings, contains information pertaining to an individual that the enrollee is not entitled to receive, such as personally identifiable information or protected health information, such portions of the record will not be furnished unless the enrollee obtains consent from the individual.

[82 FR 5134, Jan. 17, 2017]

§ 423.2044 Consolidated proceedings.

(a) *Consolidated hearing.* (1) A consolidated hearing may be held if one or more of the issues to be considered at the hearing are the same issues that are involved in one or more other appeals pending before the same ALJ.

(2) It is within the discretion of the ALJ to grant or deny an enrollee's request for consolidation. In considering an enrollee's request, the ALJ may consider factors such as whether the issue(s) may be more efficiently decided if the appeals are consolidated for hearing. In considering the enrollee's request for consolidation, the ALJ must take into account any adjudication deadlines for each appeal and may require an enrollee to waive the adjudication deadline associated with one or more appeals if consolidation otherwise prevents the ALJ from deciding all of the appeals at issue within their respective deadlines.

(3) The ALJ may also propose on his or her own motion to consolidate two or more appeals in one hearing for administrative efficiency, but may not require an enrollee to waive the adjudication deadline for any of the consolidated cases.

(4) Notice of a consolidated hearing must be included in the notice of hearing issued in accordance with §§ 423.2020 and 423.2022.

(b) *Consolidated decision and record.* (1) If the ALJ decides to hold a consolidated hearing, he or she may make either—

(i) A consolidated decision and record; or

(ii) A separate decision and record on each appeal.

(2) If a separate decision and record on each appeal is made, the ALJ is responsible for making sure that any evidence that is common to all appeals and material to the common issue to be decided, and audio recordings of any conferences that were conducted and the consolidated hearing are included in each individual administrative record, as applicable.

(3) If a hearing will not be conducted for multiple appeals that are before the same ALJ or attorney adjudicator, and the appeals involve one or more of the same issues, the ALJ or attorney adjudicator may make a consolidated decision and record at the request of the enrollee or on the ALJ's or attorney adjudicator's own motion.

(c) *Limitation on consolidated proceedings.* Consolidated proceedings may only be conducted for appeals filed by the same enrollee, unless multiple enrollees aggregated appeals to meet the amount in controversy requirement in accordance with § 423.2006 and the enrollees have all authorized disclosure of information to the other enrollees.

[82 FR 5134, Jan. 17, 2017, as amended at 84 FR 19873, May 7, 2019]

§ 423.2046 Notice of an ALJ or attorney adjudicator decision.

(a) *Decisions on requests for hearing—* (1) *General rule.* Unless the ALJ or attorney adjudicator dismisses or remands the request for hearing, the ALJ or attorney adjudicator will issue a written decision that gives the findings of fact, conclusions of law, and the reasons for the decision.

(i) The decision must be based on evidence offered at the hearing or otherwise admitted into the record, and shall include independent findings and conclusions.

(ii) A copy of the decision should be mailed or otherwise transmitted to the

enrollee at his or her last known address.

(iii) A copy of the written decision should also be provided to the IRE that issued the reconsideration determination, and to the Part D plan sponsor that issued the coverage determination or at-risk determination.

(2) *Content of the notice.* The decision must be provided in a manner calculated to be understood by an enrollee and must include—

(i) The specific reasons for the determination, including, to the extent appropriate, a summary of any clinical or scientific evidence used in making the determination;

(ii) The procedures for obtaining additional information concerning the decision; and

(iii) Notification of the right to appeal the decision to the Council, including instructions on how to initiate an appeal under this section.

(3) *Limitation on decision.* When the amount of payment for the Part D drug is an issue before the ALJ or attorney adjudicator, the ALJ or attorney adjudicator may make a finding as to the amount of payment due. If the ALJ or attorney adjudicator makes a finding concerning payment when the amount of payment was not an issue before the ALJ or attorney adjudicator, the Part D plan sponsor may independently determine the payment amount. In either of the aforementioned situations, an ALJ's or attorney adjudicator's decision is not binding on the Part D plan sponsor for purposes of determining the amount of payment due. The amount of payment determined by the Part D plan sponsor in effectuating the ALJ's or attorney adjudicator's decision is a new coverage determination under § 423.566.

(b) *Decisions on requests for review of an IRE dismissal*—(1) *General rule.* Unless the ALJ or attorney adjudicator dismisses the request for review of an IRE dismissal, or the dismissal is vacated and remanded, the ALJ or attorney adjudicator will issue a written decision affirming the IRE's dismissal. OMHA mails or otherwise transmits a copy of the decision to the enrollee.

(2) *Content of the notice.* The decision must be written in a manner calculated to be understood by an enrollee and must include—

(i) The specific reasons for the determination, including a summary of the evidence considered and applicable authorities;

(ii) The procedures for obtaining additional information concerning the decision; and

(iii) Notification that the decision is binding and is not subject to further review, unless reopened and revised by the ALJ or attorney adjudicator.

(c) *Recommended decision.* An ALJ or attorney adjudicator issues a recommended decision if he or she is directed to do so in the Council's remand order. An ALJ or attorney adjudicator may not issue a recommended decision on his or her own motion. The ALJ or attorney adjudicator mails a copy of the recommended decision to the enrollee at his or her last known address.

[82 FR 5134, Jan. 17, 2017, as amended at 83 FR 16754, Apr. 16, 2018]

§ 423.2048 The effect of an ALJ's or attorney adjudicator's decision.

(a) The decision of the ALJ or attorney adjudicator on a request for hearing is binding unless—

(1) An enrollee requests a review of the decision by the Council within the stated time period or the Council reviews the decision issued by an ALJ or attorney adjudicator under the procedures set forth in § 423.2110, and the Council issues a final decision or remand order;

(2) The decision is reopened and revised by an ALJ or attorney adjudicator or the Council under the procedures explained in § 423.1980;

(3) The expedited access to judicial review process at § 423.1990 is used;

(4) The ALJ's or attorney adjudicator's decision is a recommended decision directed to the Council and the Council issues a decision; or

(5) In a case remanded by a Federal district court, the Council assumes jurisdiction under the procedures in § 423.2138 and the Council issues a decision.

(b) The decision of the ALJ or attorney adjudicator on a request for review of an IRE dismissal is binding on the enrollee unless the decision is reopened

and revised by the ALJ or attorney adjudicator under the procedures explained in § 423.1980.

[82 FR 5135, Jan. 17, 2017]

§ 423.2050 Removal of a hearing request from OMHA to the Council.

If a request for hearing is pending before OMHA, the Council may assume responsibility for holding a hearing by requesting that OMHA send the hearing request. If the Council holds a hearing, it conducts the hearing according to the rules for hearings before an ALJ. Notice is mailed to the enrollee at his or her last known address informing him or her that the Council has assumed responsibility for the case.

[74 FR 65363, Dec. 9, 2009, as amended at 82 FR 5135, Jan. 17, 2017]

§ 423.2052 Dismissal of a request for a hearing before an ALJ or request for review of an IRE dismissal.

(a) *Dismissal of request for hearing.* An ALJ dismisses a request for a hearing under any of the following conditions:

(1) Neither the enrollee that requested the hearing nor the enrollee's representative appears at the time and place set for the hearing, if—

(i) The enrollee was notified before the time set for the hearing that the request for hearing might be dismissed for failure to appear, the record contains documentation that the enrollee acknowledged the notice of hearing, and the enrollee does not contact the ALJ within 10 calendar days after the hearing for non-expedited hearings and 2 calendar days after the hearing for expedited hearings, or does contact the ALJ but the ALJ determines the enrollee did not demonstrate good cause for not appearing; or

(ii) The record does not contain documentation that the enrollee acknowledged the notice of hearing, the ALJ sends a notice to the enrollee at his or her last known address asking why the enrollee did not appear, and the enrollee does not respond to the ALJ's notice within 10 calendar days for non-expedited hearings or within 2 calendar days for expedited hearings after receiving the notice, or does contact the ALJ but the ALJ determines the enrollee did not demonstrate good cause for not appearing. For expedited hearings, an enrollee may submit his or her response orally to the ALJ.

(iii) In determining whether good cause exists under paragraphs (a)(1)(i) and (ii) of this section, the ALJ considers any physical, mental, educational, or linguistic limitations (including any lack of facility with the English language) the enrollee may have.

(2) The person requesting a hearing has no right to it under § 423.2002.

(3) The enrollee did not request a hearing within the stated time period and the ALJ has not found good cause for extending the deadline, as provided in § 423.2014(e).

(4) The enrollee died while the request for hearing is pending and the request for hearing was filed by the enrollee or the enrollee's representative, and the enrollee's surviving spouse or estate has no remaining financial interest in the case and the enrollee's representative, if any, does not wish to continue the appeal.

(5) The ALJ dismisses a hearing request entirely or refuses to consider any one or more of the issues because an IRE, an ALJ or attorney adjudicator, or the Council has made a previous determination or decision under this subpart about the enrollee's rights on the same facts and on the same issue(s), and this previous determination or decision has become binding by either administrative or judicial action.

(6) The enrollee abandons the request for hearing. An ALJ may conclude that an enrollee has abandoned a request for hearing when OMHA attempts to schedule a hearing and is unable to contact the enrollee after making reasonable efforts to do so.

(7) The enrollee's request is not complete in accordance with § 423.2014(a)(1), even after the enrollee is provided with an opportunity to complete the request.

(b) *Dismissal of request for review of IRE dismissal.* An ALJ or attorney adjudicator dismisses a request for review of an IRE dismissal under any of the following conditions:

(1) The enrollee has no right to a review of the IRE dismissal under § 423.2004.

(2) The enrollee did not request a review within the stated time period and the ALJ or attorney adjudicator has not found good cause for extending the deadline, as provided in § 423.2014(e).

(3) The enrollee died while the request for review was pending and the request was filed by the enrollee or the enrollee's representative, and the enrollee's surviving spouse or estate has no remaining financial interest in the case and the enrollee's representative, if any, does not wish to continue the appeal.

(4) The enrollee's request is not complete in accordance with § 423.2014(a)(1), even after the enrollee is provided with an opportunity to complete the request.

(c) *Withdrawal of request.* At any time before notice of the decision, dismissal, or remand is mailed, if the enrollee asks to withdraw the request, an ALJ or attorney adjudicator may dismiss the request for hearing or request for review of an IRE dismissal. This request for withdrawal may be submitted in writing, or a request to withdraw a request for hearing may be made orally at a hearing before the ALJ. The request for withdrawal must include a clear statement that the enrollee is withdrawing the request for hearing or review of the IRE dismissal and does not intend to further proceed with the appeal. If an attorney or other legal professional on behalf of an enrollee files the request for withdrawal, the ALJ or attorney adjudicator may presume that the representative has advised the enrollee of the consequences of the withdrawal and dismissal.

(d) *Notice of dismissal.* OMHA mails or otherwise transmits a written notice of the dismissal of the hearing or review request to the enrollee at his or her last known address. The written notice provides that there is a right to request that the ALJ or attorney adjudicator vacate the dismissal action.

(e) *Vacating a dismissal.* If good and sufficient cause is established, the ALJ or attorney adjudicator may vacate his or her dismissal of a request for hearing or review within 180 calendar days of the date of the notice of dismissal.

[82 FR 5135, Jan. 17, 2017, as amended at 84 FR 19873, May 7, 2019]

§ 423.2054 Effect of dismissal of a request for a hearing or request for review of an IRE's dismissal.

(a) The dismissal of a request for a hearing is binding, unless it is vacated by the Council under § 423.2108(b), or vacated by the ALJ or attorney adjudicator under § 423.2052(e).

(b) The dismissal of a request for review of an IRE dismissal of a request for reconsideration is binding and not subject to further review unless vacated by the ALJ or attorney adjudicator under § 423.2052(e).

[82 FR 5136, Jan. 17, 2017]

§ 423.2056 Remands of requests for hearing and requests for review.

(a) *Missing appeal determination or case record.* (1) If an ALJ or attorney adjudicator requests an official copy of a missing redetermination or reconsideration for an appealed coverage determination or at-risk determination in accordance with § 423.2034, and the IRE, CMS, or Part D plan sponsor does not furnish the copy within the time frame specified in § 423.2034, an ALJ or attorney adjudicator may issue a remand directing the IRE or Part D plan sponsor to reconstruct the record or, if it is not able to do so, initiate a new appeal adjudication.

(2) If the IRE does not furnish the case file for an appealed reconsideration, an ALJ or attorney adjudicator may issue a remand directing the IRE to reconstruct the record or, if it is not able to do so, initiate a new appeal adjudication.

(3) If the IRE or Part D plan sponsor is able to reconstruct the record for a remanded case and returns the case to OMHA, the case is no longer remanded and the reconsideration is no longer vacated, and any adjudication period that applies to the appeal in accordance with § 423.2016 is extended by the period between the date of the remand and the date that case is returned to OMHA.

(b) *No redetermination.* If an ALJ or attorney adjudicator finds that the IRE issued a reconsideration and no redetermination was made with respect to the issue under appeal or the request for redetermination was dismissed, the reconsideration will be remanded to

the IRE, or its successor, to readjudicate the request for reconsideration, unless the request for redetermination was forwarded to the IRE in accordance with § 423.590(c) or (e) without a redetermination having been conducted.

(c) *Requested remand*—(1) *Request contents and timing.* At any time prior to an ALJ or attorney adjudicator issuing a decision or dismissal, the enrollee and CMS, the IRE, or the Part D plan sponsor may jointly request a remand of the appeal to the IRE. The request must include the reasons why the appeal should be remanded, and indicate whether remanding the case will likely resolve the matter in dispute.

(2) *Granting the request.* An ALJ or attorney adjudicator may grant the request and issue a remand if he or she determines that remanding the case will likely resolve the matter in dispute.

(d) *Remanding an IRE's dismissal of a request for reconsideration.* (1) Consistent with § 423.2004(b), an ALJ or attorney adjudicator will remand a case to the appropriate IRE if the ALJ or attorney adjudicator determines that an IRE's dismissal of a request for reconsideration was in error.

(2) If an official copy of the notice of dismissal or case file cannot be obtained from the IRE, an ALJ or attorney adjudicator may also remand a request for review of a dismissal in accordance with the procedures in paragraph (a) of this section.

(e) *Consideration of change in condition.* The ALJ or attorney adjudicator will remand a case to the appropriate IRE if the ALJ or attorney adjudicator determines that the enrollee wants evidence on his or her change in condition after the coverage determination or at-risk determination to be considered in the appeal.

(f) *Notice of a remand.* OMHA mails or otherwise transmits a written notice of the remand of the request for hearing or request for review to the enrollee at his or her last known address, and CMS, the IRE, and/or the Part D plan sponsor if a request to be a participant was granted by the ALJ or attorney adjudicator. The notice states that there is a right to request that the Chief ALJ or a designee review the remand, unless the remand was issued under paragraph (d)(1) of this section.

(g) *Review of remand.* Upon a request by the enrollee or CMS, the IRE, or the Part D plan sponsor filed within 30 calendar days of receiving a notice of remand, the Chief ALJ or designee will review the remand, and if the remand is not authorized by this section, vacate the remand order. The determination on a request to review a remand order is binding and not subject to further review. The review of remand procedures provided for in this paragraph (g) are not available for and do not apply to remands that are issued in paragraph (d)(1) of this section.

[82 FR 5136, Jan. 17, 2017, as amended at 83 FR 16754, Apr. 16, 2018; 84 FR 19873, May 7, 2019]

§ 423.2058 Effect of a remand.

A remand of a request for hearing or request for review is binding unless vacated by the Chief ALJ or a designee in accordance with § 423.2056(g).

[82 FR 5137, Jan. 17, 2017]

§ 423.2062 Applicability of policies not binding on the ALJ and Council.

(a) ALJs or attorney adjudicators and the Council are not bound by CMS program guidance, such as program memoranda and manual instructions, but will give substantial deference to these policies if they are applicable to a particular case.

(b) If an ALJ or attorney adjudicator or Council declines to follow a policy in a particular case, the ALJ or attorney adjudicator or Council decision must explain the reasons why the policy was not followed. An ALJ or attorney adjudicator or Council decision to disregard a policy applies only to the specific coverage determination or at-risk determination being considered and does not have precedential effect.

[74 FR 65363, Dec. 9, 2009, as amended at 82 FR 5137, Jan. 17, 2017; 83 FR 16754, Apr. 16, 2018]

§ 423.2063 Applicability of laws, regulations, CMS Rulings, and precedential decisions.

(a) All laws and regulations pertaining to the Medicare program, including, but not limited to Titles XI,

XVIII, and XIX of the Social Security Act and applicable implementing regulations, are binding on ALJs and attorney adjudicators, and the Council.

(b) CMS Rulings are published under the authority of the CMS Administrator. Consistent with § 401.108 of this chapter, rulings are binding on all CMS components, and on all HHS components that adjudicate matters under the jurisdiction of CMS.

(c) Precedential decisions designated by the Chair of the Departmental Appeals Board in accordance with § 401.109 of this chapter are binding on all CMS components, and all HHS components that adjudicate matters under the jurisdiction of CMS.

[82 FR 5137, Jan. 17, 2017]

§ 423.2100 Medicare Appeals Council review: general.

(a) An enrollee who is dissatisfied with an ALJ's or attorney adjudicator's decision or dismissal may request that the Council review the ALJ's or attorney adjudicator's decision or dismissal.

(b) When the Council reviews an ALJ's or attorney adjudicator's written decision, it undertakes a de novo review.

(c) The Council issues a final decision, dismissal order, or remands a case to the ALJ or attorney adjudicator no later than the end of the 90 calendar day period beginning on the date the request for review is received (by the entity specified in the ALJ's or attorney adjudicator's written notice of decision), unless the 90 calendar day period is extended as provided in this subpart or the enrollee requests expedited Council review.

(d) If an enrollee requests expedited Council review, the Council issues a final decision, dismissal order or remand as expeditiously as the enrollee's health condition requires, but no later than the end of the 10 calendar day period beginning on the date the request for review is received (by the entity specified in the ALJ's or attorney adjudicator's written notice of decision), unless the 10 calendar day period is extended as provided in this subpart.

[82 FR 5137, Jan. 17, 2017, as amended at 84 FR 19874, May 7, 2019]

§ 423.2102 Request for Council review when ALJ or attorney adjudicator issues decision or dismissal.

(a)(1) An enrollee may request Council review of a decision or dismissal issued by an ALJ or attorney adjudicator if the enrollee files a written request for a Council review within 60 calendar days after receipt of the ALJ's or attorney adjudicator's written decision or dismissal.

(2) An enrollee may request that Council review be expedited if the appeal involves an issue specified in § 423.566(b) but does not include solely a request for payment of Part D drugs already furnished.

(i) If an enrollee is requesting that the Council review be expedited, the enrollee submits an oral or written request within 60 calendar days after the receipt of the ALJ's or attorney adjudicator's written decision or dismissal. A prescribing physician or other prescriber may provide oral or written support for an enrollee's request for expedited review.

(ii) The Council must document all oral requests for expedited review in writing and maintain the documentation in the case files.

(3) For purposes of this section, the date of receipt of the ALJ's or attorney adjudicator's written decision or dismissal is presumed to be 5 calendar days after the date of the notice of the decision or dismissal, unless there is evidence to the contrary.

(4) The request is considered as filed on the date it is received by the entity specified in the notice of the ALJ's or attorney adjudicator's action.

(b) An enrollee requesting a review may ask that the time for filing a request for Council review be extended if—

(1) The request for an extension of time is in writing or, for expedited reviews, in writing or oral. The Council must document all oral requests in writing and maintain the documentation in the case file.

(2) The request explains why the request for review was not filed within the stated time period. If the Council finds that there is good cause for missing the deadline, the time period will be extended. To determine whether good cause exists, the Council uses the

standards outlined at § 405.942(b)(2) and (3) of this chapter.

(c) An enrollee does not have the right to seek Council review of an ALJ's or attorney adjudicator's remand to an IRE, or an ALJ's or attorney adjudicator's affirmation of an IRE's dismissal of a request for reconsideration, or dismissal of a request to review an IRE dismissal.

[82 FR 5137, Jan. 17, 2017]

§ 423.2106 Where a request for review may be filed.

When a request for a Council review is filed after an ALJ or attorney adjudicator has issued a written decision or dismissal, the request for review must be submitted to the entity specified in the notice of the ALJ's or attorney adjudicator's action. If the request for review is timely filed with an entity other than the entity specified in the notice of the ALJ's or attorney adjudicator's action, the Council's adjudication period to conduct a review begins on the date the request for review is received by the entity specified in the notice of the ALJ's or attorney adjudicator's action. Upon receipt of a request for review from an entity other than the entity specified in the notice of the ALJ's or attorney adjudicator's action, the Council sends written notice to the enrollee of the date of receipt of the request and commencement of the adjudication timeframe.

[74 FR 65363, Dec. 9, 2009, as amended at 82 FR 5137, Jan. 17, 2017]

§ 423.2108 Council Actions when request for review is filed.

(a) *General.* Except as specified in paragraph (c) of this section, when an enrollee requests that the Council review an ALJ's or attorney adjudicator's decision, the Council will review the ALJ's or attorney adjudicator's decision de novo. The enrollee requesting review does not have a right to a hearing before the Council. The Council will consider all of the evidence admitted into the administrative record. Upon completion of its review, the Council may adopt, modify, or reverse the ALJ's or attorney adjudicator's decision or remand the case to the ALJ or attorney adjudicator for further proceedings. Unless the Council's review is expedited as provided in paragraph (d) of this section, the Council must issue its action no later than 90 calendar days after receiving the request for review, unless the 90 calendar day period has been extended as provided in this subpart.

(b) *Review of ALJ's or attorney adjudicator's dismissal of a request for a hearing.* When an enrollee requests that the Council review an ALJ's or attorney adjudicator's dismissal of a request for a hearing, the Council may deny review or vacate the dismissal and remand the case to the ALJ or attorney adjudicator for further proceedings.

(c) *Council dismissal of request for review.* The Council will dismiss a request for review when the individual or entity requesting review does not have a right to a review by the MAC, or will dismiss the request for a hearing for any reason that the ALJ or attorney adjudicator could have dismissed the request for hearing.

(d) *Expedited reviews.* (1) *Standard for expedited reviews.* The Council must provide an expedited review if the appeal involves an issue specified in § 423.566(b), but does not include solely a request for payment of Part D drugs already furnished, enrollee's prescribing physician or other prescriber indicates, or the Council determines that applying the standard timeframe for making a decision may seriously jeopardize the enrollee's life or health or ability to regain maximum function. The Council may consider this standard as met if a lower level adjudicator has granted a request for an expedited appeal.

(2) *Grant of a request.* If the Council grants a request for expedited review, the Council must:

(i) Make this decision within 5 calendar days of receipt of the request for expedited review;

(ii) Give the enrollee prompt oral notice of this decision; and

(iii) Issue a decision, dismissal order or remand, as expeditiously as the enrollee's health condition requires, but no later than the end of the 10 calendar day period beginning on the date the request for review is received by the

entity specified in the ALJ's or attorney adjudicator's written notice of decision.

(3) *Denial of a request.* If the Council denies a request for expedited review, the Council must:

(i) Make this decision within 5 calendar days of receipt of the request for expedited review;

(ii) Give the enrollee and Part D plan sponsor within 5 calendar days of receiving the request written notice of the denial. The written notice must inform the enrollee of the denial and explain that the Council will process the enrollee's request using the 90 calendar day timeframe for non-expedited reviews.

(4) *Decision on a request.* A decision on a request for expedited review may not be appealed.

[74 FR 65363, Dec. 9, 2009, as amended at 82 FR 5137 Jan. 17, 2017]

§ 423.2110 Council reviews on its own motion.

(a) *General rule.* The Council may decide on its own motion to review a decision or dismissal issued by an ALJ or attorney adjudicator. CMS or the IRE may refer a case to the Council for it to consider reviewing under this authority any time within 60 calendar days of receipt of an ALJ's or attorney adjudicator's written decision or dismissal.

(b) *Referral of cases.* (1) CMS or the IRE may refer a case to the Council if, in the view of CMS or the IRE, the decision or dismissal contains an error of law material to the outcome of the appeal or presents a broad policy or procedural issue that may affect the public interest. CMS or the IRE may also request that the Council take own motion review of a case if—

(i) CMS or the IRE participated or requested to participate in the appeal at the OMHA level; and

(ii) In CMS' or the IRE's view, the ALJ's or attorney adjudicator's decision or dismissal is not supported by the preponderance of evidence in the record or the ALJ or attorney adjudicator abused his or her discretion.

(2) CMS' or the IRE's referral to the Council is made in writing and must be filed with the Council no later than 60 calendar days after the ALJ's or attorney adjudicator's written decision or dismissal is received.

(i) The written referral will state the reasons why CMS or the IRE believes that the Council should review the case on its own motion.

(ii) CMS or the IRE will send a copy of its referral to the enrollee and to the OMHA Chief ALJ.

(iii) The enrollee may file exceptions to the referral by submitting written comments to the Council within 20 calendar days of the referral notice.

(iv) An enrollee submitting comments to the Council must send the comments to CMS or the IRE.

(c) *Standard of review*—(1) *Referral by CMS or the IRE when CMS or the IRE participated or requested to participate in the OMHA level.* If CMS or the IRE participated or requested to participate in an appeal at the OMHA level, the Council exercises its own motion authority if there is an error of law material to the outcome of the case, an abuse of discretion by the ALJ or attorney adjudicator, the decision is not consistent with the preponderance of the evidence of record, or there is a broad policy or procedural issue that may affect the general public interest. In deciding whether to accept review under this standard, the Council will limit its consideration of the ALJ's or attorney adjudicator's action to those exceptions raised by CMS or the IRE.

(2) *Referral by CMS or the IRE when CMS or the IRE did not participate or request to participate in the OMHA proceedings.* The Council will accept review if the decision or dismissal contains an error of law material to the outcome of the case or presents a broad policy or procedural issue that may affect the general public interest. In deciding whether to accept review, the Council will limit its consideration of the ALJ's or attorney adjudicator's action to those exceptions raised by CMS or the IRE.

(d) *Council's action.* (1) If the Council decides to review a decision or dismissal on its own motion, it will mail the results of its action to the enrollee and to CMS or the IRE, as appropriate.

(2) The Council may adopt, modify, or reverse the decision or dismissal,

may remand the case to an ALJ or attorney adjudicator for further proceedings, or may dismiss a hearing request.

(3) The Council must issue its action no later than 90 calendar days after receipt of the CMS or the IRE referral, unless the 90 calendar day period has been extended as provided in this subpart.

(4) The Council may not issue its action before the 20 calendar day comment period has expired, unless it determines that the agency's referral does not provide a basis for reviewing the case.

(5) If the Council declines to review a decision or dismissal on its own motion, the ALJ's or attorney adjudicator's decision or dismissal is binding.

(e) *Referral timeframe.* For purposes of this section, the date of receipt of the ALJ's or attorney adjudicator's decision or dismissal is presumed to be 5 calendar days after the date of the notice of the decision or dismissal, unless there is evidence to the contrary.

[82 FR 5137, Jan. 17, 2017, as amended at 84 FR 19874, May 7, 2019]

§ 423.2112 Content of request for review.

(a)(1) The request for Council review must be filed with the entity specified in the notice of the ALJ's or attorney adjudicator's action.

(2) The request for review must be in writing and may be made on a standard form, except for requests for expedited reviews which may be made orally.

(3) The Council must document all oral requests in writing and maintain the documentation in the case file.

(4) A written request that is not made on a standard form or, for expedited requests, an oral request, is accepted if it includes the enrollee's name and telephone number, the plan name; Medicare number; the ALJ appeal number; the specific Part D drug(s) for which the review is requested; a statement that the enrollee is requesting an expedited review, if applicable; and the name of the enrollee or the representative of the enrollee.

(b) The request for review must identify the parts of the ALJ or attorney adjudicator action with which the enrollee requesting review disagrees and explain why he or she disagrees with the ALJ's or attorney adjudicator's decision, dismissal, or other determination being appealed.

(c) The Council will limit its review of an ALJ's or attorney adjudicator's actions to those exceptions raised by the enrollee in the request for review, unless the enrollee is unrepresented. For purposes of this section only, a representative is either anyone with a valid appointment as the enrollee's representative or is a member of the enrollee's family, a legal guardian or an individual who routinely acts on behalf of the enrollee, such as a family member or friend who has a power of attorney.

[74 FR 65363, Dec. 9, 2009, as amended at 82 FR 5138, Jan. 17, 2017; 84 FR 19874, May 7, 2019]

§ 423.2114 Dismissal of request for review.

The Council dismisses a request for review if the enrollee requesting review did not file the request within the stated period of time and the time for filing has not been extended. The Council also dismisses the request for review if—

(a) The enrollee asks to withdraw the request for review;

(b) The individual or entity does not have a right to request Council review; or

(c) The enrollee died while the request for review is pending and the enrollee's estate or representative, if any, either has no remaining financial interest in the case or does not want to continue the appeal.

[74 FR 65363, Dec. 9, 2009, as amended at 82 FR 5138, Jan. 17, 2017]

§ 423.2116 Effect of dismissal of request for Council review or request for hearing.

The dismissal of a request for Council review or denial of a request for review of a dismissal issued by an ALJ or attorney adjudicator is binding and not subject to further review unless reopened and vacated by the Council. The Council's dismissal of a request for

hearing is also binding and not subject to judicial review.

[74 FR 65363, Dec. 9, 2009, as amended at 82 FR 5138, Jan. 17, 2017]

§ 423.2118 Obtaining evidence from the Council.

An enrollee may request and receive a copy of all or part of the record of the ALJ's or attorney adjudicator's action, including any index of the administrative record, documentary evidence, and a copy of the audio recording of the oral proceedings. However, the enrollee may be asked to pay the costs of providing these items. If an enrollee requests evidence from the Council and an opportunity to comment on that evidence, the time beginning with the Council's receipt of the request for evidence through the expiration of the time granted for the enrollee's response will not be counted toward the adjudication deadline.

[74 FR 65363, Dec. 9, 2009, as amended at 82 FR 5138, Jan. 17, 2017]

§ 423.2120 Filing briefs with the Council.

Upon request, the Council will give the enrollee requesting review a reasonable opportunity to file a brief or other written statement about the facts and law relevant to the case. Unless the enrollee requesting review files the brief or other statement with the request for review, the time beginning with the date of receipt of the request to submit the brief and ending with the date the brief is received by the Council will not be counted toward the adjudication timeframe set forth in § 423.2100. The Council may also request, but not require, CMS, the IRE, and/or the Part D plan sponsor to file a brief or position paper if the Council determines that it is necessary to resolve the issues in the case. The Council cannot draw any adverse inference if CMS, the IRE, and/or the Part D plan sponsor either participates, or decides not to participate in Council review.

[74 FR 65363, Dec. 9, 2009, as amended at 82 FR 5138, Jan. 17, 2017]

§ 423.2122 What evidence may be submitted to the Council.

(a) *Appeal before the Council on request for review of ALJ's or attorney adjudicator's decision.* (1) If the Council is reviewing an ALJ's or attorney adjudicator's decision, the Council will consider the evidence contained in the record of the proceedings before the ALJ or attorney adjudicator, and any new evidence that relates to the period before the coverage determination or at-risk determination. If the ALJ's or attorney adjudicator's decision decides a new issue that the enrollee was not afforded an opportunity to address at the OMHA level, the Council considers any evidence related to that issue that is submitted with the request for review.

(2) If the Council determines that additional evidence is needed to resolve the issues in the case and the administrative record indicates that the previous decision-makers have not attempted to obtain the evidence, the Council may remand the case to an ALJ or attorney adjudicator to obtain the evidence and issue a new decision.

(3) The Council will not consider any new evidence submitted regarding a change in condition of an enrollee after a coverage determination or at-risk determination is made. The Council will remand a case to the Part D IRE if the Council determines that the enrollee wishes to have evidence on his or her change in condition after the coverage determination or at-risk determination considered.

(b) *Subpoenas.* When it is reasonably necessary for the full presentation of a case, the Council may, on its own initiative, issue subpoenas requiring an enrollee or Part D plan sponsor to make books, records, correspondence, papers, or other documents that are material to an issue at the hearing available for inspection and copying. The Council may not issue a subpoena to CMS, or the IRE to compel the production of evidence.

(1) To the extent a subpoena compels disclosure of a matter for which an objection based on privilege, or other protection from disclosure such as case preparation, confidentiality or undue burden, was made before the Council, the Secretary may review immediately

that subpoena or a portion of the subpoena.

(2) Upon notice to the Council that an enrollee or Part D plan sponsor intends to seek the Secretary review of the subpoena, the Council must stay all proceedings affected by the subpoena, tolling the time period for the Council to issue a final action or remand a case in response to a request for review for 15 calendar days or until the Secretary makes a decision with respect to the review request, whichever occurs first.

(3) If the Secretary does not grant review within the time allotted for the stay, the stay is lifted and the subpoena stands.

(c) *Enforcement.* (1) If the CouncilC determines that an enrollee or other person or entity subject to a subpoena issued under this section has refused to comply with the subpoena, the Council may request the Secretary to seek enforcement of the subpoena in accordance with section 205(e) of the Act, 42 U.S.C. 405(e).

(2) After submitting the enforcement request, the time period for the Council to issue a final action or remand a case in response to a request for review is stayed for 15 calendar days or until the Secretary makes a decision with respect to the enforcement request, whichever occurs first.

(3) Any enforcement request by the Council must consist of a written notice to the Secretary describing in detail the Council's findings of noncompliance and its specific request for enforcement, and providing a copy of the subpoena and evidence of its receipt by certified mail by the enrollee or other person or entity subject to the subpoena.

(4) The Council must promptly mail a copy of the notice and related documents to the enrollee or other person or entity subject to the subpoena, and to any other affected person.

[74 FR 65363, Dec. 9, 2009, as amended at 82 FR 5138, Jan. 17, 2017; 83 FR 16754, Apr. 16, 2018]

§ 423.2124 Oral argument.

An enrollee may request to appear before the Council to present oral argument.

(a) The Council grants a request for oral argument if it decides that the case raises an important question of law, policy, or fact that cannot be readily decided based on written submissions alone.

(b) The Council may decide on its own that oral argument is necessary to decide the issues in the case. If the Council decides to hear oral argument, it informs the enrollee of the time and place of the oral argument at least 10 calendar days before the scheduled date or, in the case of an expedited review, at least 2 calendar days before the scheduled date.

(c) In case of a previously unrepresented enrollee, a newly hired representative may request an extension of time for preparation of the oral argument and the Council must consider whether the extension is reasonable.

(d) The Council may also request, but not require, CMS, the IRE, and/or the Part D plan sponsor to appear before it if the Council determines that it may be helpful in resolving the issues in the case.

(e) The Council cannot draw any adverse inference if CMS, the IRE, and/or the Part D plan sponsor decide not to participate in the oral argument.

[74 FR 65363, Dec. 9, 2009, as amended at 82 FR 5138, Jan. 17, 2017]

§ 423.2126 Case remanded by the Council.

(a) *When the Council may remand a case to the ALJ or attorney adjudicator.* (1) The Council may remand a case in which additional evidence is needed or additional action by the ALJ or attorney adjudicator is required. The Council will designate in its remand order whether the ALJ or attorney adjudicator will issue a decision or a recommended decision on remand.

(2) *Action by ALJ or attorney adjudicator on remand.* The ALJ or attorney adjudicator will take any action that is ordered by the Council and may take any additional action that is not inconsistent with the Council's remand order.

(3) *Notice when case is returned with a recommended decision.* When the ALJ or attorney adjudicator sends a case to the Council with a recommended decision, a notice is mailed to the enrollee

at his or her last known address. The notice tells the enrollee that the case was sent to the Council, explains the rules for filing briefs or other written statements with the Council, and includes a copy of the recommended decision.

(4) *Filing briefs with the Council when ALJ or attorney adjudicator issues recommended decision.* (i) An enrollee may file with the Council briefs or other written statements about the facts and law relevant to the case within 20 calendar days of the date on the recommended decision or with the request for review for expedited appeals. An enrollee may ask the Council for additional time to file a brief or written statement. The Council will extend this period, as appropriate, if the enrollee shows that he or she has good cause for requesting the extension.

(ii) All other rules for filing briefs with and obtaining evidence from the Council follow the procedures explained in this subpart.

(5) *Procedures before the Council.* (i) The Council, after receiving a recommended decision, will conduct proceedings and issue its decision or dismissal according to the procedures explained in this subpart.

(ii) If the Council determines that more evidence is required, it may again remand the case to an ALJ or attorney adjudicator for further inquiry into the issues, rehearing if applicable, receipt of evidence, and another decision or recommended decision. However, if the Council decides that it can get the additional evidence more quickly, it will take appropriate action.

(b) *When the Council must remand a case to the Part D IRE.* The Council will remand a case to the appropriate Part D IRE if the Council determines that the enrollee wishes evidence on his or her change in condition after the coverage determination or at-risk determination to be considered in the appeal.

[74 FR 65363, Dec. 9, 2009, as amended at 82 FR 5138, Jan. 17, 2017; 83 FR 16754, Apr. 16, 2018]

§ 423.2128 Action of the Council.

(a) After it has reviewed all the evidence in the administrative record and any additional evidence received, subject to the limitations on Council consideration of additional evidence in § 423.2122, the Council will make a decision or remand the case to an ALJ or attorney adjudicator.

(b) The Council may adopt, modify, or reverse the ALJ or attorney adjudicator decision or recommended decision.

(c) The Council mails a copy of its decision to the enrollee at his or her last known address, to CMS, to the IRE, and to the Part D plan sponsor.

[74 FR 65363, Dec. 9, 2009, as amended at 82 FR 5139, Jan. 17, 2017]

§ 423.2130 Effect of the Council's decision.

The Council's decision is final and binding unless a Federal District Court issues a decision modifying the Council's decision or the decision is revised as the result of a reopening in accordance with § 423.1980. An enrollee may file an action in a Federal District Court within 60 calendar days after the date the enrollee receives written notice of the Council's decision.

[74 FR 65363, Dec. 9, 2009, as amended at 82 FR 5139, Jan. 17, 2017]

§ 423.2134 Extension of time to file action in Federal District Court.

(a) An enrollee may request that the time for filing an action in a Federal District Court be extended.

(b) The request must:

(1) Be in writing.

(2) Give the reasons why the action was not filed within the stated time period.

(3) Be filed with the Council.

(c) If the enrollee shows that he or she had good cause for missing the deadline, the time period will be extended. To determine whether good cause exists, the Council uses the standards specified in §§ 405.942(b)(2) or (b)(3) of this chapter.

[74 FR 65363, Dec. 9, 2009, as amended at 82 FR 5139, Jan. 17, 2017]

§ 423.2136 Judicial review.

(a) *General rule*—(1) *Review of Council decision.* To the extent authorized by sections 1876(c)(5)(B) and 1860D–4(h) of the Act, an enrollee may obtain a court review of a Council decision if—

(i) It is a final decision of the Secretary; and

(ii) The amount in controversy meets the threshold requirements of § 423.2006.

(2) *Review of ALJ's or attorney adjudicator's decision.* To the extent authorized by sections 1876(c)(5)(B) and 1860D–4(h) of the Act, the enrollee may request judicial review of an ALJ's or attorney adjudicator's decision if—

(i) The Council denied the enrollee's request for review; and

(ii) The amount in controversy meets the threshold requirements of § 423.2006.

(b) *Court in which to file civil action.* (1) Any civil action described in paragraph (a) of this section must be filed in the District Court of the United States for the judicial district in which the enrollee resides.

(2) If the enrollee does not reside within any judicial district, the civil action must be filed in the District Court of the United States for the District of Columbia.

(c) *Time for filing civil action.* (1) Any civil action described in paragraph (a) of this section must be filed within the time periods specified in § 423.2130 or § 423.2134, as applicable.

(2) For purposes of this section, the date of receipt of the notice of the Council's decision shall be presumed to be 5 calendar days after the date of the notice, unless there is a reasonable showing to the contrary.

(3) Where a case is certified for judicial review in accordance with the expedited access to judicial review process in § 423.1990, the civil action must be filed within 60 calendar days after receipt of the review entity's certification, except where the time is extended by the ALJ or attorney adjudicator or Council, as applicable, upon a showing of good cause.

(d) *Proper defendant.* (1) In any civil action described in paragraph (a) of this section, the Secretary of HHS, in his or her official capacity, is the proper defendant. Any civil action properly filed shall survive notwithstanding any change of the person holding the Office of the Secretary of HHS or any vacancy in such office.

(2) If the complaint is erroneously filed against the United States or against any agency, officer, or employee of the United States other than the Secretary, the plaintiff enrollee will be notified that he or she has named an incorrect defendant and is granted 60 calendar days from the date of receipt of the notice in which to commence the action against the correct defendant, the Secretary.

(e) *Standard of review.* (1) Under section 205(g) of the Act, the findings of the Secretary of HHS as to any fact, if supported by substantial evidence, are conclusive.

(2) When the Secretary's decision is adverse to an enrollee due to an enrollee's failure to submit proof in conformity with a regulation prescribed under section 205(a) of the Act pertaining to the type of proof an enrollee must offer to establish entitlement to payment, the court will review only whether the proof conforms with the regulation and the validity of the regulation.

[74 FR 65363, Dec. 9, 2009, as amended at 82 FR 5139, Jan. 17, 2017; 84 FR 19874, May 7, 2019]

§ 423.2138 Case remanded by a Federal District Court.

When a Federal District Court remands a case to the Secretary for further consideration, unless the court order specifies otherwise, the Council, acting on behalf of the Secretary, may make a decision, or it may remand the case to an ALJ or attorney adjudicator with instructions to take action and either issue a decision, take other action, or return the case to the Council with a recommended decision. If the Council remands a case, the procedures specified in § 423.2140 will be followed.

[74 FR 65363, Dec. 9, 2009, as amended at 82 FR 5139, Jan. 17, 2017]

§ 423.2140 Council Review of ALJ or attorney adjudicator decision in a case remanded by a Federal District Court.

(a) *General rules.* (1) In accordance with § 423.2138, when a case is remanded by a Federal District Court for further consideration and the Council remands the case to an ALJ or attorney adjudicator, a decision subsequently issued by the ALJ or attorney adjudicator becomes the final decision of the Secretary unless the Council assumes jurisdiction.

(2) The Council may assume jurisdiction based on written exceptions to the decision of the ALJ or attorney adjudicator that an enrollee files with the Council or based on its authority under paragraph (c) of this section.

(3) The Council either makes a new, independent decision based on the entire record that will be the final decision of the Secretary after remand, or remands the case to an ALJ or attorney adjudicator for further proceedings.

(b) *An enrollee files exceptions disagreeing with the decision of the ALJ or attorney adjudicator.* (1) If an enrollee disagrees with an ALJ or attorney adjudicator decision described in paragraph (a) of this section, in whole or in part, he or she may file exceptions to the decision with the Council Council .

(2) Exceptions may be filed by submitting a written statement to the Council setting forth the reasons for disagreeing with the decision of the ALJ or attorney adjudicator.

(i) The enrollee must file exceptions within 30 calendar days of the date the enrollee receives the decision of the ALJ or attorney adjudicator or submit a written request for an extension within the 30 calendar day period.

(ii) The Council will grant a timely request for a 30 calendar day extension. A request for an extension of more than 30 calendar days must include a statement of reasons as to why the enrollee needs the additional time and may be granted if the Council finds good cause under the standard established in §§405.942(b)(2) or (b)(3) of this chapter.

(3) If written exceptions are timely filed, the Council considers the enrollee's reasons for disagreeing with the decision of the ALJ or attorney adjudicator. If the Council concludes that there is no reason to change the decision of the ALJ or attorney adjudicator, it will issue a notice addressing the exceptions and explaining why no change in the decision of the ALJ or attorney adjudicator is warranted. In this instance, the decision of the ALJ or attorney adjudicator is the final decision of the Secretary after remand.

(4) When an enrollee files written exceptions to the decision of the ALJ, the Council may assume jurisdiction at any time. If the Council assumes jurisdiction, it makes a new, independent decision based on its consideration of the entire record adopting, modifying, or reversing the decision of the ALJ or attorney adjudicator or remanding the case to an ALJ or attorney adjudicator for further proceedings, including a new decision. The new decision of the Council is the final decision of the Secretary after remand.

(c) *Council assumes jurisdiction without exceptions being filed.* (1) Any time within 60 calendar days after the date of the written decision of the ALJ or attorney adjudicator, the Council may decide to assume jurisdiction of the case even though no written exceptions have been filed.

(2) Notice of this action is mailed to the enrollee at his or her last known address.

(3) The enrollee will be provided with the opportunity to file a brief or other written statement with the Council about the facts and law relevant to the case.

(4) After the brief or other written statement is received or the time allowed (usually 30 calendar days) for submitting them has expired, the Council will either issue a final decision of the Secretary affirming, modifying, or reversing the decision of the ALJ, or remand the case to an ALJ or attorney adjudicator for further proceedings, including a new decision.

(d) *Exceptions are not filed and the Council does not otherwise assume jurisdiction.* If no exceptions are filed and the Council does not assume jurisdiction over the case within 60 calendar days after the date of the ALJ's or attorney adjudicator's written decision, the decision of the ALJ or attorney adjudicator becomes the final decision of the Secretary after remand.

[74 FR 65363, Dec. 9, 2009, as amended at 82 FR 5139, Jan. 17, 2017]

Subpart V—Part D Communication Requirements

SOURCE: 73 FR 54222, Sept. 18, 2008, unless otherwise noted.

§ 423.2260 Definitions.

The definitions in this section apply for this subpart unless the context indicates otherwise.

Advertisement (Ad) means a read, written, visual, oral, watched, or heard bid for, or call to attention. Advertisements can be considered communication or marketing based on the intent and content of the message.

Alternate format means used to convey information to individuals with visual, speech, physical, hearing, and intellectual disabilities (for example, braille, large print, audio).

Banner means a type of advertisement feature typically used in television ads that is intended to be brief, and flashes limited information across a screen for the sole purpose of enticing a prospective enrollee to contact the Part D sponsor (for example, obtain more information) or to alert the viewer that information is forthcoming.

Banner-like advertisement is an advertisement that uses a banner-like feature, that is typically found in some media other than television (for example, outdoors and on the internet).

Communications means activities and use of materials created or administered by the Part D sponsor or any downstream entity to provide information to current and prospective enrollees. Marketing is a subset of communications.

Marketing means communications materials and activities that meet both the following standards for intent and content:

(1) Intended, as determined under paragraph (1)(ii) of this definition, to do any of the following:

(i)(A) Draw a beneficiary's attention to a Part D plan or plans.

(B) Influence a beneficiary's decision making process when making a Part D plan selection.

(C) Influence a beneficiary's decision to stay enrolled in a Part D plan (that is, retention-based marketing).

(ii) In evaluating the intent of an activity or material, CMS will consider objective information including, but not limited to, the audience of the activity or material, other information communicated by the activity or material, timing, and other context of the activity or material and is not limited to the Part D sponsor's stated intent.

(2) Include or address content regarding any of the following:

(i) The plan's benefits, benefits structure, premiums or cost sharing.

(ii) Measuring or ranking standards (for example, Star Ratings or plan comparisons).

Outdoor advertising (ODA) means outdoor material intended to capture the attention of a passing audience (for example, billboards, signs attached to transportation vehicles). ODA may be a communication or marketing material.

Third-party marketing organization (TPMO) are organizations and individuals, including independent agents and brokers, who are compensated to perform lead generation, marketing, sales, and enrollment related functions as a part of the chain of enrollment (the steps taken by a beneficiary from becoming aware of a Part D plan or plans to making an enrollment decision). TPMOs may be a first tier, downstream or related entity (FDRs), as defined under § 423.4, but may also be entities that are not FDRs but provide services to a Part D sponsor or a Part D sponsor's FDR.

[86 FR 6121, Jan. 19, 2021, as amended at 87 FR 27901, May 9, 2022]

§ 423.2261 Submission, review, and distribution of materials.

(a) *General requirements.* Part D sponsors must submit all marketing materials, all election forms, and certain designated communications materials for CMS review.

(1) The Health Plan Management System (HPMS) Marketing Module is the primary system of record for the collection, review, and storage of materials that must be submitted for review.

(2) Materials must be submitted to the HPMS Marketing Module by the Part D sponsor or, where materials have been developed by a Third Party Marketing Organization for multiple Part D sponsors or plans, by a Third Party Marketing Organization with prior review of each Part D sponsor on whose behalf the materials were created or will be used.

(b) *CMS review of marketing materials and election forms.* Part D sponsors may

not distribute or otherwise make available any marketing materials or election forms unless one of the following occurs:

(1) CMS has reviewed and approved the material.

(2) The material has been deemed approved; that is, CMS has not rendered a disposition for the material within 45 days (or 10 days if using CMS model or standardized marketing materials as outlined in § 422.2267(e) of this chapter) of submission to CMS.

(3) The material has been accepted under File and Use, as follows:

(i) The Part D sponsor may distribute certain types of marketing materials, designated by CMS based on the material's content, audience, and intended use, as they apply to potential risk to the beneficiary, 5 days following the submission.

(ii) The Part D sponsor must certify that the material meets all applicable CMS communications and marketing requirements in §§ 423.2260 through 423.2267.

(c) *CMS review of non-marketing communications materials.* CMS does not require submission, or submission and approval, of communications materials prior to use, other than the following exceptions.

(1) Certain designated communications materials that are critical to beneficiaries understanding or accessing their benefits (for example, the Evidence of Coverage (EOC).

(2) Communications materials that, based on feedback such as complaints or data gathered through reviews, warrant additional oversight as determined by CMS, to ensure the information being received by beneficiaries is accurate.

(d) *Standards for CMS review.* CMS reviews materials to ensure the following:

(1) Compliance with all applicable requirements under §§ 423.2260 through 423.2267.

(2) Benefit and cost information is an accurate reflection of what is contained in the Part D sponsor's bid.

(3) CMS may determine, upon review of such materials, that the materials must be modified, or may no longer be used.

[86 FR 6122, Jan. 19, 2021, as amended at 88 FR 22340, Apr. 12, 2023]

§ 423.2262 General communications materials and activity requirements.

Part D sponsors may not mislead, confuse, or provide materially inaccurate information to current or potential enrollees.

(a) *General rules.* Part D sponsors must ensure their statements and the terminology used in communications activities and materials adhere to the following requirements:

(1) Part D sponsors may not do any of the following:

(i) Provide information that is inaccurate or misleading.

(ii) Use of superlatives, unless sources of documentation or data supportive of the superlative is also referenced in the material. Such supportive documentation or data must reflect data, reports, studies, or other documentation that applies to the current contract year or prior contract year.

(A) Including data older than the prior contract year is permitted provided the current and prior contract year data are specifically identified.

(B) [Reserved]

(iii) Engage in activities that could mislead or confuse Medicare beneficiaries, or misrepresent the Part D sponsor.

(iv) Engage in any discriminatory activity such as attempting to recruit Medicare beneficiaries from higher income areas without making comparable efforts to enroll Medicare beneficiaries from lower income areas, or vice versa.

(v) Target potential enrollees based on higher or lower income levels.

(vi) Target potential enrollees based on health status.

(vii) State or imply plans are only available to seniors rather than to all Medicare beneficiaries.

(viii) Employ Part D plan names that suggest that a plan is not available to all Medicare beneficiaries.

(ix) Display the names or logos or both of co-branded network pharmacies on the sponsor's member identification

card, unless the pharmacy names or logos or both are related to the member selection of specific pharmacies.

(x) Use a plan name that does not include the plan type. The plan type should be included at the end of the plan name, for example, ''Super Medicare Drug Plan (PDP)''. Part D sponsors are not required to repeat the plan type when the plan name is used multiple times in the same material.

(xi) Claim they are recommended or endorsed by CMS, Medicare, the Secretary, or HHS.

(xii) Convey that a failure to pay premium will not result in disenrollment except for factually accurate descriptions of the PDP sponsor's policies adopted in accordance with § 423.44(b)(1) and (d)(1) of this chapter.

(xiii) Use the term ''free'' to describe a $0 premium, any type of reduction in premium, reduction in deductibles or cost sharing, low-income subsidy, or cost sharing pertaining to dual eligible individuals.

(xiv) State or imply a plan is available only to or is designed for Medicaid beneficiaries.

(xv) Market a Part D plan not designed to serve dual eligible beneficiaries as if it were a plan designed to serve dual eligible beneficiaries.

(xvi) Target marketing efforts primarily to dual eligible individuals.

(xvii) Claim a relationship with the state Medicaid agency, unless a contract to coordinate Medicaid services for enrollees in that plan is in place.

(xviii) Use of the Medicare name, CMS logo, and products or information issued by the Federal Government, including the Medicare card in a misleading way. Use of the Medicare card image is permitted only with authorization from CMS.

(2) Part D sponsors may do the following:

(i) State that the Part D sponsor is approved to participate in Medicare programs or is contracted to administer Medicare benefits or both.

(ii) Use the term ''Medicare-approved'' to describe benefits or services in materials or both.

(b) *Product endorsements and testimonials.* (1) Product endorsements and testimonials may take any of the following forms:

(i) Television or video ads.

(ii) Radio ads.

(iii) Print ads.

(iv) Social media ads. In cases of social media, the use of a previous post, whether or not associated with or originated by the Part D sponsor, is considered a product endorsement or testimonial.

(v) Other types of ads.

(2) Part D sponsors may use individuals to endorse the Part D sponsor's product provided the endorsement or testimonial adheres to the following requirements:

(i) The speaker must identify the Part D sponsor's product or company by name.

(ii) Medicare beneficiaries endorsing or promoting the Part D sponsor must have been an enrollee at the time the endorsement or testimonial was created.

(iii) The endorsement or testimonial must clearly state that the individual was paid for the endorsement or testimonial, if applicable.

(iv) If an individual is used (for example, an actor) to portray a real or fictitious situation, the advertisement must state that it is an actor portrayal.

(c) *Requirements when including certain telephone numbers in materials.* (1) Part D sponsors must adhere to the following requirements for including certain telephone numbers in materials:

(i) When a Part D sponsor includes its customer service number, the hours of operation must be prominently included at least once.

(ii) When a Part D sponsor includes its customer service number, it must provide a toll-free TTY number in conjunction with the customer service number in the same font size.

(iii) On every material where 1–800–MEDICARE or Medicare TTY appears, the Part D sponsor must prominently include, at least once, the hours and days of operation for 1–800–MEDICARE (that is, 24 hours a day/7 days a week).

(2) The following advertisement types are exempt from these requirements:

(i) Outdoor advertising.

(ii) Banners or banner-like ads.

(iii) Radio advertisements and sponsorships.

(d) *Standardized material identification (SMID).* (1) Part D sponsors must use a standardized method of identification for oversight and tracking of materials received by beneficiaries.

(2) The SMID consists of the following three parts:

(i) The Part D sponsor's contract or Multi-Contract Entity (MCE) number, (that is, ''S'' for PDPs, or ''Y'' for MCE, a means of identification available for Plans/Part D sponsors that have multiple PDP contracts) followed by an underscore, except that the SMID for multi-plan marketing materials must begin with the word ''MULTI-PLAN'' instead of the Part D sponsor's contract number (for example, S1234_abc123_C or MULTI-PLAN_efg456_M).

(ii) A series of alpha numeric characters (at the Part D sponsor's discretion) unique to the material followed by an underscore.

(iii) An uppercase ''C'' for communication materials or an uppercase ''M'' for marketing materials (for example, S1234_abc123_C or S5678_efg456_M).

(3) The SMID is required on all materials except the following:

(i) Membership ID card.

(ii) Envelopes, radio ads, outdoor advertisements, banners, banner-like ads, and social media comments and posts.

(iii) OMB-approved forms/documents, except those materials specified in § 423.2267.

(iv) Corporate notices or forms (that is, not Part D-specific) meeting the definition of communications such as privacy notices and authorization to disclose protected health information (PHI).

(v) Agent-developed communications materials that are not marketing.

(4) Non-English and alternate format materials, based on previously created materials, may have the same SMID as the material on which they are based.

[86 FR 6122, Jan. 19, 2021, as amended at 88 FR 22340, Apr. 12, 2023]

§ 423.2263 General marketing requirements.

Marketing is a subset of communications and therefore must follow the requirements outlined in § 423.2262 as well as this section. Marketing (as defined in § 423.2260) must additionally meet the following requirements:

(a) Part D sponsors may begin marketing prospective plan year offerings on October 1 of each year for the following contract year. Part D sponsors may market the current and prospective year simultaneously provided materials clearly indicate what year is being discussed.

(b) In marketing, Part D sponsors may not do any of the following:

(1) Provide cash or other monetary rebates as an inducement for enrollment or otherwise.

(2) Offer gifts to beneficiaries, unless the gifts are of nominal value (as governed by guidance published by the HHS OIG), are offered to similarly situated beneficiaries without regard to whether or not the beneficiary enrolls, and are not in the form of cash or other monetary rebates.

(3) Provide meals to potential enrollees regardless of value.

(4) Market non-health care related products to prospective enrollees during any Part D sales activity or presentation. This is considered cross-selling and is prohibited.

(5) Compare their plan to other plans, unless the information is accurate, not misleading, and can be supported by the Part D sponsor making the comparison.

(6) Display the names or logos or both of pharmacy co-branding partners on marketing materials, unless the materials clearly indicate via a disclaimer or in the body that ''Other pharmacies are available in the network.''

(7) Knowingly target or send unsolicited marketing materials to any Part D enrollee during the Open Enrollment Period (OEP).

(i) During the OEP, a Part D sponsors may do any of the following:

(A) Conduct marketing activities that focus on other enrollment opportunities, including but not limited to marketing to age-ins (who have not yet made an enrollment decision), marketing by 5-star plans regarding their continuous enrollment special election period (SEP), and marketing to dual-eligible and LIS beneficiaries who, in general, may make changes once per calendar quarter during the first nine months of the year;

(B) Send marketing materials when a beneficiary makes a proactive request;

(C) At the beneficiary's request, have one-on-one meetings with a sales agent;

(D) At the beneficiary's request, provide information on the OEP through the call center; and

(E) Include educational information, excluding marketing, on the Part D sponsor's website about the existence of OEP.

(ii) During the OEP, a Part D sponsors may not:

(A) Send unsolicited materials advertising the ability or opportunity to make an additional enrollment change or referencing the OEP;

(B) Specifically target beneficiaries who are in the OEP because they made a choice during Annual Enrollment Period (AEP) by purchase of mailing lists or other means of identification;

(C) Engage in or promote agent or broker activities that intend to target the OEP as an opportunity to make further sales; or

(D) Call or otherwise contact former enrollees who have selected a new plan during the AEP.

(8) Advertise benefits that are not available to beneficiaries in the service area(s) where the marketing appears, unless the advertisement is in local media that serves the service area(s) where the benefits are available and reaching beneficiaries who reside in other service areas is unavoidable.

(9) Market any products or plans, benefits, or costs, unless the Part D sponsor or marketing name(s) as listed in HPMS of the entities offering the referenced products or plans, benefits, or costs are identified in the marketing material.

(i) Part D sponsor or marketing names must be in 12-point font in print and may not be in the form of a disclaimer or in fine print.

(ii) For television, online, or social media, the Part D sponsor or marketing name(s) must be either read at the same pace as the phone number or must be displayed throughout the entire advertisement in a font size equivalent to the advertised phone number, contact information or benefits.

(iii) For radio or other voice-based advertisements, Part D sponsor or marketing names must be read at the same pace as phone numbers or contact information.

(10) Part D sponsors may not include information about savings available to potential enrollees that are based on a comparison of typical expenses borne by uninsured individuals, unpaid costs of dually eligible beneficiaries, or other unrealized costs of a Medicare beneficiary.

(c) The following requirements apply to how Part D sponsors must display CMS-issued Star Ratings:

(1) References to individual Star Rating measure(s) must also include references to the overall Star Rating for MA–PDs and the summary rating for PDP plans.

(2) May not use an individual underlying category, domain, or measure rating to imply overall higher Star Ratings.

(3) Must be clear that the rating is out of 5 stars.

(4) Must clearly identify the Star Ratings contract year.

(5) May only market the Star Ratings in the service area(s) for which the Star Rating is applicable unless using Star Ratings to convey overall Part D sponsor performance (for example, ''Plan X has achieved 4.5 stars in Montgomery, Chester, and Delaware Counties), in which case the Part D sponsor must do so in a way that is not confusing or misleading.

(6) The following requirements apply to all 5 Star PDP contracts:

(i) May not market the 5-star special enrollment period, as defined in § 423.38(c)(20), after November 30 of each year if the contract has not received an overall 5 star for the next contract year.

(ii) May use CMS' 5- star icon or may create their own icon.

(7) The following requirements apply to all Low Performing MA contracts:

(i) The Low Performing Icon must be included on all materials about or referencing the specific contract's Star Ratings.

(ii) Must state the Low Performing Icon means that the Part D sponsor's contract received a summary rating of 2.5 stars or below in Part D for the last 3 years.

(iii) May not attempt to refute or minimize Low Performing Status.

[86 FR 6123, Jan. 19, 2021, as amended at 88 FR 22340, Apr. 12, 2023]

§ 423.2264 Beneficiary contact.

For the purpose of this section, beneficiary contact means any outreach activities to a beneficiary or a beneficiary's caregivers by the Part D sponsor or its agents and brokers.

(a) *Unsolicited contact.* Subject to the rules for contact for plan business in paragraph (b) of this section, the following rules apply when materials or activities are given or supplied to a beneficiary or their caregiver without prior request:

(1) Part D sponsors may make unsolicited direct contact by conventional mail and other print media (for example, advertisements and direct mail) or email (provided every email contains an opt-out option).

(2) Part D sponsors may not do any of the following if unsolicited:

(i) Use door to door solicitation, including leaving information of any kind, except that information may be left when an appointment is pre-scheduled but the beneficiary is not home.

(A) Contact is unsolicited door-to-door contact unless an appointment, at the beneficiary's home at the applicable time and date, was previously scheduled.

(B) [Reserved]

(ii) Approach enrollees in common areas such as parking lots, hallways, lobbies.

(iii) Send direct messages from social media platforms.

(iv) Use telephone solicitation (that is, cold calling), robocalls, text messages, or voicemail messages, including, but not limited to, the following:

(A) Calls based on referrals.

(B) Calls to former enrollees who have disenrolled or those in the process of disenrolling, except to conduct disenrollment surveys for quality improvement purposes.

(C) Calls to beneficiaries who attended a sales event, unless the beneficiary gave express permission to be contacted.

(D) Calls to prospective enrollees to confirm receipt of mailed information.

(3) Calls are not considered unsolicited if the beneficiary provides consent or initiates contact with the plan. For example, returning phone calls or calling an individual who has completed a business reply card requesting contact is not considered unsolicited.

(b) *Contact for plan business.* Part D sponsors may contact current, and to a more limited extent, former members, including those enrolled in other products offered by the parent organization, to discuss plan business, in accordance with the following requirements:

(1) A Part D sponsor may conduct the following activities as plan business:

(i) Call current enrollees, including those in non-Medicare products, to discuss Medicare products. Examples of such calls include, but are not limited to the following:

(A) Enrollees aging into Medicare from commercial products.

(B) Existing enrollees, including Medicaid enrollees, to discuss other Medicare products or plan benefits.

(C) Members in an MA or cost plan to discuss other Medicare products.

(ii) Call beneficiaries who submit enrollment applications to conduct business related to enrollment.

(iii) With prior CMS approval, call LIS enrollees that a plan is prospectively losing due to reassignment. CMS decisions to approve calls are for limited circumstances based on the following:

(A) The proximity of cost of the losing plan as compared to the national benchmark; and

(B) The selection of plans in the service area that are below the benchmark.

(iv) Agents/brokers calling clients who are enrolled in other products they may sell, such as automotive or home insurance.

(v) Part D sponsors may not make unsolicited calls about other lines of business as a means of generating leads for Medicare plans.

(2) If the Part D sponsor reaches out to beneficiaries regarding plan business, as outlined in this section, the Part D sponsor must provide notice to all beneficiaries whom the plan contacts as least once annually, in writing, of the individual's ability to opt

out of future calls regarding plan business.

(c) *Events with beneficiaries.* Part D sponsors and their agent or brokers may hold educational events, marketing or sales events, and personal marketing appointments to meet with Medicare beneficiaries, either face-to-face or virtually. The requirements for each type of event are as follows:

(1) Educational events must be advertised as such and be designed to generally inform beneficiaries about Medicare, including Medicare Advantage, Prescription Drug programs, or any other Medicare program.

(i) At educational events, Part D sponsors and agents/brokers may not market specific Part D sponsors or benefits.

(ii) Part D sponsors holding or participating in educational events may do any of the following:

(A) Distribute communication materials.

(B) Answer beneficiary initiated questions pertaining to Part D plans.

(C) Distribute business cards.

(D) Make available and receive beneficiary contact information, including Business Reply Cards, but not including Scope of Appointment forms.

(iii) Part D sponsors holding or participating in educational events may not conduct sales or marketing presentations or distribute or accept plan applications.

(iv) Part D sponsors may schedule appointments with residents of long-term care facilities (for example, nursing homes, assisted living facilities, board and care homes) upon a resident's request. If a resident did not request an appointment, any visit by an agent or broker is prohibited as unsolicited door-to-door marketing.

(2) Marketing or sales events are group events that fall within the definition of marketing at § 423.2260.

(i) Marketing events are prohibited from taking place within 12 hours of an educational event, in the same location. The same location is defined as the entire building or adjacent buildings.

(ii) Part D sponsors holding or participating in marketing events may do any of the following:

(A) Provide marketing materials.

(B) Distribute and accept plan applications.

(C) Collect Scope of Appointment forms for future personal marketing appointments.

(D) Conduct marketing presentations.

(iii) Part D sponsors holding or participating in marketing events may not do any of the following:

(A) Require sign in sheets or require attendees to provide contact information as a prerequisite for attending an event.

(B) Conduct activities, including health screenings, health surveys, or other activities that are used for or could be viewed as being used to target a subset of members (that is ''cherry-picking'').

(C) Use information collected for raffles or drawings for any purpose other than raffles or drawings.

(3) Personal marketing appointments are those appointments that are tailored to an individual or small group (for example, a married couple). Personal marketing appointments are not defined by the location.

(i) At least 48 hours prior to the scheduled personal marketing appointment, the Part D plan (or agent or broker, as applicable) must agree upon and record the Scope of Appointment with the beneficiary(ies), except for:

(A) SOAs that are completed during the last four days prior to a valid election period for the beneficiary.

(B) Unscheduled in person visits (walk-ins) initiated by the beneficiary.

(ii) Part D sponsors holding a personal marketing appointment may do any of the following:

(A) Provide marketing materials.

(B) Distribute and accept plan applications.

(C) Conduct marketing presentations.

(D) Review the individual needs of the beneficiary including, but not limited to, health care needs and history, commonly used medications, and financial concerns.

(iii) Part D sponsors holding a personal marketing appointment may not do any of the following:

(A) Market any health care related product during a marketing appointment beyond the scope agreed upon by the beneficiary, and documented by the

plan in a Scope of Appointment, business reply card, or request to receive additional information, which is valid for 12 months following the date of beneficiary's signature date or the date of the beneficiary's initial request for information.

(B) Market additional health related lines of plan business not identified prior to an individual appointment without a separate Scope of Appointment, identifying the additional lines of business to be discussed; such Scope of Appointment is valid for 12 months following the beneficiary's signature date.

(C) Market non-health related products such as annuities.

[86 FR 6124, Jan. 19, 2021, as amended at 88 FR 22340, Apr. 12, 2023; 88 FR 34780, May 31, 2023]

§ 423.2265 Websites.

As required under § 423.128(d)(2), Part D sponsors must have a website.

(a) *General website requirements.* (1) Part D sponsor websites must meet all of the following requirements:

(i) Maintain current year contract content through December 31 of each year.

(ii) Notify users when they will leave the Part D sponsor's Medicare site.

(iii) Include or provide access to (for example, through a hyperlink) applicable notices, statements, disclosures, or disclaimers with corresponding content. Overarching disclaimers, such as the Federal Contracting Statement, are not required on every page.

(iv) Reflect the most current information within 30 days of any material change

(v) Keep PDP content separate and distinct from other lines of business, including Medicare Supplemental Plans.

(2) Part D sponsor websites may not do any of the following:

(i) Require beneficiaries to enter any information other than zip code, county, or state for access to non-beneficiary-specific website content.

(ii) Provide links to foreign drug sales, including advertising links.

(iii) State that the Part D sponsor is not responsible for the content of their social media pages or the website of any first tier, downstream, or related entity that provides information on behalf of the Part D sponsor.

(b) *Required content.* A Part D sponsor's websites must include the following content:

(1) A toll-free customer service number, TTY number, and days and hours of operation.

(2) A physical or Post Office Box address.

(3) A PDF or copy of a printable pharmacy directory.

(4) A searchable pharmacy directory.

(5) A searchable formulary.

(6) Information on enrollees' and Part D sponsors' rights and responsibilities upon disenrollment. Part D sponsors may either post this information or provide specific information on where it is located in the Evidence of Coverage together with a link to that document.

(7) A description of and information on how to file a grievance, request an organization determination, and an appeal.

(8) Prominently displayed link to the *Medicare.gov* electronic complaint.

(9) A Notice of Privacy Practices as required under the HIPAA Privacy Rule (45 CFR 164.520).

(10) Prescription Drug Transition Policy.

(11) LIS Premium Summary Chart.

(12) Prescription Drug Transition Policy.

(13) A separate section or page about MTM programs providing the following:

(i) Explanation of MTM program, including eligibility requirements, the purpose and benefits of MTM, how to obtain MTM service documents including the Medication list, that the service is free, and a summary of services.

(ii) Information on how to obtain information about the MTM program, including how the member will know they are eligible and enrolled into the MTM program, the comprehensive medication review and targeted medication reviews, a description of how reviews are conducted and delivered, including time commitments and materials beneficiaries will receive.

(14) Instructions on how to appoint a representative including a link to the

downloadable version of the CMS Appointment of Representative Form (CMS Form-1696).

(15) Enrollment instructions and forms.

(16) Information about the Medicare Prescription Payment Plan as described in § 423.137(m)(2).

(c) *Required posted materials.* A Part D sponsor's website must provide access to the following materials, in a printable format, within the timeframes specified in paragraphs (c)(1) and (2) of this section.

(1) The following materials for each plan year must be posted on the website by October 15 prior to the beginning of the plan year:

(i) Evidence of Coverage.

(ii) Annual Notice of Change (for renewing plans).

(iii) Summary of Benefits.

(iv) Pharmacy Directory.

(v) Formulary.

(vi) Utilization Management Forms for physicians and enrollees.

(2) The following materials must be posted on the website throughout the year and be updated as required:

(i) Prior Authorization Forms for Physicians and Enrollees.

(ii) Part D Model Coverage Determination and Redetermination Request Forms.

(iii) Exception request forms for physicians (which must be posted by January 1 for new plans).

(iv) CMS Star Ratings document, which must be posted within 21 days after its release on the Medicare Plan Finder.

[86 FR 6125, Jan. 19, 2021, as amended at 87 FR 27901, May 9, 2022; 90 FR 15920, Apr. 15, 2025]

§ 423.2266 Activities with healthcare providers or in the healthcare setting.

(a) *Where marketing is prohibited.* The requirements in paragraphs (c) through (e) of this section apply to activities in the health care setting. Marketing activities and materials are not permitted in areas where care is being administered, including but not limited to the following:

(1) Exam rooms.

(2) Hospital patient rooms.

(3) Treatment areas where patients interact with a provider and his/her clinical team and receive treatment (including such areas in dialysis treatment facilities).

(4) Pharmacy counter areas.

(b) *Where marketing is permitted.* Marketing activities and materials are permitted in common areas within the health care setting, including the following:

(1) Common entryways.

(2) Vestibules.

(3) Waiting rooms.

(4) Hospital or nursing home cafeterias.

(5) Community, recreational, or conference rooms.

(c) *Provider-initiated activities.* Provider-initiated activities are activities conducted by a provider at the request of the patient, or as a matter of a course of treatment, and occur when meeting with the patient as part of the professional relationship between the provider and patient. Provider-initiated activities do not include activities conducted at the request of the Part D sponsor or pursuant to the network participation agreement between the Part D sponsor and the provider. Provider-initiated activities that meet this definition in this paragraph (c) fall outside of the definition of marketing in § 423.2260. Permissible provider-initiated activities include:

(1) Distributing unaltered, printed materials created by CMS, such as reports from Medicare Plan Finder, the ''Medicare & You'' handbook, or ''Medicare Options Compare'' (from *https://www.medicare.gov*) including in areas where care is delivered.

(2) Providing the names of Part D sponsors with which they contract or participate or both.

(3) Answering questions or discussing the merits of a Part D plan or plans, including cost sharing and benefit information including in areas where care is delivered.

(4) Referring patients to other sources of information, such as State Health Insurance Assistance Program (SHIP) representatives, plan marketing representatives, State Medicaid Office, local Social Security Offices, CMS' website at *https://www.medicare.gov,* or 1–800–MEDICARE.

(5) Referring patients to Part D marketing materials available in common areas.

(6) Providing information and assistance in applying for the LIS.

(7) Announcing new or continuing affiliations with Part D sponsors, once a contractual agreement is signed. Announcements may be made through any means of distribution.

(d) *Plan-initiated provider activities.* Plan-initiated provider activities are those activities conducted by a provider at the request of a Part D sponsor. During a plan-initiated provider activity, the provider is acting on behalf of the Part D sponsor. For the purpose of plan-initiated activities, the Part D sponsor is responsible for compliance with all applicable regulatory requirements.

(1) During plan-initiated provider activities, Part D sponsors must ensure that the provider does not:

(i) Accept/collect scope of appointment forms.

(ii) Accept Medicare enrollment applications.

(iii) Make phone calls or direct, urge, or attempt to persuade their patients to enroll in a specific plan based on financial or any other interests of the provider.

(iv) Mail marketing materials on behalf of a Part D sponsor.

(v) Offer inducements to persuade patients to enroll with a particular Part D plan or sponsor.

(vi) Conduct health screenings as a marketing activity.

(vii) Distribute marketing materials or enrollment forms in areas where care is being delivered.

(viii) Offer anything of value to induce enrollees to select the provider.

(ix) Accept compensation from the Part D sponsor for any marketing or enrollment activities performed on behalf of the Part D sponsor.

(2) During plan-initiated provider activities, the provider may do any of the following:

(i) Make available, distribute, and display communications materials, including in areas where care is being delivered.

(ii) Provide or make available marketing materials and enrollment forms in common areas.

(e) *Part D sponsor activities in the healthcare setting.* Part D sponsor activities in the health care setting are those activities, including marketing activities that are conducted by Part D sponsor or on behalf of the Part D sponsor, or by any downstream entity, but not by a provider. All marketing must comply with the requirements in paragraphs (a) and (b) of this section. However, during Part D sponsor activities, the following is permitted:

(1) Accepting and collect Scope of Appointment forms.

(2) Accepting enrollment forms.

(3) Making available, distributing, and displaying communications materials, including in areas where care is being delivered.

[86 FR 6125, Jan. 19, 2021]

§ 423.2267 Required materials and content.

For information CMS deems to be vital to the beneficiary, including information related to enrollment, benefits, health, and rights, the agency may develop materials or content that are either standardized or provided in a model form. Such materials and content are collectively referred to as required.

(a) *Standards for required materials and content.* All required materials and content, regardless of categorization as standardized in paragraph (b) of this section or model in paragraph (c) of this section, must meet the following:

(1) Be in a 12pt font, Times New Roman or equivalent.

(2) For markets with a significant non-English speaking population, be in the language of these individuals. Specifically, Part D sponsors must translate required materials into any non-English language that is the primary language of at least 5 percent of the individuals in a plan benefit package (PBP) service area.

(3) Be provided to enrollees on a standing basis in any non-English language identified in paragraphs (a)(2) and (4) of this section and/or accessible format using auxiliary aids and services upon receiving a request for the materials in a non-English language or accessible format or when otherwise

learning of the enrollee's primary language and/or need for an accessible format. This requirement also applies to the individualized plans of care described in § 422.101(f)(1)(ii) of this chapter for special needs plan enrollees.

(4) For any fully integrated dual eligible special needs plan or highly integrated dual eligible special needs plan as defined at § 422.2 of this chapter, or applicable integrated plan as defined at § 422.561 of this chapter, be translated into the language(s) required by the Medicaid translation standard as specified through their capitated Medicaid managed care contract in addition to the language(s) required by the Medicare translation standard in paragraph (a)(2) of this section.

(5) Be provided to the beneficiary within CMS's specified timeframes.

(b) *Standardized materials.* Standardized materials and content are required materials and content that must be used in the form and manner provided by CMS.

(1) When CMS issues standardized material or content, a Part D sponsor must use the document without alteration except for the following:

(i) Populating variable fields.

(ii) Correcting grammatical errors.

(iii) Adding customer service phone numbers.

(iv) Adding plan name, logo, or both.

(v) Deleting content that does not pertain to the plan type (for example, removing MA language for a Part D plan).

(vi) Adding the SMID.

(vii) A Notice of Privacy Practices as required under the HIPAA Privacy Rule (45 CFR 164.520).

(2) When CMS issues standardized content, Part D sponsors—

(3) The Part D sponsor may develop accompanying language for standardized material or content, provided that language does not conflict with the standardized material or content. For example, CMS may issue standardized content associated with an appeal notification and Part D sponsor may draft a letter that includes the standardized content in the body of the letter; the remaining language in the letter is at the sponsor's discretion, provided it does not conflict with the standardized content or other regulatory standards.

(c) *Model materials.* Model materials and content are those required materials and content created by CMS as an example of how to convey beneficiary information. When drafting required materials or content based on CMS models, Part D sponsors:

(1) Must accurately convey the vital information in the required material or content to the beneficiary, although the Part D sponsor is not required to use CMS model materials or content verbatim; and

(2) Must follow CMS's specified order of content, when specified.

(d) *Delivery of required materials.* Part D sponsors must mail required materials in hard copy or provide them electronically, following the requirements in paragraphs (d)(1) and (2) of this section.

(1) For hard copy mailed materials, each enrollee must receive his or her own copy, except in cases of non-beneficiary-specific material(s) where the Part D sponsor has determined multiple enrollees are living in the same household and it has reason to believe the enrollees are related. In that case, the Part D sponsor may mail one copy to the household. The Part D sponsor must provide all enrollees an opt-out process so the enrollees can each receive his or her own copy, instead of a copy to the household. Materials specific to an individual beneficiary must always be mailed to that individual.

(2) Materials may be delivered electronically following the requirements in paragraphs (d)(2)(i) and (ii) of this section.

(i) Without prior authorization from the enrollee, Part D sponsors may mail new and current enrollees a notice informing enrollees how to electronically access the following required materials: the Evidence of Coverage, Provider and Pharmacy Directories, and Formulary. The following requirements apply:

(A) The Part D sponsor may mail one notice for all materials or multiple notices.

(B) Notices for prospective year materials may not be mailed prior to September 1 of each year, but must be sent in time for an enrollee to access the specified materials by October 15 of each year.

(C) The Part D sponsor may send the notice throughout the year to new enrollees.

(D) The notice must include the website address to access the materials, the date the materials will be available if not currently available, and a phone number to request that hard copy materials be mailed.

(E) The notice must provide the enrollee with the option to request hardcopy materials. Requests may be material specific, and must have the option of a one-time request or a permanent request that must stay in place until the enrollee chooses to receive electronic materials again.

(F) Hard copies of requested materials must be sent within three business days of the request.

(ii) With prior authorization from the enrollee, the Part D sponsor may provide any required material or content electronically. To do so, the Part D sponsor must do all of the following:

(A) Obtain prior consent from the enrollee. The consent must specify both the media type and the specific materials being provided in that media type.

(B) Provide instructions on how and when enrollees can access the materials.

(C) Have a process through which an enrollee can request hard copies be mailed, providing the beneficiary with the option of a one-time request or a permanent request (which must stay in place until the enrollee chooses to receive electronic materials again), and with the option of requesting hard copies for all or a subset of materials. Hard copies must be mailed within three business days of the request.

(D) Have a process for automatic mailing of hard copies when electronic versions or the chosen media type is undeliverable.

(e) *CMS required materials and content.* The following are required materials that must be provided to current and prospective enrollees, as applicable, in the form and manner outlined in this section. Unless otherwise noted or instructed by CMS and subject to §423.2263(a) of this chapter, required materials may be sent once a fully executed contract is in place, but no later than the due dates listed for each material in this section.

(1) *Evidence of Coverage (EOC).* The EOC is a standardized communications material through which certain required information (under §423.128(b)) must be provided annually and must be provided:

(i) To current enrollees of plan by October 15, prior to the year to which the EOC applies.

(ii) To new enrollees within 10 calendar days from receipt of CMS confirmation of enrollment or by last day of month prior to effective date, whichever is later.

(2) *Part D explanation of benefits (EOB).* The EOB is a model communications material through which plans must provide the information required under §423.128(e). Part D sponsors must provide enrollees with an EOB no later than the end of the month following any month in which the enrollee utilized their prescription drug benefit.

(3) *Annual Notice of Change (ANOC).* The ANOC is a standardized marketing material through which plans must provide the information required under §423.128(g)(2) annually.

(i) Must send for enrollee receipt no later than September 30 of each year.

(ii) Enrollees with an October 1, November 1, or December 1 effective date must receive within 10 calendar days from receipt of CMS confirmation of enrollment or by last day of month prior to effective date, whichever is later.

(4) *Pre-enrollment checklist (PECL).* The PECL is a standardized communications material that plans must provide to prospective enrollees with the enrollment form, so that the enrollees understand important plan benefits and rules. For telephonic enrollments the contents of the PECL must be reviewed with the prospective enrollee prior to the completion of the enrollment. It references information on the following:

(i) The EOC.

(ii) Provider directory.

(iii) Pharmacy directory.

(iv) Formulary.

(v) Premiums/copayments/coinsurance.

(vi) Emergency/urgent coverage.

(vii) Plan-type rules.

(viii) Effect on current coverage.

(5) *Summary of Benefits (SB)*. Part D sponsors must disseminate a summary of highly utilized coverage that include benefits and cost sharing to prospective enrollees, known as the SB. The SB is a model marketing material. It must be in a clear and accurate format.

(i) The SB must be provided with an enrollment form as follows:

(A) In hardcopy with a paper enrollment form.

(B) For online enrollment, the SB must be made available electronically (for example, via a link) prior to the completion and submission of enrollment request.

(C) For telephonic enrollment, the beneficiary must be verbally told where the SB can be accessed.

(ii) The SB must include the following information:

(A) Information on prescription drug expenses, including:

(*1*) Monthly plan premium

(*2*) Deductible, the initial coverage phase, coverage gap, and catastrophic coverage.

(*3*) A statement that costs may differ based on pharmacy type or status (for example, preferred/non-preferred, mail order, long-term care (LTC) or home infusion, and 30- or 90-day supply), when applicable.

(*4*) For dual eligible enrollees with differing levels of cost must state how cost sharing and benefits differ depending on the level of Medicaid eligibility.

(B) Plan sponsors may describe or identify other health related benefits in the SB.

(6) *Enrollment/Election form*. This is the model communications material through which plans must provide the information required under § 423.32(b).

(7) *Enrollment Notice*. This is a model communications material through which plans must provide the information required under § 423.32(d).

(8) *Disenrollment Notice*. This is a model communications material through which plans must provide the information required under § 423.36(b)(2).

(9) *Formulary*. This is a model communications material through which Part D sponsors must provide information required under § 423.128(b)(4).

(i) Must be provided to current enrollees of plan by October 15 of each year.

(ii) Must also provide to new enrollees within 10 calendar days from receipt of CMS confirmation of enrollment or by last day of month prior to effective date, whichever is later.

(10) *Low Income Subsidy (LIS) Notice*. This is a model communications content through which Part D sponsors must notify potential enrollees of what their plan premium will be once they are eligible for Extra Help and receive the low-income subsidy.

(11) *Low Income Subsidy (LIS) Rider*. This is a model communications material provided to all enrollees who qualify for Extra Help. In the LIS Rider, the Part D sponsors must convey how much help the beneficiary will receive in the benefit year toward their Part D premium, deductible, and copayments provide to all beneficiaries who qualify for Extra Help.

(i) The LIS Rider must be provided at least once per year by September 30.

(ii) The LIS Rider must be sent to enrollees who qualify for Extra Help or have a change in LIS levels within 30 days of receiving notification from CMS.

(12) *Midyear Change Notification*. This is a model communications material through which plans must provide a notice to enrollees when there is a midyear change in benefits or plan rules, under the following timelines:

(i) Notices of changes in plan rules, unless otherwise addressed elsewhere in the regulation, must be provided 30 days in advance.

(ii) National Coverage Determination (NCD) changes announced or finalized less than 30 days before effective date, a notification is required as soon as possible.

(iii) Midyear NCD or legislative changes must be provided no later than 30 days after the NCD is announced or the legislative change is effective.

(A) Plans may include the change in next plan mass mailing (for example, newsletter), provided it is within 30 days.

(B) The notice must also appear on the MA organization's website.

(13) *Non-renewal notice*. This is a standardized communications material

through which plans must provide the information required under § 423.507.

(i) The Non-renewal Notice must be provided at least 90 calendar days before the date on which the nonrenewal is effective. For contracts ending on December 31, the notice must be dated October 2 to ensure national consistency in the application of Medigap Guaranteed Issue (GI) rights to all enrollees, except for those enrollees in Medicare-Medicaid Plans (MMPs) and special needs plans (SNPs). Information about non-renewals or service area reductions may not be released to the public, including the Non-renewal Notice in this section, until CMS provides notification to the plan.

(ii) The Non-renewal Notice must do all of the following:

(A) Inform the enrollee that the plan will no longer be offered and the date the plan will end.

(B) Provide information about any applicable open enrollment periods or special election periods or both (for example, Medicare open enrollment, nonrenewal special election period), including the last day the enrollee has to make a Medicare prescription drug plan selection.

(C) Explain what the enrollee must do to continue receiving Medicare coverage and what will happen if the enrollee chooses to do nothing.

(D) As required under § 423.507(a)(2)(ii)(A), provide a CMS-approved written description of alternative MA plan, MA–PD plan, and PDP options available for obtaining qualified Medicare services within the beneficiary's region in the enrollee's notice.

(E) Specify when coverage will start after a new Medicare plan is chosen.

(F) List 1–800–MEDICARE contact information together with other organizations that may be able to assist with comparing plans (for example, SHIPs).

(G) Include the Part D sponsor's call center telephone number, TTY number, and hours and days of operation.

(14) *Part D Transition Letter*. This is a model communications material that must be provided to the beneficiary when they receive a transition fill for a nonformulary drug. The Part D Transition Letter must be sent within three days of adjudication of temporary transition fill.

(15) *Pharmacy Directory*. This is a model communications material through which Part D sponsors must provide the information required under § 423.128. The pharmacy directory must meet all of the following:

(i) Be provided to current enrollees by October 15 of the year prior to the applicable year.

(ii) Be provided to new enrollees within 10 calendars days from receipt of CMS confirmation of enrollment or by last day of month prior to effective date, whichever is later.

(iii) Be provided to current enrollees upon request, within three business days of the request.

(iv) Be updated any time the Part D sponsor becomes aware of changes.

(A) All updates to the online pharmacy directories must be completed within 30 days of receiving information requiring update.

(B)(*1*) Updates to hardcopy provider directories must be completed within 30 days.

(*2*) Hardcopy directories that include separate updates via addenda are considered up-to-date.

(16) *Prescription transfer letter*. This is a model communications material that must be sent when a Part D sponsor requests permission from an enrollee to fill a prescription at a different network pharmacy than the one currently being used by enrollee.

(17) *Star Ratings Document*. This is a standardized marketing material through which Star Ratings information is conveyed to prospective enrollees.

(i) The Star Ratings Document is generated through HPMS.

(ii) The Star Ratings Document must be provided with an enrollment form as follows:

(A) In hardcopy with a paper enrollment form.

(B) For online enrollment, made available electronically (for example, via a link) prior to the completion and submission of enrollment request.

(C) For telephonic enrollment, the beneficiary must be verbally told where they can access the Star Ratings Document.

(iii) New Part D sponsors that have no Star Ratings are not required to

provide the Star Ratings Document until the following contract year.

(iv) Updated Star Ratings must be used within 21 calendar days of release of updated information on Medicare Plan Finder.

(v) Updated Star Ratings must not be used until CMS releases Star Ratings on Medicare Plan Finder.

(18) *Coverage Determination Notices.* This is a model communications material through which plans must provide the information under § 423.568.

(19) *Excluded Provider Notices.* This is a model communications material through which plans must notify enrollees when a provider they use has been excluded from participating in the Medicare program based on an OIG exclusion or the CMS preclusion list.

(20) *Notice of Denial of Medicare Prescription Drug Coverage.* This is a standardized material used to convey detailed descriptions of denied drug coverage and appeal rights.

(21) *Medicare Prescription Drug Coverage and Your Rights.* This is a standardized communications material used to convey a beneficiary's appeal rights when a drug cannot be filled at point-of-sale.

(22) *Medicare Part D Coverage Determination Request Form.* This is a model communications material used to collect additional information from a prescriber.

(23) *Request for Additional Information.* This is a standardized communications material used by the Part D sponsor to request a beneficiary obtain additional information from the prescriber regarding a beneficiary's exception request.

(24) *Notice of Right to an Expedited Grievance.* This is a model communications material used to convey a Medicare beneficiary's rights to request that a decision be made on a grievance or appeal within a shorter timeframe.

(25) *Notice of Inquiry.* This is a model communications material from a prescription drug plan informing a beneficiary if a drug is covered by the formulary.

(26) *Notice of Case Status.* This is a model communications material used to inform a beneficiary of the denial of an appeal and additional appeal rights.

(27) *Request for Reconsideration of Medicare Prescription Drug Denial.* This is a model communications material used to inform the beneficiary of rights to an independent review of a Part D sponsor's decision.

(28) *Notice of Redetermination.* This is a model communications material used to convey instructions for requesting an appeal of an adverse coverage determination.

(29) *LEP Reconsideration Request Form.* This is a model communication used to request an appeal of a decision on an LEP by the independent review entity.

(30) *Request for Administrative Law Judge (ALJ) Hearing or Review of Dismissal.* This is a model communication used by an enrollee to request a hearing by the ALJ or a review of the IRE dismissal.

(31) *Appointment of Representative (AOR).* This is a standardized material used to assign an individual to act on behalf of a beneficiary for the purpose of an appeal, grievance, or coverage determination.

(32) *Member ID card.* The member ID card is a model communications material that plans must provide to enrollees as required under § 423.128(d)(2). The member ID card—

(i) Must be provided to new enrollees within 10 calendars days from receipt of CMS confirmation of enrollment or by the last day of month prior to the plan effective date, whichever is later;

(ii) Must include the Part D sponsor's—

(A) Website address;

(B) Customer service number (the member ID card is excluded from the hours of operations requirement under § 423.2262(c)(1)(i)); and

(C) Contract/PBP number;

(iii) Must include, if issued for a preferred provider organization (PPO) and PFFS plan, the phrase ''Medicare limiting charges apply.'';

(iv) May not use a member's Social Security number (SSN), in whole or in part;

(v) Must be updated whenever information on a member's existing card changes; in such cases an updated card must be provided to the member;

(vi) Is excluded from the translation requirement under paragraphs (a)(2) through (4) of this section;

(vii) Is excluded from the 12-point font size requirement under paragraph (a)(1) of this section; and

(viii) For dual eligible special needs plans that are applicable integrated plans, as defined in § 422.561 of this chapter, must be an integrated member ID card that serves as the ID card for both the Medicare and Medicaid plans in which the enrollee is enrolled, beginning no later than contract year 2027.

(33) *Notice of availability of language assistance services and auxiliary aids and services (Notice of Availability).*

(i) Prior to contract year 2026 marketing on September 30, 2025, the notice is referred to as the *Multi-language insert (MLI).* This is a standardized communications material which states, ''We have free interpreter services to answer any questions you may have about our health or drug plan. To get an interpreter, just call us at [1–xxx–xxx–xxxx]. Someone who speaks [language] can help you. This is a free service.'' in the following languages: Spanish, Chinese, Tagalog, French, Vietnamese, German, Korean, Russian, Arabic, Italian, Portuguese, French Creole, Polish, Hindi, and Japanese.

(A) Additional languages that meet the 5-percent service area threshold, as required under paragraph (a)(2) of this section, must be added to the MLI used in that service area. A plan may also opt to include in the MLI any additional language that do not meet the 5 percent service area threshold, where it determines that this inclusion would be appropriate.

(B) Except where otherwise provided in paragraph (e)(33)(i)(G) of this section, the MLI must be provided with all required materials under paragraph (e) of this section.

(C) The MLI may be included as a part of the required material or as a standalone material in conjunction with the required material.

(D) When used as a standalone material, the MLI may include organization name and logo.

(E) When mailing multiple required materials together, only one MLI is required.

(F) The MLI may be provided electronically when a required material is provided electronically as permitted under paragraph (d)(2) of this section.

(G) At plan option for CY 2025 marketing and communications beginning September 30, 2024, the plan may use the model notice described in § 423.2267(e)(33)(ii) to satisfy the MLI requirements set forth in paragraph (e)(33)(i) of this section.

(ii) For CY 2026 marketing and communications beginning September 30, 2025, the required notice is referred to as the *Notice of availability of language assistance services and auxiliary aids and services (Notice of Availability).* This is a model communications material through which MA organizations must provide a notice of availability of language assistance services and auxiliary aids and services that, at a minimum, states that the MA organization provides language assistance services and appropriate auxiliary aids and services free of charge.

(A) This notice of availability of language assistance services and auxiliary aids and services must be provided in English and at least the 15 languages most commonly spoken by individuals with limited English proficiency of the relevant State or States associated with the plan's service area and must be provided in alternate formats for individuals with disabilities who require auxiliary aids and services to ensure effective communication.

(B) If there are additional languages in a particular service area that meet the 5 percent service area threshold, described in paragraph (a)(2) of this section, beyond the languages described in paragraph (e)(33)(i) of this section, the notice of availability of language assistance services and auxiliary aids and services must also be translated into those languages. MA organizations may also opt to translate the notice in any additional languages that do not meet the 5-percent service area threshold, where the MA organization determines that this inclusion would be appropriate.

(C) The notice must be provided with all required materials under paragraph (e) of this section.

(D) The notice may be included as a part of the required material or as a standalone material in conjunction with the required material.

(E) When used as a standalone material, the notice may include organization name and logo.

(F) When mailing multiple required materials together, only one notice is required.

(G) The notice may be provided electronically when a required material is provided electronically as permitted under paragraph (d)(2) of this section.

(34) *Federal Contracting Statement*. This is model content through which plans must convey that they have a contract with Medicare and that enrollment in the plan depends on contract renewal.

(i) The Federal Contracting Statement must include all of the following:

(A) Legal or marketing name of the organization.

(B) Type of plan (for example PDP).

(C) A statement that the organization has a contract with Medicare (when applicable, Part D sponsors may incorporate a statement that the organization has a contract with the State/Medicaid program).

(D) A statement that enrollment depends on contract renewal.

(ii) Part D sponsors must include the Federal Contracting Statement on all marketing materials with the exception of the following:

(A) Banner and banner-like advertisements.

(B) Outdoor advertisements.

(C) Text messages.

(D) Social media.

(E) Envelopes

(35) *Star Ratings Disclaimer*. This is model content through which plans must:

(i) Convey that plan sponsors are evaluated yearly by Medicare

(ii) Convey that the ratings are based on a 5-star rating system

(iii) Include the model content in disclaimer form or within the material whenever Star Ratings are mentioned in marketing materials, with the exception of when Star Ratings are published on small objects (that is, a give-away items such as a pens or rulers).

(36) *Accommodations Disclaimer*. This is model content through which plans must:

(i) Convey that accommodations for persons with special needs is available

(ii) Provide a telephone number and TTY number

(iii) Include the model content in disclaimer form or within the body of the material on any advertisement of invitation to all events as described under § 423.2264(c).

(37) *Mailing Statements*. This is standardized content. It consists of statements on envelopes that Part D sponsor must include when mailing information to current members, as follows:

(i) Part D sponsors must include the following statement when mailing information about the enrollee's current plan: ''Important [Insert Plan Name] information.''

(ii) Part D sponsors must include the following statement when mailing health and wellness information ''Health and wellness or prevention information.''

(iii) The Part D sponsor must include the plan name; however, if the plan name is elsewhere on the envelope, the plan name does not need to be repeated in the disclaimer.

(iv) Delegated or sub-contracted entities and downstream entities that conduct mailings on behalf of a multiple Part D sponsors must also comply with this requirement, however, they do not have to include a plan name.

(38) *Promotional Give-Away Disclaimer*. This is model content. The disclaimer consists of a statement that must make clear that there is no obligation to enroll in a plan, and must be included when offering a promotional give-away such as a drawing, prizes, or a free gift.

(39) *Provider Co-Branded Material Disclaimer*. This is model content through which Part D sponsors must:

(i) Convey, as applicable, that other pharmacies, physicians or providers are available in the plan's network.

(ii) Include the model content in disclaimer form or within the material whenever co-branding relationships with network provider are mentioned.

(40) *Limited access to preferred cost-sharing pharmacies*. This is standardized content that must—

(i) Be used on all materials mentioning preferred pharmacies when there is limited access to preferred pharmacies; and

(ii) Include the following language: ''<insert organization/plan name>'s pharmacy network includes limited lower-cost, preferred pharmacies in <insert geographic area type(s) and state(s) for which plan is an outlier)>. The lower costs advertised in our plan materials for these pharmacies may not be available at the pharmacy you use. For up-to-date information about our network pharmacies, including whether there are any lower-cost preferred pharmacies in your area, please call <insert Member Services phone number and TTY> or consult the online pharmacy directory at <insert website>.''

(41) *Third-party marketing organization disclaimer*. This is standardized content. If a TPMO does not sell for all Part D sponsors in the service area the disclaimer consists of the statement: ''We do not offer every plan available in your area. Currently we represent [insert number of organizations] organizations which offer [insert number of plans] products in your area. Please contact *Medicare.gov*, 1–800–MEDICARE, or your local State Health Insurance Program to get information on all of your options.'' If the TPMO sells for all Part D sponsors in the service area the disclaimer consists of the statement: ''Currently we represent [insert number of organizations] organizations which offer [insert number of plans] products in your area. You can always contact *Medicare.gov*, 1–800–MEDICARE, or your local State Health Insurance Program for help with plan choices.'' The Part D sponsor must ensure that the disclaimer is as follows:

(i) Used by any TPMO, as defined under § 422.2260, that sells plans on behalf of more than one Part D sponsor.

(ii) Verbally conveyed within the first minute of a sales call.

(iii) Electronically conveyed when communicating with a beneficiary through email, online chat, or other electronic means of communication.

(iv) Prominently displayed on TPMO websites.

(v) Included in any marketing materials, including print materials and television advertisements, developed, used or distributed by the TPMO.

(42) [Reserved]

(43) *Comprehensive medication review—written summary*. This is the standardized communications material Part D sponsors must provide to all MTM program enrollees who receive a comprehensive medication review, as required under § 423.153(d)(1)(vii)(B).

(44) *Safe disposal information*. This is model communications material Part D sponsors must provide to all enrollees targeted for its MTM program, as required under § 423.153(d)(1)(vii)(E).

(45) *Election request form*. This is a model communications material that Part D sponsors must provide to allow enrollees to request to opt into the Medicare Prescription Payment Plan, as required under § 423.137(d)(10)(i).

(46) *Notice of election approval*. This is a model communications material that Part D sponsors must provide upon accepting a Medicare Prescription Payment Plan election request, as required under § 423.137(d)(10)(ii).

(47) *Medicare Prescription Payment Plan Likely to Benefit Notice*. This is a standardized communications material that Part D sponsors must provide to enrollees identified as being likely to benefit from opting into the Medicare Prescription Payment Plan, as required under § 423.137(e)(4).

(48) *Notice of failure to pay*. This is a model communications material that Part D sponsors must provide to Medicare Prescription Payment Plan participants who fail to pay a program bill, as required under § 423.137(f)(2)(ii)(C).

(49) *Involuntary termination notice*. This is a model communications material that Part D sponsors must provide to Medicare Prescription Payment Plan participants who are being involuntarily terminated from the program due to failure to pay, as required under § 423.137(f)(2)(ii)(D).

(50) *Voluntary termination notice*. This is a model communications material that Part D sponsors must provide to Medicare Prescription Payment Plan participants who request to voluntarily leave the program, as required under § 423.137(f)(2)(i)(A)(*2*).

(51) *Renewal notice*. This is a model communications material that Part D sponsors must send to Medicare Prescription Payment Plan participants alerting them that their participation

in the program will automatically renew for the subsequent plan year, as required under § 423.137(d)(10)(iv).

[86 FR 6126, Jan. 19, 2021, as amended at 86 FR 29528, June 2, 2021; 87 FR 27901, May 9, 2022; 88 FR 22341, Apr. 12, 2023; 88 FR 34780, May 31, 2023; 89 FR 30842, Apr. 23, 2024; 90 FR 15920, Apr. 15, 2025]

§ 423.2272 Licensing of marketing representatives and confirmation of marketing resources.

In its marketing, the Part D organization must—

(a) Demonstrate to CMS's satisfaction that marketing resources are allocated to marketing to the disabled Medicare population as well as beneficiaries age 65 and over.

(b) Establish and maintain a system for confirming that enrolled beneficiaries have in fact enrolled in the PDP and understand the rules applicable under the plan.

(c) Employ as marketing representatives only individuals who are licensed by the State to conduct direct marketing activities (as defined in the Medicare Marketing Guidelines) in that State, and whom the sponsor has informed that State it has appointed, consistent with the appointment process provided for under State law.

(d) Report to the State in which the MAO appoints an agent or broker, the termination of any such agent or broker, including the reasons for such termination if State law requires that the reasons for the termination be reported.

(e) Establish and implement an oversight plan that monitors agent and broker activities, identifies non-compliance with CMS requirements, and reports non-compliance to CMS.

[73 FR 54222, Sept. 18, 2008, as amended at 73 FR 54253, Sept. 18, 2008; 76 FR 21577, Apr. 15, 2011; 83 FR 16755, Apr. 16, 2018; 88 FR 22341, Apr. 12, 2023]

§ 423.2274 Agent, broker, and other third-party requirements.

If a Part D sponsor uses agents and brokers to sell its Medicare Part D plans, the requirements in paragraphs (a) through (e) of this section are applicable. If a Part D sponsor makes payments to third parties, the requirements in paragraph (f) of this section are applicable.

(a) *Definitions.* For purposes of this section, the following definitions are applicable:

Compensation. (i) Includes monetary or non-monetary remuneration of any kind relating to the sale, renewal, or services related to a plan or product offered by a Part D sponsor including, but not limited to the following:

(A) Commissions.

(B) Bonuses.

(C) Gifts.

(D) Prizes or Awards.

(E) Beginning with contract year 2025, payment of fees to comply with state appointment laws, training, certification, and testing costs.

(F) Beginning with contract year 2025, reimbursement for mileage to, and from, appointments with beneficiaries.

(G) Beginning with contract year 2025, reimbursement for actual costs associated with beneficiary sales appointments such as venue rent, snacks, and materials.

(H) Beginning with contract year 2025, any other payments made to an agent or broker that are tied to enrollment, related to an enrollment in a Part D plan or product, or for services conducted as a part of the relationship associated with the enrollment into a Part D plan or product.

(ii) Does not include any of the following:

(A) Payment of fees to comply with State appointment laws, training, certification, and testing costs.

(B) Reimbursement for mileage to, and from, appointments with beneficiaries.

(C) Reimbursement for actual costs associated with beneficiary sales appointments such as venue rent, snacks, and materials.

Fair market value (FMV) means, for purposes of evaluating agent or broker compensation under the requirements of this section only, the amount that CMS determines could reasonably be expected to be paid for an enrollment or continued enrollment into a Part D plan. Beginning January 1, 2021, the national FMV is 81. In contract year 2025, there will be a one-time increase of $100

to the FMV to account for administrative payments included under the compensation rate. For subsequent years, FMV is calculated by adding the current year FMV and the produce of the current year FMV and Annual Percentage Increase for Part D, which is published for each year in the rate announcement issued under § 422.312.

Initial enrollment year means the first year that a beneficiary is enrolled in a plan versus subsequent years (c.f., *renewal year*) that a beneficiary remains enrolled in a plan.

Like plan type means one of the following:

(i) PDP replaced with another PDP.

(ii) MA or MA–PD replaced with another MA or MA–PD.

(iii) Cost plan replaced with another cost plan.

Plan year and *enrollment year* mean the year beginning January 1 and ending December 31.

Renewal year means all years following the initial enrollment year in the same plan or in different plan that is a like plan type.

Unlike plan type means one of the following:

(i) An MA or MA–PD plan to a PDP or Section 1876 Cost Plan.

(ii) A PDP to a Section 1876 Cost Plan or an MA or MA–PD plan.

(iii) A Section 1876 Cost Plan to an MA or MA–PD plan or PDP.

(b) *Agent/broker requirements.* Agents and brokers who represent Part D sponsors must follow the requirements in paragraphs (b)(1) through (3) of this section. Representation includes selling products (including Medicare Advantage plans, Medicare Advantage-Prescription Drug plans, Medicare Prescription Drug plans, and section 1876 Cost plans) as well as outreach to existing or potential beneficiaries and answering or potentially answering questions from existing or potential beneficiaries.

(1) Be licensed and appointed under State law (if required under applicable State law).

(2) Be trained and tested annually as required under paragraph (c)(4) of this section, and achieve an 85 percent or higher on all forms of testing.

(3) Secure and document a Scope of Appointment prior to meeting with potential enrollees.

(c) *Part D sponsor oversight.* Part D sponsors must oversee first tier, downstream, and related entities that represent Part D sponsor to ensure agents and brokers abide by all applicable State and Federal laws, regulations, and requirements. Part D sponsors must do all of the following:

(1) As required under applicable State law, employ as marketing representatives only individuals who are licensed by the State to conduct marketing (as defined in this subpart) of health insurance in that State, and whom the Part D sponsor has informed that State it has appointed, consistent with the appointment process for agents and brokers provided for under State law.

(2) As required under applicable State law, report the termination of an agent or broker to the State and the reason for termination if required by state law.

(3) Report to CMS all enrollments made by unlicensed agents or brokers and for-cause terminations of agents or brokers.

(4) On an annual basis, provide training and testing to agents and brokers on Medicare rules and regulations, the plan products that agents and brokers will sell including any details specific to each plan product, and relevant State and Federal requirements.

(5) On an annual basis for plan years through 2024, by the last Friday in July, report to CMS whether the MA organization intends to use employed, captive, or independent agents or brokers in the upcoming plan year and the specific rates or range of rates the plan will pay independent agents and brokers. Following the reporting deadline, MA organizations may not change their decisions related to agent or broker type, or their compensation rates and ranges, until the next plan year.

(6) On an annual basis by October 1, have in place full compensation structures for the following plan year. The structure must include details on compensation dissemination, including specifying payment amounts for initial enrollment year and renewal year compensation.

(7) Submit agent or broker marketing materials to CMS through HPMS prior to use, following the requirements for marketing materials in this subpart.

(8) Ensure beneficiaries are not charged marketing consulting fees when considering enrollment in Part D plans.

(9) Establish and maintain a system for confirming that:

(i) Beneficiaries enrolled by agents or brokers understand the product, including the rules applicable under the plan.

(ii) Agents and brokers appropriately complete Scope of Appointment records for all marketing appointments (including telephonic and walk-in).

(10) Demonstrate that marketing resources are allocated to marketing to the disabled Medicare population as well as to Medicare beneficiaries age 65 and over.

(11) Must comply with State requests for information about the performance of a licensed agent or broker as part of a state investigation into the individual's conduct. CMS will establish and maintain a memorandum of understanding (MOU) to share compliance and oversight information with States that agree to the MOU.

(12) Ensure that, prior to an enrollment CMS' required questions and topics regarding beneficiary needs in a health plan choice are fully discussed. Topics include information regarding pharmacies (that is, whether or not the beneficiary's current pharmacy is in the plan's network), prescription drug coverage and costs (including whether or not the beneficiary's current prescriptions are covered), premiums, and other services or incentives.

(13) Beginning with contract year 2025, ensure that no provision of a contract with an agent, broker, or other TPMO has a direct or indirect effect of creating an incentive that would reasonably be expected to inhibit an agent or broker's ability to objectively assess and recommend which plan best fits the health care needs of a beneficiary.

(d) *Compensation requirements.* Part D sponsors must ensure they meet the requirements in paragraphs (d)(1) through (5) of this section in order to pay compensation. These compensation requirements only apply to independent agents and brokers.

(1) *General rules.* (i) MA organizations may only pay agents or brokers who meet the requirements in paragraph (b) of this section.

(ii) For contract years through contract year 2024, Part D sponsors may determine, through their contracts, the amount of compensation to be paid, provided it does not exceed limitations outlined in this section. Beginning with contract year 2025, Part D sponsors are limited to the compensation amounts outlined in this section.

(iii) Part D sponsors may determine their payment schedule (for example, monthly or quarterly). Payments (including payments for AEP enrollments) must be made during the year of the beneficiary's enrollment.

(iv) Part D sponsors may only pay compensation for the number of months a member is enrolled.

(2) Initial enrollment year compensation. For each enrollment in an initial enrollment year for contract years through contract year 2024, Part D sponsors may pay compensation at or below FMV.

(i) Part D sponsors may pay either a full or pro-rated initial enrollment year compensation for:

(A) A beneficiary's first year of enrollment in any plan; or

(B) A beneficiary's move from an employer group plan to a non-employer group plan (either within the same parent organization or between parent organizations).

(ii) Part D sponsors must pay prorated initial enrollment year compensation for:

(A) A beneficiary's plan change(s) during their initial enrollment year.

(B) A beneficiary's selection of an ''unlike plan type'' change. In that case, the new plan would only pay the months that the beneficiary is enrolled, and the previous plan would recoup the months that the beneficiary was not in the plan.

(3) *Renewal compensation.* For each enrollment in a renewal year for contract years through contract year 2024, Part D sponsors may pay compensation at a rate of up to 50 percent of FMV. For contract years beginning with contract year 2025, for each enrollment in

a renewal year, MA organizations may pay compensation at 50 percent of FMV.

(i) Part D sponsors may pay compensation for a renewal year:

(A) In any year following the initial enrollment year the beneficiary remains in the same plan; or

(B) When a beneficiary enrolls in a new ''like plan type''.

(ii) [Reserved]

(4) *Other compensation scenarios.* (i) When a beneficiary enrolls in a PDP, the Part D sponsor may pay only the PDP compensation (and not compensation for MA enrollment under § 422.2274 of this chapter).

(ii) When a beneficiary enrolls in both a section 1876 Cost Plan and a stand-alone PDP, the 1876 Cost Plan sponsor may pay compensation for the cost plan enrollment and the Part D sponsor must pay compensation for the Part D enrollment.

(iii) When a beneficiary enrolls in a MA-only plan and a PDP, the MA plan may pay for the MA plan enrollment and the Part D sponsor may pay for the PDP enrollment.

(5) *Additional compensation, payment, and compensation recovery requirements (Charge-backs).* (i) Part D sponsors must retroactively pay or recoup funds for retroactive beneficiary changes for the current and previous calendar years. Part D sponsors may choose to recoup or pay compensation for years prior to the previous calendar year, but they must do both (recoup amounts owed and pay amounts due) during the same year.

(ii) Compensation recovery is required when:

(A) A beneficiary makes any plan change (regardless of the parent organization) within the first three months of enrollment (known as rapid disenrollment), except as provided in paragraph (d)(5)(iii) of this section.

(B) Any other time period a beneficiary is not enrolled in a plan, but the plan paid compensation based on that time period.

(iii) Rapid disenrollment compensation recovery does not apply when:

(A) A beneficiary enrolls effective October 1, November 1, or December 1 and subsequently uses the Annual Election Period to change plans for an effective date of January 1.

(B) A beneficiary's enrollment change is not in the best interests of the Medicare program, including for the following reasons:

(*1*) Other creditable coverage (*for example*, an employer plan).

(*2*) Moving into or out of an institution.

(*3*) Gain or loss of employer/union sponsored coverage.

(*4*) Plan termination, non-renewal, or CMS imposed sanction.

(*5*) To coordinate with Part D enrollment periods or the State Pharmaceutical Assistance Program.

(*6*) Becoming LIS or dually eligible for Medicare and Medicaid.

(*7*) Qualifying for another plan based on special needs.

(*8*) Due to an auto, facilitated, or passive enrollment.

(*9*) Death.

(*10*) Moving out of the service area.

(*11*) Non-payment of premium.

(*12*) Loss of entitlement or retroactive notice of entitlement.

(*13*) Moving into a 5-star plan.

(*14*) Moving from an LPI plan into a plan with three or more stars.

(iv)(A) When rapid disenrollment compensation recovery applies, the entire compensation must be recovered.

(B) For other compensation recovery, plans must recover a pro-rated amount of compensation (whether paid for an initial enrollment year or renewal year) from an agent or broker equal to the number of months not enrolled.

(*1*) If a plan has paid full initial compensation, and the enrollee disenrolls prior to the end of the enrollment year, the total number of months not enrolled (including months prior to the effective date of enrollment) must be recovered from the agent or broker.

(*2*) Example: A beneficiary enrolls upon turning 65 effective April 1 and disenrolls September 30 of the same year. The plan paid full initial enrollment year compensation. Recovery is equal to 6/12ths of the initial enrollment year compensation (for January through March and October through December).

(e) *Payments other than compensation (administrative payments).* (1) For contract years through contract year 2024,

payments for services other than enrollment of beneficiaries (for example, training, customer service, agent recruitment, operational overhead, or assistance with completion of health risk assessments) must not exceed the value of those services in the marketplace.

(2) Beginning with contract year 2025, administrative payments are included in the calculation of enrollment-based compensation.

(f) *Payments for referrals.* Payments may be made to individuals for the referral (including a recommendation, provision, or other means of referring beneficiaries), recommendation, provision, or other means of referring beneficiaries to an agent, broker or other entity for potential enrollment into a plan. The payment may not exceed $100 for a referral into an MA or MA–PD plan and $25 for a referral into a PDP plan.

(g) *TPMO oversight.* In addition to any applicable FDR requirements under § 423.505(i), when doing business with a TPMO, either directly or indirectly through a downstream entity, Part D sponsor must implement the following as a part of their oversight of TPMOs:

(1) When TPMOs is not otherwise an FDR, the Part D sponsor is responsible for ensuring that the TPMO adheres to any requirements that apply to the Part D sponsor.

(2) Contracts, written arrangements, and agreements between the TPMO and a Part D plan, or between a TPMO and a Part D plan's FDR, must ensure the TPMO:

(i) Discloses to the plan any subcontracted relationships used for marketing, lead generation, and enrollment.

(ii) Record all marketing, sales, and enrollment calls, including the audio portion of calls occurring via web-based technology, in their entirety.

(iii) Report to plans monthly any staff disciplinary actions or violations of any requirements that apply to the Part D sponsor associated with beneficiary interaction to the plan.

(iv) Use the TPMO disclaimer as required under § 423.2267(e)(41).

(3) Ensure that the TPMO, when conducting lead generating activities, either directly or indirectly for a Part D sponsor, must, when applicable:

(i) Disclose to the beneficiary that his or her information will be provided to a licensed agent for future contact. This disclosure must be provided:

(A) Verbally when communicating with a beneficiary through telephone;

(B) In writing when communicating with a beneficiary through mail or other paper; and

(C) Electronically when communicating with a beneficiary through email, online chat, or other electronic messaging platform.

(ii) When applicable, disclose to the beneficiary that he or she is being transferred to a licensed agent who can enroll him or her into a new plan.

(4) Beginning October 1, 2024, personal beneficiary data collected by a TPMO for marketing or enrolling them into a Part D plan may only be shared with another TPMO when prior express written consent is given by the beneficiary. Prior express written consent from the beneficiary to share the information and be contacted for marketing or enrollment purposes must be obtained through a clear and conspicuous disclosure that lists each entity receiving the data and allows the beneficiary to consent or reject to the sharing of their data with each individual TPMO.

[86 FR 6129, Jan. 19, 2021, as amended at 87 FR 27901, May 9, 2022; 88 FR 22342, Apr. 12, 2023; 89 FR 30842, Apr. 23, 2024]

§ 423.2276 Employer group retiree marketing.

Part D sponsors may develop marketing materials designed for members of an employer group who are eligible for employer-sponsored benefits through the Part D sponsor, and furnish these materials only to the group members. These materials are not subject to CMS prior review and approval.

Subpart W—Medicare Coverage Gap Discount Program

SOURCE: 77 FR 22172, Apr. 12, 2012, unless otherwise noted.

§ 423.2300 Scope.

This subpart implements provisions included in sections 1860D–14A and

1860D–43 of the Act. This subpart sets forth requirements regarding the following:

(a) Condition for coverage of applicable drugs under Part D.

(b) The Medicare Coverage Gap Discount Program Agreement.

(c) Coverage gap discount payment processes for Part D sponsors.

(d) Provision of applicable discounts on applicable drugs for applicable beneficiaries.

(e) Manufacturer audit and dispute resolution processes.

(f) Resolution of beneficiary disputes involving coverage gap discounts.

(g) Compliance monitoring and civil money penalties.

(h) The termination of the Discount Program Agreement.

§ 423.2305 Definitions.

As used in this subpart, unless otherwise specified—

Applicable discount means 50 percent or, with respect to a plan year after plan year 2018, 70 percent of the portion of the negotiated price (as defined in this section) of the applicable drug of a manufacturer that falls within the coverage gap and that remains after such negotiated price is reduced by any supplemental benefits that are available.

Applicable number of calendar days means, with respect to claims for reimbursement submitted electronically, 14 days, and otherwise, 30 days.

Date of dispensing means the date of service.

Labeler code means the first segment of the Food and Drug Administration national drug code (NDC) that identifies a particular manufacturer.

Manufacturer means any entity which is engaged in the production, preparation, propagation, compounding, conversion or processing of prescription drug products, either directly or indirectly, by extraction from substances of natural origin, or independently by means of chemical synthesis, or by a combination of extraction and chemical synthesis. For purposes of the Discount Program, such term does not include a wholesale distributor of drugs or a retail pharmacy licensed under State law, but includes entities otherwise engaged in repackaging or changing the container, wrapper, or labeling of any applicable drug product in furtherance of the distribution of the applicable drug from the original place of manufacture to the person who makes the final delivery or sale to the ultimate consumer or user.

Medicare Coverage Gap Discount Program (or Discount Program) means the Medicare coverage gap discount program established under section1860D–14A of the Act.

Medicare Coverage Gap Discount Program Agreement (or Discount Program Agreement) means the agreement described in section 1860D–14A(b) of the Act.

Medicare Part D discount information means the information sent from CMS or the TPA to the manufacturer along with each quarterly invoice that is derived from applicable data elements available on prescription drug events as determined by CMS.

National Drug Code (NDC) means the unique identifying prescription drug product number that is listed with the Food and Drug Administration (FDA) identifying the product and package size and type.

Negotiated price for purposes of the Discount Program, means the price for a covered Part D drug that—

(1) The Part D sponsor (or other intermediary contracting organization) and the network dispensing pharmacy or other network dispensing provider have negotiated as the lowest possible reimbursement such network entity will receive, in total, for a particular drug;

(i) Includes all price concessions (as defined in § 423.100) from network pharmacies or other network providers; and

(ii) Excludes additional contingent amounts, such as incentive fees, if these amounts increase prices;

(2) Is reduced by those discounts, direct or indirect subsidies, rebates, nonpharmacy price concessions, and direct or indirect remuneration that the Part D sponsor has elected to pass through to Part D enrollees at the point-of-sale; and

(3) Excludes any dispensing fee or vaccine administration fee for the applicable drug.

(4)In connection with applicable drugs dispensed by an out-of-network

provider in accordance with the applicable beneficiary's Part D plan out-of-network policies, the negotiated price means the plan allowance as set forth in § 423.124, less any dispensing fee or vaccine administration fee.

Other health or prescription drug coverage means any coverage or financial assistance under other health benefit plans or programs that provide coverage or financial assistance for the purchase or provision of prescription drug coverage on behalf of applicable beneficiaries, including, in the case of employer group health or waiver plans, other than basic prescription drug coverage as defined in § 423.100.

Third Party Administrator (TPA) means the CMS contractor responsible for administering the requirements established by the CMS to carry out section 1860D–14A of the Act.

[77 FR 22172, Apr. 12, 2012, as amended at 86 FR 6131, Jan. 19, 2021; 87 FR 27902, May 9, 2022]

§ 423.2310 Condition for coverage of drugs under Part D.

(a) *Covered Part D drug coverage requirement.* Except as specified in paragraph (b) of this section, in order for coverage to be available under Medicare Part D for applicable drugs of a manufacturer, the manufacturer must do all of the following:

(1) Participate in the Discount Program.

(2) Have entered into and have in effect an agreement described in § 423.2315(b).

(3) Have entered into and have in effect, under terms and conditions specified by CMS, a contract with the TPA.

(b) *Exception to covered drug coverage requirement.* Paragraph (a) of this section does not apply to an applicable drug if CMS has made a determination that the availability of the applicable drug is essential to the health of beneficiaries enrolled in Medicare Part D.

§ 423.2315 Medicare Coverage Gap Discount Program Agreement.

(a) *General rule.* The Medicare Coverage Gap Discount Program Agreement (or Discount Program Agreement) between the manufacturer and CMS must contain the provisions specified in paragraph (b) of this section, and may contain such other provisions as are established in a model agreement consistent with section 1860D–14A (a)(1) of the Act.

(b) *Agreement requirements.* The manufacturer agrees to the following:

(1) All the applicable requirements and conditions set forth in this part and general instructions.

(2) Reimburse all applicable discounts provided by Part D sponsors on behalf of the manufacturer for all applicable drugs having NDCs with the manufacturer's FDA-assigned labeler code(s) invoiced to the manufacturer within a maximum of 3 years of the date of dispensing based upon information reported to CMS by Part D sponsors.

(3) Pay each Part D sponsor in the manner specified by CMS within 38 calendar days of receipt of the invoice and Medicare Part D Discount Information for the applicable discounts included on the invoice, except as specified in § 423.2330(c)(3).

(4) Provide CMS with all labeler codes for all the manufacturer's applicable drugs and to promptly update such list with any additional labeler codes for applicable drugs no later than 3 business days after learning of a new code assigned by the FDA.

(5) Collect, have available, and maintain appropriate data, including data related to manufacturer's labeler codes, FDA drug approvals, FDA NDC Directory listings, NDC last lot expiration dates, utilization and pricing information relied on by the manufacturer to dispute quarterly invoices, and any other data CMS determines are necessary to carry out the Discount Program, for a period of not less than 10 years from the date of payment of the invoice.

(6) Comply with the audit and dispute resolution requirements in § 423.2330.

(7) Electronically list and maintain up-to-date electronic FDA listings of all NDCs of the manufacturer, including providing timely information about discontinued drugs to enable the publication of accurate information regarding what drugs, identified by NDC, are in current distribution.

(8) Maintain up-to-date NDC listings with the electronic database vendors

for which the manufacturer provides NDCs for pharmacy claims processing.

(9) Enter into and have in effect, under terms and conditions specified by CMS, an agreement with the TPA that has a contract with CMS under section 1860D–14(A)(d)(3) of the Act.

(10) Pay quarterly invoices directly to accounts established by Part D sponsors via electronic funds transfer, or other manner if specified by CMS, within the time period specified in paragraph (b)(3) of this section and within 5 business days of the transfer to provide the TPA with electronic documentation of such payment in a manner specified by CMS.

(11) Use information disclosed to the manufacturer on the invoice, as part of the Medicare Part D Discount Information, or upon audit or dispute only for purposes of paying the discount under the Discount Program.

(c) *Timing and length of agreement.* (1) For 2011, a manufacturer must enter into a Discount Program Agreement not later than 30 days after the date of establishment of the model Discount Program Agreement.

(2) For 2012 and subsequent years, for a Discount Program Agreement to be effective for a year, a manufacturer must enter into a Discount Program Agreement not later than January 30th of the preceding year.

(3) Unless terminated in accordance with §423.2345, the initial period of a Discount Program Agreement is 24 months and the agreement is automatically renewed for a 1-year period on January first each year for a period of 1 year thereafter.

(d) *Compliance with requirements for administration of the Program.* Each manufacturer with an agreement in effect under this subpart must comply with the requirements imposed by CMS or the third party administrator (as defined in §423.2305) for purposes of administering the program.

§423.2320 Payment processes for Part D sponsors.

(a) *Interim payments.* CMS provides monthly interim coverage gap discount program payments as necessary for Part D sponsors to advance coverage gap discounts to beneficiaries.

(b) *Coverage Gap Discount Reconciliation.* CMS reconciles interim payments with invoiced manufacturer discount amounts made available to each Part D plan's enrollee under the Discount Program.

(c) *Manufacturer bankruptcy.* In the event that a manufacturer declares bankruptcy, as described in Title 11 of the United States Code, and as a result of the bankruptcy, does not pay the quarterly invoices described in §423.2315(b)(10) used for a particular contract year's Coverage Gap Discount Reconciliation described in paragraph (b) of this section, CMS adjusts the Coverage Gap Discount Reconciliation amount of each of the affected Part D sponsors to account for the total unpaid quarterly invoiced amount owed to each of the Part D sponsors for that particular contract year being reconciled.

[77 FR 22172, Apr. 12, 2012, as amended at 80 FR 7965, Feb. 12, 2015]

§423.2325 Provision of applicable discounts.

(a) *General rule.* On behalf of the manufacturers, Part D sponsors must provide applicable beneficiaries with applicable discounts on applicable drugs at the point-of-sale.

(b) *Discount determination.* (1) Part D sponsors must determine the following:

(i) Whether an enrollee is an applicable beneficiary (as defined in §423.100).

(ii) Whether a Part D drug is an applicable drug (as defined in §423.100).

(iii) The amount of the applicable discount (as defined in §423.2305) to be provided at the point-of-sale.

(2) Part D sponsors must make retroactive adjustments to the applicable discount as necessary to reflect changes to the claim or beneficiary eligibility determined after the date of dispensing.

(3) Part D sponsors must determine whether any affected beneficiaries need to be notified by the Part D sponsor that an applicable drug is eligible for Part D coverage whenever CMS specifies a retroactive effective date for a labeler code and notify such beneficiaries.

(c) *Exception to point-of-sale requirement.* Part D sponsors must provide an applicable discount for applicable

drugs submitted by applicable beneficiaries via paper claims, including out-of-network and in-network paper claims, if such claims are payable under the Part D plan.

(d) *Collection of data.* Part D sponsors must provide CMS with appropriate data on the applicable discounts provided by the Part D sponsors in a manner specified by CMS.

(e) *Supplemental benefits.* (1) An applicable discount must be applied to beneficiary cost-sharing after supplemental benefits (as defined in § 423.100) have been applied to the claim for an applicable drug.

(2) No applicable discount is available if supplemental benefits (as defined in § 423.100) eliminate the coverage gap so that a beneficiary has zero cost-sharing.

(f) *Other health or prescription drug coverage.* An applicable discount must be applied to beneficiary cost-sharing when Part D is the primary payer before any other health or prescription drug coverage is applied.

(g) *Pharmacy prompt payment.* Part D sponsors must reimburse a network pharmacy (as defined in § 423.100) the amount of the applicable discount no later than the applicable number of calendar days after the date of dispensing of an applicable drug. For long-term care and home infusion pharmacies, the date of dispensing can be interpreted as the date the pharmacy submits the discounted claim for reimbursement.

(h) *Treatment of employer group waiver plans.* As of 2014, Part D sponsors offering employer group waiver plans must provide applicable discounts to applicable beneficiaries who are employer group waiver plan enrollees as determined consistent with the defined standard benefit.

[77 FR 22172, Apr. 12, 2012, as amended at 80 FR 7966, Feb. 12, 2015]

§ 423.2330 Manufacturer discount payment audit and dispute resolution.

(a) *Third-party Administration (TPA) audits.* (1) Manufacturers participating in the Discount Program may conduct periodic audits, no more often than annually, directly or through third parties as specified in this section.

(2) The manufacturer must provide the TPA with 60 days notice of the reasonable basis for the audit and a description of the information required for the audit.

(3) The manufacturer must have the right to audit a statistically significant sample of data and information held by the TPA that were used to determine applicable discounts for applicable drugs having NDCs with the manufacturer's FDA-assigned labeler code(s). Such data and information will be made available on-site, and with the exception of work papers, such information cannot be removed from the audit site.

(4) The auditor for the manufacturer may release only an opinion of the audit results and is prohibited from releasing other information obtained from the audit, including work papers, to its client, employer, or any other party.

(b) *Manufacturer audits.* (1) A manufacturer is subject to periodic audit by CMS no more often than annually, directly or through third parties, as specified in this section.

(2) CMS provides the manufacturer with 60 days notice of the audit and a description of the information required for the audit.

(3) CMS has the right to audit appropriate data, including data related to a manufacturer's FDA-assigned labeler codes, NDC last lot expiration dates, utilization, and pricing information relied on by the manufacturer to dispute quarterly invoices, and any other data CMS determines are necessary to carry out the Discount Program.

(c) *Dispute resolution.* (1) Manufacturers may dispute applicable discounts invoiced to the manufacturer on quarterly invoices by providing notice of the dispute to the TPA in a manner specified by CMS within 60 days of receipt of the information that is the subject of the dispute.

(2) Such notice must be accompanied by supporting evidence that is material, specific, and related to the dispute in a manner specified by CMS.

(3) The manufacturer must not withhold any invoiced discount payments pending dispute resolution with the sole exception of invoiced amounts for

applicable drugs that do not have labeler codes provided by the manufacturer to CMS in accordance with § 423.2315(b)(4). If payment is withheld in accordance with this paragraph, the manufacturer must notify the TPA and applicable Part D sponsors within 38 days of receipt of the applicable invoice that payment is being withheld for this reason.

(4) If the manufacturer receives an unfavorable determination from the TPA, or the dispute is not resolved within 60 calendar days of the TPA's receipt of the notice of dispute, the manufacturer may request review by the independent review entity contracted by CMS within—

(i) Thirty calendar days of the unfavorable determination; or

(ii) Ninety calendar days after the TPA's receipt of the notice of dispute if dispute is not resolved within 60 days, whichever is earlier.

(5) The independent review entity must make a determination within 90 calendar days of receipt of the manufacturer's request for review.

(6)(i) CMS or a manufacturer that receives an unfavorable determination from the independent review entity may request review by the CMS Administrator within 30 calendar days of receipt of the notification of such determination.

(ii) The decision of the CMS Administrator is final and binding.

(7) CMS adjusts future invoices (or implements an alternative reimbursement process if determined necessary by CMS) if the dispute is resolved in favor of the manufacturer.

[77 FR 22172, Apr. 12, 2012, as amended at 85 FR 72909, Nov. 16, 2020]

§ 423.2335 Beneficiary dispute resolution.

The Part D coverage determination and appeals process as described in §§ 423.558 through 423.638 applies to beneficiary disputes involving the availability and amount of applicable discounts under the Discount Program.

§ 423.2340 Compliance monitoring and civil money penalties.

(a) *General rule.* CMS monitors compliance by a manufacturer with the terms of the Discount Program Agreement.

(b) *Basis for imposing civil money penalties.* CMS imposes a civil money penalty (CMP) on a manufacturer that fails to provide applicable beneficiaries applicable discounts for applicable drugs of the manufacturer in accordance with the Discount Program Agreement.

(c) *Determination of the civil money penalty amounts.* CMS imposes a CMP for each failure by a manufacturer to provide an applicable discount in accordance with the Discount Program Agreement equal to the sum of the following:

(1) The amount of applicable discount the manufacturer would have paid under the Discount Program Agreement, which will then be used to pay the applicable discount that the manufacturer had failed to provide.

(2) Twenty-five percent of such amount.

(d) *Procedures for imposing civil money penalties.* If CMS makes a determination to impose a CMP described in paragraph (c) of this section, CMS sends a written notice of its decision to impose a CMP to include the following:

(1) A description of the basis for the determination.

(2) The basis for the penalty.

(3) The amount of the penalty.

(4) The date the penalty is due.

(5) The manufacturer's right to a hearing (as specified in § 423.1006).

(6) Information about where to file the request for hearing.

(e) *Collection of civil money penalties imposed by CMS.* (1) When a manufacturer does not request a hearing, CMS initiates the collection of the CMP following the expiration of the timeframe for requesting an ALJ hearing as specified in § 423.1020.

(2) If a manufacturer requests a hearing and the Administrator upholds CMS' decision to impose a CMP, CMS may initiate collection of the CMP once the Administrator's decision is final.

(f) *Other applicable provisions.* The provisions of section 1128A of the Act (except subsections (a) and (b) of section of 1128A of the Act) apply to CMPs under this section to the same extent

that they apply to a CMP or procedure under section 1128A(a) of the Act.

§ 423.2345 Termination of Discount Program Agreement.

(a)(1) CMS may terminate the Discount Program Agreement for a knowing and willful violation of the requirements of the agreement or other good cause shown in relation to the manufacturer's participation in the Discount Program.

(2) The termination must not be effective earlier than 30 days after the date of notice to the manufacturer of such termination and must not be effective prior to resolution of timely appeal requests received in accordance with paragraphs (a)(4) and (5) of this section.

(3)(i) CMS provides the manufacturer with an opportunity to cure any ground for termination for cause or to show the manufacturer is in compliance with the Discount Program Agreement within 30 calendar days of receipt of the written termination notice.

(ii) If the manufacturer cures the violation, or establishes that it was in compliance within the cure period, CMS repeals the termination notice by written notice.

(4) CMS provides upon request a manufacturer with a hearing with the hearing officer concerning such termination if requested in writing within 15 calendar days of receiving notice of the termination. The hearing takes place prior to the effective date of the termination with sufficient time for such effective date to be repealed if CMS determines appropriate.

(5)(i) CMS or a manufacturer that has received an unfavorable determination from the hearing officer may request review by the CMS Administrator within 30 calendar days of receipt of the notification of such determination.

(ii) The decision of the CMS Administrator is final and binding.

(b)(1) The manufacturer may terminate the Discount Program Agreement for any reason.

(2) Such termination is effective as of the day after the end of the calendar year if the termination occurs before January 30 of a calendar year, or as of the day after the end of the succeeding calendar year if the termination occurs on or after January 30 of a calendar year.

(c) Any termination does not affect the manufacturer's responsibility to reimburse Part D sponsors for applicable discounts incurred before the effective date of the termination.

(d) Upon the effective date of termination of the Discount Program Agreement, CMS ceases releasing data to the manufacturer except as necessary to ensure that the manufacturer reimburses applicable discounts for previous time periods in which the Discount Program Agreement was in effect, and notifies the manufacturer to destroy data files provided by CMS under the Discount Program Agreement.

(e) Manufacturer reinstatement is available only upon payment of any and all outstanding applicable discounts incurred during any previous period under the Discount Program Agreement. The timing of any such reinstatement is consistent with the requirements for entering into a Discount Program Agreement under § 423.2315(c) of this subpart.

Subpart X—Requirements for a Minimum Medical Loss Ratio

SOURCE: 78 FR 31310, May 23, 2013, unless otherwise noted.

§ 423.2400 Basis and scope.

This subpart is based on sections 1857(e)(4), 1860D–12(b)(3)(D), and 1106 of the Act, and sets forth medical loss ratio requirements for Part D sponsors, financial penalties and sanctions against Part D sponsors when minimum medical loss ratios are not achieved by Part D sponsors and release of medical loss ratio data to entities outside of CMS.

[81 FR 80558, Nov. 15, 2016]

§ 423.2401 Definitions.

Non-claims costs means those expenses for administrative services that are not—

(1) Incurred claims (as provided in § 423.2420(b)(2) through (b)(4));

(2) Expenditures on quality improving activities (as provided in § 423.2430);

(3) Licensing and regulatory fees (as provided in § 423.2420(c)(2)(i)); or

(4) State and Federal taxes and assessments (as provided in § 423.2420(c)(2)(ii) and (iii)).

§ 423.2410 General requirements.

(a) For contracts beginning in 2014 or subsequent contract years, a Part D sponsor (defined at § 423.4) is required to report the information required under § 423.2460 for each contract under this part for each contract year.

(b) If CMS determines for a contract year that a Part D sponsor has an MLR for a contract that is less than 0.85, the Part D sponsor must remit to CMS an amount equal to the product of the following:

(1) The total revenue of the prescription drug plan for the contract year.

(2) The difference between 0.85 and the MLR for the contract year.

(c) If CMS determines that a Part D sponsor has an MLR for a contract that is less than 0.85 for 3 or more consecutive contract years, CMS does not permit the enrollment of new enrollees under the contract for coverage during the second succeeding contract year.

(d) If CMS determines that a Part D sponsor has an MLR for a contract that is less than 0.85 for 5 consecutive contract years, CMS terminates the contract under the authority at 423.509(b)(1) and (d) effective as of the second succeeding contract year.

[78 FR 31310, May 23, 2013; 78 FR 43821, July 22, 2013; 83 FR 16756, Apr. 16, 2018]

§ 423.2420 Calculation of medical loss ratio.

(a) *Determination of the MLR.* (1) The MLR for each contract under this part is the ratio of the numerator (as defined in paragraph (b) of this section) to the denominator (as defined in paragraph (c) of this section). An MLR may be increased by a credibility adjustment according to the rules at § 423.2440, or subject to an adjustment determined by CMS to be warranted based on exceptional circumstances for areas outside the 50 states and the District of Columbia.

(2) The MLR must reflect costs and revenues for benefits described at § 423.104(d) through (f). The MLR for MA–PD plans (defined at § 422.2 of this chapter) must also reflect costs and revenues for benefits described at § 422.100(c) of this chapter.

(b) *Determining the MLR numerator.* (1) For a contract year, the numerator of the MLR for a Part D prescription drug contract must equal the sum of paragraphs (b)(1)(i) through (iii) of this section and must be in accordance with paragraphs (b)(5) and (b)(6) of this section.

(i) Incurred claims for all enrollees, as defined in paragraphs (b)(2) through (4) of this section.

(ii) The expenditures under the contract for activities that improve health care quality, as defined in § 423.2430;

(2) *Incurred claims for prescription drug costs.* Incurred claims must include the following:

(i) Direct drug costs that are actually paid (as defined in § 423.308, which are net of prescription drug rebates and other direct or indirect remuneration as defined herein) by the Part D sponsor.

(ii) Unpaid claims reserves for the current contract year, including claims reported in the process of adjustment.

(iii) Percentage withholds from payments made to contracted providers.

(iv) Claims incurred but not reported based on past experience, and modified to reflect current conditions such as changes in exposure, claim frequency or severity.

(v) Changes in other claims-related reserves.

(vi) Claims that are recoverable for anticipated coordination of benefits.

(vii) Claims payments recoveries received as a result of subrogation.

(viii) [Reserved]

(ix) Reserves for contingent benefits and the Part D claim portion of lawsuits.

(3) Adjustments that must be deducted from incurred claims include the following:

(i) Overpayment recoveries received from providers.

(4) *Exclusions from incurred claims.* The following amounts must not be included in incurred claims:

(i) Non-claims costs, as defined in § 423.2401, which include the following:

(A) Amounts paid to third party vendors for secondary network savings.

(B) Amounts paid to third party vendors for any of the following:

(*1*) Network development.

(*2*) Administrative fees.

(*3*) Claims processing.

(*4*) Utilization management.

(C) Amounts paid, including amounts paid to a pharmacy, for professional or administrative services that do not represent compensation or reimbursement for covered services provided to an enrollee, such as the following:

(*1*) Medical record copying costs.

(*2*) Attorneys' fees.

(*3*) Subrogation vendor fees.

(*4*) Bona fide service fees.

(*5*) Compensation to any of the following:

(*i*) Paraprofessionals.

(*ii*) Janitors.

(*iii*) Quality assurance analysts.

(*iv*) Administrative supervisors.

(*v*) Secretaries to medical personnel.

(*vi*) Medical record clerks.

(D) Unsettled balances from the Medicare Prescription Payment Plan.

(ii) Amounts paid to CMS as a remittance under § 423.2410(b).

(5) Incurred claims under this part for policies issued by one Part D sponsor and later assumed by another entity must be reported by the assuming organization for the entire MLR reporting year during which the policies were assumed and no incurred claims under this part for that contract year must be reported by the ceding Part D sponsor.

(6) Reinsured incurred claims for a block of business that was subject to indemnity reinsurance and administrative agreements effective before March 23, 2010, for which the assuming entity is responsible for 100 percent of the ceding entity's financial risk and takes on all of the administration of the block, must be reported by the assuming issuer and must not be reported by the ceding issuer.

(c) *Determining the MLR denominator.* For a contract year, the denominator of the MLR for a Part D prescription drug contract must equal the total revenue under the contract. Total revenue under the contract is as described in paragraph (c)(1) of this section, net of deductions described in paragraph (c)(2) of this section, taking into account the exclusions described in and paragraph (c)(3) of this section, and be in accordance with paragraphs (c)(4) and (5) of this section.

(1) CMS' payments to the Part D sponsor for all enrollees under a contract, reported on a direct basis, including the following:

(i) Payments under § 423.329(a)(1) and (2).

(ii) Payment adjustments resulting from reconciliation per § 423.329(c)(2)(ii).

(iii) All premiums paid by or on behalf of enrollees to the Part D sponsor as a condition of receiving coverage under a Part D plan, including CMS' payments for low income premium subsidies under § 422.304(b)(2) of this chapter.

(iv) All unpaid premium amounts that a Part D sponsor could have collected from enrollees in the Part D plan(s) under the contract.

(v) All changes in unearned premium reserves.

(vi) Payments under § 423.315(e).

(2) The following amounts must be deducted from total revenue in calculating the MLR:

(i) *Licensing and regulatory fees.* Statutory assessments to defray operating expenses of any State or Federal department, such as the ''user fee'' described in section 1857(e)(2) of the Act, and examination fees in lieu of premium taxes as specified by State law.

(ii) *Federal taxes and assessments.* All Federal taxes and assessments allocated to health insurance coverage.

(iii) *State taxes and assessments.* State taxes and assessments, such as the following:

(A) Any industry-wide (or subset) assessments (other than surcharges on specific claims) paid to the State directly.

(B) Guaranty fund assessments.

(C) Assessments of State industrial boards or other boards for operating expenses or for benefits to sick employed persons in connection with disability benefit laws or similar taxes levied by States.

(D) State income, excise, and business taxes other than premium taxes.

(iv) *Community benefit expenditures.* Community benefit expenditures are payments made by a Federal income

tax-exempt Part D sponsor for community benefit expenditures as defined in paragraph (c)(2)(iii)(A) of this section, limited to the amount defined in paragraph (c)(2)(iii)(B) of this section, and allocated to a contract as required under paragraph (d)(1) of this section.

(A) Community benefit expenditures means expenditures for activities or programs that seek to achieve the objectives of improving access to health services, enhancing public health and relief of government burden.

(B) Such payment may be deducted up to the limit of either 3 percent of total revenue under this part or the highest premium tax rate in the State for which the Part D sponsor is licensed, multiplied by the Part D sponsor's earned premium for the contract.

(3) The following amounts must not be included in total revenue:

(i) The amount of unpaid premiums for which the Part D sponsor can demonstrate to CMS that it made a reasonable effort to collect.

(ii) Coverage Gap Discount Program payments under § 423.2320.

(4) Total revenue (as defined at § 423.2420(c)) of this chapter) for policies issued by one Part D sponsor and later assumed by another entity must be reported by the assuming entity for the entire MLR reporting year during which the policies were assumed and no revenue under this part for that contract year must be reported by the ceding Part D sponsor.

(5) Total revenue (as defined at § 423.2420(c) of this chapter) that is reinsured for a block of business that was subject to indemnity reinsurance and administrative agreements effective before March 23, 2010, for which the assuming entity is responsible for 100 percent of the ceding entity's financial risk and takes on all of the administration of the block, must be reported by the assuming issuer and must not be reported by the ceding issuer.

(d) *Allocation of expenses*—(1) *General requirements.* (i) Each expense must be included under only one type of expense, unless a portion of the expense fits under the definition of or criteria for one type of expense and the remainder fits into a different type of expense, in which case the expense must be prorated between types of expenses.

(ii) Expenditures that benefit multiple contracts, or contracts other than those being reported, including but not limited to those that are for or benefit self-funded plans, must be reported on a pro rata share.

(2) *Description of the methods used to allocate expenses.* (i) Allocation to each category must be based on a generally accepted accounting method that is expected to yield the most accurate results. Specific identification of an expense with an activity that is represented by one of the categories in paragraph (b) or (c) of this section will generally be the most accurate method.

(ii) Shared expenses, including expenses under the terms of a management contract, must be apportioned pro rata to the entities incurring the expense.

(iii)(A) Any basis adopted to apportion expenses must be that which is expected to yield the most accurate results and may result from special studies of employee activities, salary ratios, premium ratios or similar analyses.

(B) Expenses that relate solely to the operations of a reporting entity, such as personnel costs associated with the adjusting and paying of claims, must be borne solely by the reporting entity and are not to be apportioned to other entities within a group.

[78 FR 31310, May 23, 2013; 78 FR 43821, July 22, 2013; 83 FR 16756, Apr. 16, 2018; 90 FR 15920, Apr. 15, 2025]

§ 423.2430 Activities that improve health care quality.

(a) *Activity requirements.* (1) Activities conducted by a Part D sponsor to improve quality must either—

(i) Fall into one of the categories in paragraph (a)(2) of this section and meet all of the requirements in paragraph (a)(3) of this section; or

(ii) Be listed in paragraph (a)(4) of this section.

(2) *Categories of quality improving activities.* The activity must be designed to achieve one or more of the following:

(i) To improve health outcomes through the implementation of activities such as quality reporting, effective case management, care coordination,

chronic disease management, and medication and care compliance initiatives, including through the use of the medical homes model as defined for purposes of section 3602 of the Patient Protection and Affordable Care Act, for treatment or services under the plan or coverage.

(ii) To prevent hospital readmissions through a comprehensive program for hospital discharge that includes patient-centered education and counseling, comprehensive discharge planning, and post-discharge reinforcement by an appropriate health care professional.

(iii) To improve patient safety and reduce medical errors through the appropriate use of best clinical practices, evidence-based medicine, and health information technology under the plan or coverage.

(iv) To promote health and wellness.

(v) To enhance the use of health care data to improve quality, transparency, and outcomes and support meaningful use of health information technology. Activities, such as Health Information Technology (HIT) expenses, are required to accomplish the activities that improve health care quality and that are designed for use by health plans, health care providers, or enrollees for the electronic creation, maintenance, access, or exchange of health information, and are consistent with meaningful use requirements, and which may in whole or in part improve quality of care, or provide the technological infrastructure to enhance current quality improving activities or make new quality improvement initiatives possible.

(3) The activity must be designed for all of the following:

(i) To improve health quality.

(ii) To increase the likelihood of desired health outcomes in ways that are capable of being objectively measured and of producing verifiable results and achievements.

(iii) To be directed toward individual enrollees or incurred for the benefit of specified segments of enrollees or provide health improvements to the population beyond those enrolled in coverage as long as no additional costs are incurred due to the non-enrollees.

(iv) To be grounded in evidence-based medicine, widely accepted best clinical practice, or criteria issued by recognized professional medical associations, accreditation bodies, government agencies or other nationally recognized health care quality organizations.

(4)(i) Medication Therapy Management Programs meeting the requirements of § 423.153(d).

(ii) Fraud reduction activities, including fraud prevention, fraud detection, and fraud recovery.

(b) *Exclusions.* Expenditures and activities that must not be included in quality improving activities include, but are not limited to, the following:

(1) Those that are designed primarily to control or contain costs other than those that are related to fraud reduction.

(2) The pro rata share of expenses that are for lines of business or products other than those being reported, including but not limited to, those that are for or benefit self-funded plans.

(3) Those which otherwise meet the definitions for quality improving activities but which were paid for with grant money or other funding separate from premium revenue.

(4) Those activities that can be billed or allocated by a pharmacy for care delivery and that are reimbursed as clinical services.

(5) Establishing or maintaining a claims adjudication system, including costs directly related to upgrades in health information technology that are designed primarily or solely to improve claims payment capabilities (and that are not related to fraud reduction activities under paragraph (a)(4)(ii) of this section) or to meet regulatory requirements for processing claims, including ICD–10 implementation costs in excess of 0.3 percent of total revenue under this part, and maintenance of ICD–10 code sets adopted in accordance with the Health Insurance Portability and Accountability Act (HIPAA), 42 U.S.C. 1320d-2, as amended.

(6) That portion of the activities of health care professional hotlines that does not meet the definition of activities that improve health quality.

(7) All retrospective and concurrent utilization review.

(8) [Reserved]

(9) The cost of developing and executing pharmacy contracts and fees associated with establishing or managing a pharmacy network, including fees paid to a vendor for the same reason.

(10) Pharmacy network credentialing.

(11) Marketing expenses.

(12) Costs associated with calculating and administering individual enrollee or employee incentives.

(13) That portion of prospective utilization review that does not meet the definition of activities that improve health quality.

(14) Any function or activity not expressly permitted by CMS under this part.

[78 FR 31310, May 23, 2013, as amended at 83 FR 16756, Apr. 16, 2018]

§ 423.2440 Credibility adjustment.

(a) A Part D sponsor may add the credibility adjustment specified under paragraph (e) of this section to a contract's MLR if the contract's experience is partially credible, as defined in paragraph (d)(1) of this section.

(b) A Part D sponsor may not add a credibility adjustment to a contract's MLR if the contract's experience is fully credible, as defined in paragraph (d)(2) of this section.

(c) For those contract years for which a contract has non-credible experience, as defined in paragraph (d)(3) of this section, sanctions under § 423.2410(b) through (d) will not apply.

(d)(1) A contract's experience is partially credible if it is based on the experience of at least 4,800 member months and fewer than or equal to 360,000 member months.

(2) A contract's experience is fully credible if it is based on the experience of more than 360,000 member months.

(3) A contract's experience is non-credible if it is based on the experience of fewer than 4,800 member months.

(e) The credibility adjustment for partially credible experience is determined based on the number of member months for all enrollees under the contract and the factors shown in Table 1 of this section. When the number of member months used to determine credibility exactly matches a member month category listed in Table 1 of this section, the value associated with that number of member months is the credibility adjustment. The credibility adjustment for a number of member months between the values shown in Table 1 of this section is determined by linear interpolation.

TABLE 1 TO § 423.2440—CREDIBILITY ADJUSTMENTS FOR PART D CONTRACTS

Member months	Credibility adjustment (additional percentage points)
<4,800	N/A (Non-credible).
4,800	8.4%.
12,000	5.3%.
24,000	3.7%.
48,000	2.6%.
120,000	1.7%.
240,000	1.2%.
360,000	1.0%.
>360,000	0.0% (Fully credible).

[85 FR 33911, June 2, 2020]

§ 423.2450 [Reserved]

§ 423.2460 Reporting requirements.

(a) Except as provided in paragraph (b) of this section, for each contract year, each Part D sponsor must submit to CMS, in a timeframe and manner specified by CMS, a report that includes the data needed by the Part D sponsor to calculate and verify the medical loss ratio (MLR) and remittance amount, if any, for each contract under this part, including the amount of incurred claims for prescription drugs, supplemental benefits, total revenue, expenditures on quality improving activities, non-claims costs, taxes, licensing and regulatory fees, and any remittance owed to CMS under § 423.2410.

(b) For contract years 2018 through 2022, each Part D sponsor must submit to CMS, in a timeframe and manner specified by CMS, the following information:

(1) *Fully credible and partially credible contracts.* For each contract under this part that has fully credible or partially credible experience, as determined in accordance with § 423.2440(d), the Part D sponsor must report to CMS the MLR for the contract and the amount of any remittance owed to CMS under § 423.2410.

(2) *Non-credible contracts.* For each contract under this part that has non-

credible experience, as determined in accordance with § 423.2440(d), the Part D sponsor must report to CMS that the contract is non-credible.

(c) Total revenue included as part of the MLR calculation must be net of all projected reconciliations.

(d) Subject to paragraph (e) of this section, the MLR is reported once, and is not reopened as a result of any payment reconciliation processes.

(e) With respect to a Part D sponsor that has already submitted to CMS the MLR report or MLR data required under paragraph (a) or (b) of this section, respectively, for a contract for a contract year, paragraph (d) of this section does not prohibit resubmission of the MLR report or MLR data for the purpose of correcting the prior MLR report or data submission. Such resubmission must be authorized or directed by CMS, and upon receipt and acceptance by CMS, is regarded as the contract's MLR report or data submission for the contract year for purposes of this subpart.

[83 FR 16756, Apr. 16, 2018, as amended at 87 FR 27902, May 9, 2022]

§ 423.2470 Remittance to CMS if the applicable MLR requirement is not met.

(a) *General requirement.* For each contract year, a Part D sponsor must provide a remittance to CMS if the contract's MLR does not meet the minimum percentage required by § 423.2410(b).

(b) *Amount of remittance.* For each contract that does not meet MLR requirement for a contract year, the Part D sponsor must remit to CMS the amount by which the MLR requirement exceeds the contract's actual MLR multiplied by the total revenue of the contract, as provided in § 423.2420(c), for the contract year.

(c) *Timing of remittance.* CMS will deduct the remittance from plan payments in a timely manner after the MLR is reported, on a schedule determined by CMS.

(d) *Treatment of remittance.* Payment to CMS must not be included in the numerator or denominator of any year's MLR.

§ 423.2480 MLR review and non-compliance.

To ensure the accuracy of MLR reporting, CMS conducts selected review of data submitted under § 423.2460 to determine that the MLRs and remittance amounts under § 423.2410(b) and sanctions under § 423.2410(c) and (d), were accurately calculated, reported, and applied.

(a) The reviews will include a validation of amounts included in both the numerator and denominator of the MLR calculation reported to CMS.

(b) Part D sponsors are required to maintain evidence of the amounts reported to CMS and to validate all data necessary to calculate MLRs.

(c)(1) Documents and records must be maintained for 10 years from the date such calculations were reported to CMS with respect to a given contract year.

(2) Part D sponsors must require any third party vendor supplying drug cost contracting and claim adjudication services to the Part D sponsors to provide all underlying data associated with MLR reporting to that Part D sponsor in a timely manner, when requested by the Part D sponsor, regardless of current contractual limitations, in order to validate the accuracy of MLR reporting.

(d) Data submitted under § 423.2460, calculations, or any other MLR submission required by this subpart found to be materially incorrect or fraudulent—

(1) Are noted by CMS;

(2) Appropriate remittance amounts are recouped by CMS; and

(3) Sanctions may be imposed by CMS as provided in § 423.752.

[78 FR 31310, May 23, 2013, as amended at 83 FR 16756, Apr. 16, 2018]

§ 423.2490 Release of Part D MLR data.

(a) *Terminology.* Subject to the exclusions in paragraph (b) of this section, Part D MLR data consists of the information submitted under § 423.2460.

(b) *Exclusions from Part D MLR data.* For the purpose of this section, the following items are excluded from Part D MLR data:

(1) Narrative descriptions that Part D sponsors submit to support the information reported to CMS pursuant to

the reporting requirements at § 423.2460, such as descriptions of expense allocation methods.

(2) Information that is reported at the plan level, such as the number of member months associated with each plan under a contract, including information submitted for a contract consisting of only one plan.

(3) Any information that could be used to identify Medicare beneficiaries or other individuals.

(4) MLR review correspondence.

(5) Any information for a contract for those contract years for which the contract is determined to be non-credible, as defined in accordance with § 423.2440(d).

(c) *Data release*. CMS releases to the public Part D MLR data, for each contract for each contract year, no earlier than 18 months after the end of the applicable contract year

[81 FR 80558, Nov. 15, 2016, as amended at 83 FR 16756, Apr. 16, 2018]

Subpart Y—Transitional Coverage and Retroactive Medicare Part D Coverage for Certain Low-Income Beneficiaries Through the Limited Income Newly Eligible Transition (LI NET) Program

SOURCE: 88 FR 22342, Apr. 12, 2023, unless otherwise noted.

§ 423.2500 Basis and scope.

(a) *Basis*. This subpart is based on section 1860D–14 of the Social Security Act.

(b) *Scope*. This subpart sets forth the requirements for the Limited Income Newly Eligible Transition (LI NET) program that begins no later than January 1, 2024. Under this program, eligible individuals are provided transitional coverage for Part D drugs.

§ 423.2504 LI NET eligibility and enrollment.

(a) *Eligibility*. An individual is eligible for LI NET coverage if they satisfy the criteria at paragraph (a)(1) or (2) of this section.

(1) *LIS-eligible*. The individual is a low-income subsidy eligible individual as defined at § 423.773 and—

(i) Has not yet enrolled in a prescription drug plan or an MA–PD plan; or

(ii) Has enrolled in a prescription drug plan or MA–PD plan but their coverage has not yet taken effect.

(2) *Immediate need individuals*. An individual who states their eligibility for LIS and immediate need for their prescription, but whose eligibility as defined at § 423.773 cannot be confirmed at the point-of-sale, will be granted immediate need LI NET coverage.

(3) *Documentation of LIS eligibility*. Individuals may provide documentation to the LI NET sponsor to demonstrate LIS eligibility. Documentation may include, but is not limited to:

(i) A copy of the beneficiary's Medicaid card that includes their name and the eligibility date;

(ii) A copy of a letter from the State or SSA showing LIS or ''Extra Help'' status;

(iii) The date that a verification call was made to the State Medicaid Agency, the name and telephone number of the State staff person who verified the Medicaid period, and the Medicaid eligibility dates confirmed on the call;

(iv) A copy of a State document that confirms active Medicaid status;

(v) A screen-print from the State's Medicaid systems showing Medicaid status; or

(vi) Evidence at point-of-sale of recent Medicaid billing and payment in the pharmacy's patient profile.

(4) *Confirmation of LIS eligibility*. CMS uses documentation submitted under paragraph (a)(3) of this section to confirm LIS eligibility.

(5) *Inability to confirmation of eligibility*. If CMS cannot confirm an immediate need individual's eligibility during the period of LI NET coverage, the individual will not be auto-enrolled into a standalone Part D plan in accordance with § 423.34(d) following their LI NET coverage.

(b) *Enrollment*. Individuals who are eligible for LI NET as defined in § 423.2504 are enrolled into the LI NET program as follows:

(1) *Automatic enrollment*. Beneficiaries who are LIS-eligible and whose auto-enrollment into a Part D plan (as outlined in § 423.34(d)(1)) has not taken effect will be automatically enrolled by CMS into the LI NET program unless

the beneficiary has affirmatively declined enrollment in Part D per § 423.34(e);

(2) *Point-of-sale enrollment.* An individual who is not automatically enrolled in accordance with paragraph (b)(1) of this section and whose claim is submitted at the point-of-sale and accepted by the LI NET sponsor will be enrolled into the LI NET program by the LI NET sponsor; or

(3) *Direct reimbursement request.* An individual described in paragraph (a)(1) of this section who is not automatically enrolled in accordance with paragraph (b)(1) or at the point-of-sale as provided in paragraph (b)(2) of this section and who submits a direct reimbursement request form, receipts for reimbursement for eligible claims paid out of pocket (with and optional documentation of LIS eligibility listed in paragraph (a)(3) of this section), will be retroactively enrolled into the LI NET program by the LI NET sponsor. The LI NET sponsor has 14 calendar days to reply with a coverage decision; or

(4) *LI NET application form.* An individual who is not enrolled through one of the methods in paragraphs (b)(1) though (3) of this section may submit an LI NET application form to the LI NET sponsor (with optional documentation of LIS eligibility listed in paragraph (a)(3) of this section). If no documentation is submitted and accepted, the LI NET sponsor will periodically check for eligibility and enroll applicants once LIS eligibility is confirmed.

(c) *Duration of LI NET enrollment.* (1) Enrollment begins on the first day of the month an individual is identified as eligible under this section and ends after 2 months, with a longer LI NET enrollment for those with retroactive coverage per paragraph (c)(2) of this section.

(2) Retroactive LI NET coverage begins on the date an individual is identified as eligible for a low-income subsidy as a full-benefit dual eligible or an SSI benefit recipient, or 36 months prior to the date such individual enrolls in (or opts out of) Part D coverage, whichever is later. LI NET coverage ends with enrollment into a Part D plan or opting out of Part D coverage.

(d) *Ending LI NET enrollment.* An individual's enrollment in the LI NET program ends when:

(1) The individual is auto-enrolled into a standalone Part D plan in accordance with the guidelines at § 423.34(d) and that coverage has taken effect.

(2) The individual elects another Part D plan and that coverage has taken effect.

(3) The individual voluntarily disenrolls from the LI NET program.

(4) The individual is involuntarily disenrolled under § 423.44(b).

(5) LIS eligibility for an individual in LI NET due to an immediate need cannot be confirmed within the period of LI NET coverage.

§ 423.2508 LI NET benefits and beneficiary protections.

(a) *Formulary.* The LI NET program provides access to all Part D drugs under an open formulary.

(b) *Network.* The LI NET sponsor must allow its network and out-of-network pharmacies that are in good standing to process claims under the program. Licensed pharmacies are considered to be in good standing for the LI NET program so long as they: are not revoked from Medicare under § 424.535; do not appear on the Office of Inspector General's list of entities excluded from Federally funded health care programs pursuant to section 1128 of the Act or from Medicare and State health care programs under section 1156 of the Act (unless waived by the OIG); do not appear on the preclusion list as defined at § 423.100; and do not have a determination by the LI NET sponsor of a credible allegation of fraud as defined at § 423.4.

(c) *Safety.* The following provisions necessary to improve patient safety and ensure appropriate dispensing of medication apply to the LI NET program and LI NET sponsor, as applicable:

(1) Sections 423.153(b) and (c) for dispensing and point-of-sale safety edits;

(2) Section 423.154 for appropriate dispensing of prescription drugs in long-term care facilities;

(3) Sections 423.159 and 423.160 for electronic prescribing, excepting the

requirements pertaining to formulary standards in §423.160(b)(5);

(4) Section 423.162 for QIO activities; and

(5) Section 423.165 for compliance deemed on the basis of accreditation.

(d) *Cost sharing.* (1) LI NET beneficiaries under §423.2504(a)(1) will pay the applicable cost sharing for their low-income category as established for each year in the Rate Announcement publication specified in §422.312 of this chapter.

(2) LI NET beneficiaries under §423.2504(a)(2) will pay the cost sharing associated with the category of non-institutionalized full-benefit dual eligible individuals with incomes above 100% of the Federal poverty level and full-subsidy-non-FBDE individuals. If the beneficiary is later confirmed to belong to a different LIS category, the LI NET sponsor must reimburse the beneficiary for the difference between the cost sharing they paid versus what they would have paid in their LIS category.

(e) *Appeals.* LI NET enrollees have rights with respect to Part D grievances, coverage determinations, and appeals processes set out in subpart M of this part.

§423.2512 LI NET sponsor requirements.

The LI NET program is administered by one or more Part D sponsor(s) that meet all of the requirements in paragraphs (a) through (c) of this section.

(a) *Pharmacies and access to Part D drugs.* (1) The LI NET sponsor must be a PDP sponsor that has an established contracted pharmacy network in all geographic areas of the United States in which low-income subsidies are available.

(2) The LI NET sponsor must meet the requirements for providing access to Part D drugs under §423.120(a), (c), and (d).

(b) *Experience.* The LI NET sponsor must have a minimum of two consecutive years contracting with CMS as a Part D sponsor.

(c) *Other LI NET sponsor requirements.* The LI NET sponsor must:

(1) Have the technical capability and the infrastructure to provide immediate, current, and retroactive coverage for LI NET enrollees;

(2) Have the technical capability to develop the infrastructure necessary for verifying Medicaid dual eligibility status for presumed eligible LI NET enrollees.

(3) Identify, develop, and conduct outreach plans in consultation with CMS targeting key stakeholders to inform them about the LI NET program.

(4) Establish and manage a toll-free customer call center per §423.128(d)(1) and fax line that can be accessed by pharmacy providers and beneficiaries, or others acting on their behalf, for purposes that include but are not limited to: handling inquiries about services under the LI NET program, providing the status of eligibility or claims, and having the ability to accept supporting documentation.

(5) Timely respond to beneficiary requests for reimbursement of claims by issuing reimbursement for eligible claims submitted by beneficiaries no later than 30 days after receipt, or, if the drug is not covered, the LI NET sponsor has 14 days to send communication to the beneficiary with a reason for the denial.

(6) Adjudicate claims from out-of-network pharmacies that are in good standing (as defined in §423.2508(b)) according to the LI NET sponsor's standard reimbursement for their network pharmacies.

§423.2516 Selection of LI NET sponsor and contracting provisions.

(a) *Appointment by CMS.* CMS appoints a Part D sponsor that meets the requirements at §423.2512 to serve as the LI NET sponsor.

(b) *Selection criteria.* In appointing a LI NET sponsor, CMS evaluates the following:

(1) Experience covering low-income beneficiaries, including but not limited to enrolling and providing coverage to low-income subsidy individuals as defined in §423.34;

(2) Pharmacy access as outlined in §423.120;

(3) Past performance, including Star Ratings (as detailed in §423.186), previous intermediate sanctions (as detailed in §423.750), and consistent with past performance in §423.503(b); and

(4) Ability to meet the requirements listed in § 423.505 that are not waived under § 423.2536.

(c) *Term of appointment.* The term of the appointment will be ongoing provided mutual agreement between CMS and the selected party, subject to an annual contracting and bid process (per § 423.2524(b)) to determine payment rates for the upcoming year.

§ 423.2518 Intermediate sanctions for the LI NET sponsor.

In the event it is determined that the LI NET sponsor violated its contract, CMS may impose intermediate sanctions as outlined in subpart O of this part.

§ 423.2520 Non-renewal or termination of appointment.

(a) *Notice of non-renewal.* If the LI NET sponsor decides for any reason to non-renew its existing contract, it must notify CMS by January 1 of the year before the next contract year. Except as provided in paragraph (c) of this section, if CMS decides for any reason to non-renew the existing contract with the incumbent LI NET sponsor, CMS notifies the LI NET sponsor by January 1 of the year before the next contract year.

(b) *Selection of successor and transition period.* After a notice of non-renewal or termination, CMS selects a successor for the LI NET contract from among potentially eligible entities (as detailed in § 423.2516). The outgoing LI NET sponsor must coordinate with the successor for a period of no less than 3 months to ensure seamless transition of the LI NET program, including timely transfer of any data or files.

(c) *Immediate termination for cause.* (1) Notwithstanding paragraph (a) of this section, CMS may immediately terminate the existing LI NET contract for any of the reasons specified at § 423.509(a)(4)(i) and (xii) or § (b)(2)(i)(A) and (B).

(2) CMS sends notice of an immediate termination as specified at § 423.509(b)(2)(ii).

(d) *Appeal rights.* Subpart N of this part applies to a termination under paragraph (c) of this section.

§ 423.2524 Bidding and payments to LI NET sponsor.

(a) *Source of payments.* CMS payments under this section are made from the Medicare Prescription Drug Account.

(b) *Submission of bids and related information.* (1) The submission of LI NET bids and related information must follow the requirements and limitations in § 423.265(b), (c), (d)(1), (d)(2)(i), (ii), (iv), and (v), (d)(4) and (6), and (e).

(2) The review, negotiation, and approval of the LI NET bid would follow the provisions in § 423.272(a) and (b)(1) and (4).

(3) Basic rule for bid. The bid must reflect the LI NET sponsor's estimate of its revenue needs for Payment Rates A and B per paragraph (c) of this section.

(c) *Monthly payments.* CMS provides advance monthly LI NET payments equal to the sum of Payment Rates A and B as established in the LI NET sponsor's approved bid, as outlined in paragraph (b) of this section. LI NET payments are made on a prospective per-member, per-month basis.

(1) Payment Rate A is an annual rate of payment for projected administrative costs. An annual percentage-based cap on Payment Rate A limiting the year over year increase to Payment Rate A is set as part of the bid review and negotiation under § 423.272(a).

(i) For the 2024 plan year, the LI NET sponsor includes in its bid the assumption that Payment Rate A cannot exceed a 2% increase from the prior year's Payment A, which is a figure CMS will provide to the LI NET sponsor.

(ii) For the 2025 plan year and subsequent plan years, the LI NET sponsor will specify its assumption for any increase needed to the prior year's Payment Rate A, submitting justification to CMS in their bid if the cap exceeds 2%.

(2) Payment Rate B reflects the projected net costs of the Part D drugs dispensed to individuals who receive the LI NET benefit.

(d) *Payment reconciliation and risk corridors*—(1) *Reconciliation.* CMS conducts LI NET payment reconciliation each year for Payment Rates A and B after

the annual PDE data submission deadline has passed and makes the resulting payment adjustment consistent with § 423.343(a).

(2) *Risk corridors.* As part of LI NET payment reconciliation, CMS will apply risk corridors to Payment Rate B as follows:

(i) There will be no risk sharing in the symmetrical 1% risk corridor around the target amount as defined in § 423.308.

(ii) There will be symmetrical risk sharing of 0.1% beyond the 1% risk corridor.

(iii) To carry out this section, § 423.336(c) applies to LI NET.

(e) *Reopening.* The LI NET contract will be subject to payment reopenings per § 423.346 as applicable.

(f) *Payment appeals.* The LI NET sponsor can appeal under § 423.350.

(g) *Overpayments.* The overpayment provisions at §§ 423.352 and 423.360 apply to LI NET.

§ 423.2536 Waiver of Part D program requirements.

CMS waives the following Part D program requirements for the LI NET program:

(a) *General information.* Paragraphs (1) and (3)(B) of section 1860D–4(a) of the Act (relating to dissemination of general information; availability of information on changes in formulary through the internet).

(b) *Formularies.* Subparagraphs (A) and (B) of section 1860D–4(b)(3) of the Act (relating to requirements on development and application of formularies; formulary development) and formulary requirements in §§ 423.120(b) and 423.128(e)(5) and (6).

(c) *Medicare Prescription Payment Plan.* Section 423.137.

(d) *Cost control and quality improvement requirements.* Provisions under subpart D of this part, including requirements about medication therapy management, are waived except for the provisions in § 423.2508(c)(1) through (5).

(1) Section 423.153(b) and (c) for dispensing and point-of-sale safety edits;

(2) Section 423.154 for appropriate dispensing of prescription drugs in long-term care facilities;

(3) Sections 423.159 and 423.160 for electronic prescribing, excepting the requirements pertaining to formulary standards in § 423.160(b)(5);

(4) Section 423.162 for QIO activities; and

(5) Section 423.165 for compliance deemed on the basis of accreditation.

(e) *Out-of-network access.* Section 423.124 Special rules for out-of-network access to Part D drugs at out-of-network pharmacies, except for § 423.124(a)(2), which applies to LI NET.

(f) *Medicare contract determinations and appeals.* Subpart N, except for the provisions that apply to LI NET in § 423.2520(d).

(g) *Risk-sharing arrangements.* Section 423.336(a), (b), and (d).

(h) *Certification of accuracy of data for price comparison.* Section 423.505(k)(6).

(i) *Part D communication requirements.* Portions of subpart V of this part related to Part D communication requirements that are inapplicable to LI NET, including:

(1) Section 423.2265(b)(4), (5), (11), (13), and (16);

(2) Section 423.2265(c);

(3) Section 423.2266(a);

(4) Section 423.2267(e)(3) through (5), (9) through (12), (14) through (17), (25), (29), (33), and (45) through (51); and

(5) Section 423.2274.

(j) *Medicare Coverage Gap Discount Program.* Subpart W of this part.

(k) *Requirements for a minimum medical loss ratio.* Subpart X of this part.

(l) *Recovery audit contractor Part C appeals process.* Subpart Z of this part.

[88 FR 22342, Apr. 12, 2023; 88 FR 34780, May 31, 2023; 90 FR 15920, Apr. 15, 2025]

Subpart Z—Recovery Audit Contractor Part D Appeals Process

SOURCE: 79 FR 29967, May 23, 2014, unless otherwise noted.

§ 423.2600 Payment appeals.

If the Part D RAC did not apply its stated payment methodology correctly, a Part D plan sponsor may appeal the findings of the applied methodology. The payment methodology itself is not subject to appeal.

§ 423.2605 Request for reconsideration.

(a) *Time for filing a request.* The request for reconsideration must be filed

with the designated independent reviewer within 60 calendar days from the date of the demand letter received by the Part D plan sponsor.

(b) *Content of request.* (1) The request for reconsideration must be in writing and specify the findings or issues with which the Part D plan sponsor disagrees.

(2) The Part D plan sponsor must include with its request all supporting documentary evidence it wishes the independent reviewer to consider.

(i) This material must be submitted in the format requested by CMS.

(ii) Documentation, evidence, or substantiation submitted after the filing of the reconsideration request will not be considered.

(c) *CMS Rebuttal.* CMS may file a rebuttal to the Part D plan sponsor's reconsideration request.

(1) The rebuttal must be submitted within 30 calendar days of the review entity's notification to CMS that it has received the Part D plan sponsor's reconsideration request.

(2) CMS sends its rebuttal to the Part D plan sponsor at the same time it is submitted to the independent reviewer.

(d) *Review entity.* An independent reviewer conducts the reconsideration. The independent reviewer reviews the demand for repayment, the evidence and findings upon which it was based, and any evidence that the Part D plan sponsor or CMS submitted in accordance with this section.

(e) *Notification of decision.* The independent reviewer informs CMS and the Part D plan sponsor of its decision in writing.

(f) *Effect of decision.* A reconsideration decision is final and binding unless the Part D plan sponsor requests a hearing official review in accordance with § 423.2610.

(g) *Right to hearing official review.* A Part D plan sponsor that is dissatisfied with the independent reviewer's reconsideration decision is entitled to a hearing official review as provided in § 423.2610.

§ 423.2610 Hearing official review.

(a) *Time for filing a request.* A Part D plan sponsor must file with CMS a request for a hearing official review within 30 calendar days from the date of the independent reviewer's issuance of a determination.

(b) *Content of the request.* (1) The request must be in writing and must provide evidence or reasons or both to substantiate the request.

(2) The Part D plan sponsor must submit with its request all supporting documentation, evidence, and substantiation that it wants to be considered.

(3) No new evidence may be submitted.

(4) Documentation, evidence, or substantiation submitted after the filing of the request will not be considered.

(c) *CMS rebuttal.* CMS may file a rebuttal to the Part D plan sponsor's hearing official review request.

(1) The rebuttal must be submitted within 30 calendar days of the Part D plan sponsor's submission of its hearing official review request.

(2) CMS sends its rebuttal to the Part D plan sponsor at the same time it is submitted to the hearing official.

(d) *Conducting a review.* A CMS-designated hearing official conducts the hearing on the record.

(1) The hearing is not to be conducted live or via telephone unless the hearing official, in his or her sole discretion, requests a live or telephonic hearing.

(2) In all cases, the hearing official's review is limited to information that meets one or more of the following:

(i) The Part D RAC used in making its determinations.

(ii) The independent reviewer used in making its determinations.

(iii) The Part D plan sponsor submits with its hearing request.

(iv) CMS submits in accordance with paragraph (c) of this section.

(3) Neither the Part D plan sponsor nor CMS may submit new evidence.

(e) *Hearing official decision.* The CMS hearing official decides the case within 60 days and sends a written decision to the Part D plan sponsor and CMS, explaining the basis for the decision.

(f) *Effect of hearing official decision.* The hearing official's decision is final and binding, unless the decision is reversed or modified by the CMS Administrator in accordance with § 423.2610.

§ 423.2615 Review by the Administrator.

(a) *Request for review by Administrator.* If a Part D plan sponsor is dissatisfied with the hearing official's decision, it may request that the CMS Administrator review the decision.

(1) The request must be filed with the CMS Administrator within 30 calendar days of the date of the hearing official's decision.

(2) The request must provide evidence or reasons to substantiate the request.

(b) *Content of request.* The Part D plan sponsor must submit with its request all supporting documentation, evidence, and substantiation that it wants to be considered.

(1) Documentation, evidence, or substantiation submitted after the filing of the request will not be considered.

(2) Neither the Part D plan sponsor nor CMS may submit new evidence.

(c) *Discretionary review.* After receiving a request for review, the CMS Administrator has the discretion to review the hearing official's decision in accordance with paragraph (e) of this section or to decline to review said decision.

(d) *Notification of decision whether to review.* The CMS Administrator notifies the Part D plan sponsor within 45 days of receiving the Part D plan sponsor's hearing request of whether he or she intends to review the hearing official's decision. If the Administrator agrees to review the hearing official's decision, CMS may file a rebuttal statement within 30 days of the Administrator's notice to the plan sponsor that the request for review has been accepted. CMS sends its rebuttal statement to the plan sponsor at the same time it is submitted to the Administrator. If the CMS Administrator declines to review the hearing official's decision, the hearing official's decision is final and binding.

(e) *Administrator review.* If the CMS Administrator agrees to review the hearing official's decision, he or she determines, based upon this decision, the hearing record, and any arguments submitted by the Part D plan sponsor or CMS in accordance with this section, whether the determination should be upheld, reversed, or modified. The CMS Administrator furnishes a written decision, which is final and binding, to the Part D plan sponsor and to CMS.

PART 424—CONDITIONS FOR MEDICARE PAYMENT

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AUTHORITY: 42 U.S.C. 1302 and 1395hh.

SOURCE: 53 FR 6634, Mar. 2, 1988, unless otherwise noted.

Subpart A—General Provisions

§ 424.1 Basis and scope.

(a) *Statutory basis.* (1) This part is based on the indicated provisions of the following sections of the Act:

1814—Basic conditions for, and limitations on, Medicare payments for Part A services.

1815—Payment to providers for Part A services.

1820—Conditions for designating certain hospitals as critical assess hospitals.

1833(e)—Requirement to furnish information to determine payment.

1834(a)—Payment for durable medical equipment.

1834(j)—Requirements for suppliers of medical equipment and supplies.

1835—Procedures for payment to providers for Part B services.

1842(b)(3)(B)(ii)—Assignment of Part B Medicare claims.

1842(b)(6)—Payment to entities other than the supplier.

1848—Payment for physician services.

1870(e) and (f)—Settlement of claims after death of the beneficiary.

(2) Section 424.444(c) is also based on section 216(j) of the Act.

(b) *Scope.* This part sets forth certain specific conditions and limitations applicable to Medicare payments and cites other conditions and limitations set forth elsewhere in this chapter. This subpart A provides a general overview. Other subparts deal specifically with—

(1) The requirement that the need for services be certified and that a physician establish a plan of treatment (subpart B);

(2) The procedures and time limits for filing claims (subpart C);

(3) The individuals or entities to whom payment may be made (subparts D and E);

(4) The limitations on assignment and reassignment of claims (subpart F);

(5) Special requirements that apply to services furnished by nonparticipating U.S. hospitals and foreign hospitals (subparts G and H); and

(6) The replacement and reclamation of Medicare payment checks (subpart M).

(c) *Other applicable rules.* Except for § 424.40(c)(3), this part does not deal with the conditions for payment of rural health clinic (RHC) services, Federally qualified health center (FQHC) services, or ambulatory surgical center (ASC) services. Those conditions are set forth in part 405, subpart X, and part 481 subpart A of this chapter for RHC and FQHC services; and in part 416 of this chapter, for ASC services. The rules for physician certification of terminal illness, required in connection with hospice care, are set forth in § 418.22 of this chapter.

[53 FR 6634, Mar. 2, 1988, as amended at 60 FR 38271, July 26, 1995; 60 FR 50442, Sept. 29, 1995; 62 FR 46035, Aug. 29, 1997; 71 FR 20775, Apr. 21, 2006; 71 FR 48409, Aug. 18, 2006]

§ 424.3 Definitions.

As used in this part, unless the context indicates otherwise—

HCPCS means Healthcare Common Procedure Coding System.

ICD–9–CM means International Classification of Diseases, Ninth Revision, Clinical Modification.

Nonparticipating hospital means a hospital that does not have in effect a provider agreement to participate in Medicare.

Participating hospital means a hospital that has in effect a provider agreement to participate in Medicare.

[53 FR 6634, Mar. 2, 1988, as amended at 59 FR 10299, Mar. 4, 1994; 63 FR 26311, May 12, 1998; 70 FR 45055, Aug. 4, 2005]

§ 424.5 Basic conditions.

(a) As a basis for Medicare payment, the following conditions must be met:

(1) *Types of services.* The services must be—

(i) Covered services, as specified in part 409 or part 410 of this chapter; or

(ii) Services excluded from coverage as custodial care or services not reasonable and necessary, but reimbursable in accordance with §§ 405.332 through 405.334 of this chapter, pertaining to limitation of liability.

(2) *Sources of services.* The services must have been furnished by a provider, nonparticipating hospital, or supplier that was, at the time it furnished the services, qualified to have payment made for them.

(3) *Beneficiary of services.* Except as provided in § 409.68 of this chapter, the services must have been furnished while the individual was eligible to have payment made for them. (Section 409.68 provides for payment of inpatient hospital services furnished before the hospital is notified that the beneficiary has exhausted the Medicare benefits available for the current benefit period.)

(4) *Certification of need for services.* When required, the provider must obtain certification and recertification of the need for the services in accordance with subpart B of this part.

(5) *Claim for payment.* The provider, supplier, or beneficiary, as appropriate, must file a claim that includes or makes reference to a request for payment, in accordance with subpart C of this part.

(6) *Sufficient information.* The provider, supplier, or beneficiary, as appropriate, must furnish to the intermediary or carrier sufficient information to determine whether payment is due and the amount of payment.

(b) Additional conditions applicable in certain circumstances or to certain services are set forth in other sections of this part.

[53 FR 6635, Mar. 2, 1988; 53 FR 12945, Apr. 20, 1988; 60 FR 38271, July 26, 1995]

§ 424.7 General limitations.

(a) *Utilization review finding on medical necessity.* When a QIO or a UR committee notifies a hospital or SNF of its finding that further services are not medically necessary, the following rules apply:

(1) *Hospitals subject to PPS.* Payment may not be made for inpatient hospital services furnished by a PPS hospital after the second day after the day on which the hospital received the notice.

(2) *Hospitals not subject to PPS and SNFs*—(i) *Basic rule.* Except as provided in paragraph (a)(2)(ii) of this section, payment may not be made for inpatient hospital services or posthospital SNF care furnished after the day on which the hospital or SNF received the notice.

(ii) *Exception.* Payment may be made for 1 or 2 additional days if the QIO or UR committee approves them as necessary for planning for post-discharge care.

(b) *Failure to make timely utilization review.* Payment may not be made for inpatient hospital services or posthospital SNF care furnished, after the 20th consecutive day of a stay, to an individual who is admitted to the hospital or SNF after CMS has determined that the hospital or SNF has failed to make timely utilization review in long stay cases. (This provision does not apply to a hospital or SNF for which a QIO has assumed binding review.)

[53 FR 6635, Mar. 2, 1988; 53 FR 12945, Apr. 20, 1988]

Subpart B—Certification and Plan Requirements

§ 424.10 Purpose and scope.

(a) *Purpose.* The physician has a major role in determining utilization of health services furnished by providers. The physician decides upon admissions, orders tests, drugs, and treatments, and determines the length of

stay. Accordingly, sections 1814(a)(2) and 1835(a)(2) of the Act establish as a condition for Medicare payment that a physician certify the necessity of the services and, in some instances, recertify the continued need for those services.

Section 1814(a)(2) of the Act also permits nurse practitioners, clinical nurse specialists, or physician assistants to certify and recertify the need for post-hospital extended care services.

(b) *Scope.* This subpart sets forth the timing, content, and signature requirements for certification and recertification with respect to certain Medicare services furnished by providers.

[60 FR 38271, July 26, 1995, as amended at 78 FR 47968, Aug. 6, 2013]

§ 424.11 General procedures.

(a) *Responsibility of the provider.* The provider must—

(1) Obtain the required certification and recertification statements;

(2) Keep them on file for verification by the intermediary, if necessary; and

(3) Certify, on the appropriate billing form, that the statements have been obtained and are on file.

(b) *Obtaining the certification and recertification statements.* No specific procedures or forms are required for certification and recertification statements. The provider may adopt any method that permits verification. The certification and recertification statements may be entered on forms, notes, or records that the appropriate individual signs, or on a special separate form. Except as provided in paragraph (d) of this section for delayed certifications, there must be a separate signed statement for each certification or recertification. If supporting information for the signed statement is contained in other provider records (such as physicians' progress notes), it need not be repeated in the statement itself.

(c) *Required information.* The succeeding sections of this subpart set forth specific information required for different types of services.

(d) *Timeliness.* (1) The succeeding sections of this subpart also specify the timeframes for certification and for initial and subsequent recertifications.

(2) A hospital or SNF may provide for obtaining a certification or recertification earlier than required by these regulations or vary the timeframe (within the prescribed outer limits) for different diagnostic or clinical categories.

(3) Delayed certification and recertification statements are acceptable when there is a legitimate reason for delay. (For instance, the patient was unaware of his or her entitlement when he or she was treated.) Delayed certification and recertification statements must include an explanation of the reasons for the delay.

(4) A delayed certification may be included with one or more recertifications on a single signed statement.

(5) For all inpatient hospital services, including inpatient psychiatric facility services, a delayed certification may not extend past discharge.

(e) *Limitation on authorization to sign statements.* A certification or recertification statement may be signed only by one of the following:

(1) A physician who is a doctor of medicine or osteopathy.

(2) A dentist in the circumstances specified in § 424.13(d).

(3) A doctor of podiatric medicine if his or her certification is consistent with the functions he or she is authorized to perform under State law.

(4) A nurse practitioner or clinical nurse specialist as defined in paragraph (e)(5) or (e)(6) of this section, or a physician assistant as defined in section 1861(aa)(5)(A) of the Act, in the circumstances specified in § 424.20(e).

(5) For purposes of this section, to qualify as a nurse practitioner, an individual must—

(i) Be a registered professional nurse who is currently licensed to practice nursing in the State where he or she practices; be authorized to perform the services of a nurse practitioner in accordance with State law; and have a master's degree in nursing;

(ii) Be certified as a nurse practitioner by a professional association recognized by CMS that has, at a minimum, eligibility requirements that meet the standards in paragraph (e)(5)(i) of this section; or

(iii) Meet the requirements for a nurse practitioner set forth in paragraph (e)(5)(i) of this section, except for the master's degree requirement, and

have received before August 25, 1998 a certificate of completion from a formal advanced practice program that prepares registered nurses to perform an expanded role in the delivery of primary care.

(6) For purposes of this section, to qualify as a clinical nurse specialist, an individual must—

(i) Be a registered professional nurse who is currently licensed to practice nursing in the State where he or she practices; be authorized to perform the services of a clinical nurse specialist in accordance with State law; and have a master's degree in a defined clinical area of nursing;

(ii) Be certified as a clinical nurse specialist by a professional association recognized by CMS that has at a minimum, eligibility requirements that meet the standards in paragraph (e)(6)(i) of this section; or

(iii) Meet the requirements for a clinical nurse specialist set forth in paragraph (e)(6)(i) of this section, except for the master's degree requirement, and have received before August 25, 1998 a certificate of completion from a formal advanced practice program that prepares registered nurses to perform an expanded role in the delivery of primary care.

[53 FR 6634, Mar. 2, 1988, as amended at 56 FR 8845, Mar. 1, 1991; 60 FR 38272, July 26, 1995; 78 FR 47968, Aug. 6, 2013; 78 FR 50969, Aug. 19, 2013; 79 FR 50359, Aug. 22, 2014; 83 FR 41706, Aug. 17, 2018]

§ 424.13 Requirements for inpatient services of hospitals other than inpatient psychiatric facilities.

(a) *Content of certification and recertification.* Medicare Part A pays for inpatient hospital services (other than inpatient psychiatric facility services) for cases that are 20 inpatient days or more, or are outlier cases under subpart F of part 412 of this chapter, only if a physician certifies or recertifies the following:

(1) The reasons for either—

(i) Continued hospitalization of the patient for medical treatment or medically required diagnostic study; or

(ii) Special or unusual services for cost outlier cases (under the prospective payment system set forth in subpart F of part 412 of this chapter).

(2) The estimated time the patient will need to remain in the hospital.

(3) The plans for posthospital care, if appropriate.

(b) *Timing of certification.* For outlier cases under subpart F of part 412 of this chapter, the certification must be signed and documented in the medical record and as specified in paragraphs (e) through (h) of this section. For all other cases, the certification must be signed and documented no later than 20 days into the hospital stay.

(c) *Certification of need for hospitalization when a SNF bed is not available.* (1) The physician may certify or recertify need for continued hospitalization if he or she finds that the patient could receive proper treatment in a SNF but no bed is available in a participating SNF.

(2) If this is the basis for the physician's certification or recertification, the required statement must so indicate; and the certifying physician is expected to continue efforts to place the patient in a participating SNF as soon as a bed becomes available.

(d) *Signatures*—(1) *Basic rule.* Except as specified in paragraph (d)(2) of this section, certifications and recertifications must be signed by the physician responsible for the case, or by another physician who has knowledge of the case and who is authorized to do so by the responsible physician or by the hospital's medical staff.

(2) *Exception.* If the intermediary requests certification of the need to admit a patient in connection with dental procedures, because his or her underlying medical condition and clinical status or the severity of the dental procedures require hospitalization, that certification may be signed by the dentist caring for the patient.

(e) *Timing of certifications and recertifications: Outlier cases not subject to the prospective payment system (PPS).* (1) For outlier cases that are not subject to the PPS, certification is required no later than as of the 12th day of hospitalization. A hospital may, at its option, provide for the certification to be made earlier, or it may vary the timing of the certification within the 12-day period by diagnostic or clinical categories.

(2) The first recertification is required no later than as of the 18th day of hospitalization.

(3) Subsequent recertifications are required at intervals established by the UR committee (on a case-by-case basis if it so chooses), but no less frequently than every 30 days.

(f) *Timing of certification and recertification: Outlier cases subject to PPS.* For outlier cases subject to the PPS, certification is required as follows:

(1) For day outlier cases, certification is required no later than 1 day after the hospital reasonably assumes that the case meets the outlier criteria, established in accordance with § 412.80(a)(1)(i) of this chapter, or no later than 20 days into the hospital stay, whichever is earlier. The first and subsequent recertifications are required at intervals established by the UR committee (on a case-by-case basis if it so chooses) but not less frequently than every 30 days.

(2) For cost outlier cases, certification is required no later than the date on which the hospital requests cost outlier payment or 20 days into the hospital stay, whichever is earlier. If possible, certification must be made before the hospital incurs costs for which it will seek cost outlier payment. In cost outlier cases, the first and subsequent recertifications are required at intervals established by the UR committee (on a case-by-case basis if it so chooses).

(g) *Recertification requirement fulfilled by utilization review.* (1) At the hospital's option, extended stay review by its UR committee may take the place of the second and subsequent recertifications required for outlier cases not subject to PPS and for PPS day-outlier cases.

(2) A utilization review that is used to fulfill the recertification requirement is considered timely if performed no later than the seventh day after the day the recertification would have been required. The next recertification would need to be made no later than the 30th day following such review; if review by the UR committee took the place of this recertification, the review could be performed as late as the seventh day following the 30th day.

(h) *Description of procedures.* The hospital must have available on file a written description that specifies the time schedule for certifications and recertifications, and indicates whether utilization review of long-stay cases fulfills the requirement for second and subsequent recertifications of all outlier cases not subject to PPS and of PPS day outlier cases.

[78 FR 50969, Aug. 19, 2013, as amended at 79 FR 67033, Nov. 10, 2014]

§ 424.14 Requirements for inpatient services of inpatient psychiatric facilities.

(a) *Requirements for certification and recertification: General considerations.* Certification begins with the order for inpatient admission. The content requirements differ from those for other hospitals because the care furnished in inpatient psychiatric facilities is often purely custodial and thus not covered under Medicare. The purpose of the statements, therefore, is to help ensure that Medicare pays only for services of the type appropriate for Medicare coverage. Accordingly, Medicare Part A pays for inpatient services in an inpatient psychiatric facility only if a physician certifies and recertifies the need for services consistent with the requirements of this section, as appropriate.

(b) *Content of certification.* The physician must certify—

(1) That inpatient psychiatric services were required for treatment that could reasonably be expected to improve the patient's condition, or for diagnostic study.

(2) That the inpatient psychiatric services were provided in accordance with § 412.3 of this chapter.

(c) *Content of recertification.* (1) Inpatient services furnished since the previous certification or recertification were, and continue to be, required—

(i) For treatment that could reasonably be expected to improve the patient's condition; or

(ii) For diagnostic study; and

(2) The hospital records show that the services furnished were—

(i) Intensive treatment services;

(ii) Admission and related services necessary for diagnostic study; or

(iii) Equivalent services.

(3) The patient continues to need, on a daily basis, active treatment furnished directly by or requiring the supervision of inpatient psychiatric facility personnel.

(d) *Timing of certification and recertification.* (1) Certification is required at the time of admission or as soon thereafter as is reasonable and practicable, and must be completed and documented in the medical record prior to discharge.

(2) The first recertification is required as of the 12th day of hospitalization. Subsequent recertifications are required at intervals established by the UR committee (on a case-by-case basis if it so chooses), but no less frequently than every 30 days.

(e) *Other requirements.* Inpatient psychiatric facilities must also meet the requirements set forth in § 424.13(c), (d), (g), and (h).

[53 FR 6634, Mar. 2, 1988, as amended at 71 FR 27087, May 9, 2006; 71 FR 37504, June 30, 2006; 78 FR 50970, Aug. 19, 2013]

§ 424.15 Requirements for inpatient CAH services.

(a) Medicare Part A pays for inpatient CAH services only if a physician certifies that the individual may reasonably be expected to be discharged or transferred to a hospital within 96 hours after admission to the CAH, and that the services are provided in accordance with § 412.3 of this chapter.

(b) Certification begins with the order for inpatient admission. All certification requirements must be completed, signed, and documented in the medical record no later than 1 day before the date on which the claim for payment for the inpatient CAH service is submitted.

[78 FR 50970, Aug. 19, 2013, as amended at 79 FR 50359, Aug. 22, 2014]

§ 424.16 Timing of certification for individual admitted to a hospital before entitlement to Medicare benefits.

(a) *Basic rule.* If an indivdual is admitted to a hospital before becoming entitled to Medicare benefits (for instance, before attaining age 65), the day of entitlement (instead of the day of admission) is the starting point for the time limits specified in subpart B of this part for certification and recertification.

(b) *Example. (Hospital that is not a psychiatric hospital and is not subject to PPS).* For a patient who is admitted on August 15 and becomes entitled on September 1—

(1) The certification is required no later than September 12;

(2) The first recertification is required no later than September 18; and

(3) Subsequent recertifications are required at least every 30 days after September 18.

[53 FR 6635, Mar. 2, 1988; 53 FR 12945, Apr. 20, 1988, as amended at 78 FR 50970, Aug. 19, 2013]

§ 424.20 Requirements for posthospital SNF care.

Medicare Part A pays for posthospital SNF care furnished by an SNF, or a hospital or CAH with a swing-bed approval, only if the certification and recertification for services are consistent with the content of paragraph (a) or (c) of this section, as appropriate.

(a) *Content of certification*—(1) *General requirements.* Posthospital SNF care is or was required because—

(i) The individual needs or needed on a daily basis skilled nursing care (furnished directly by or requiring the supervision of skilled nursing personnel) or other skilled rehabilitation services that, as a practical matter, can only be provided in an SNF or a swing-bed hospital on an inpatient basis, and the SNF care is or was needed for a condition for which the individual received inpatient care in a participating hospital or a qualified hospital, as defined in § 409.3 of this chapter, or for a new condition that arose while the individual was receiving care in the SNF or swing-bed hospital for a condition for which he or she received inpatient care in a participating or qualified hospital; or

(ii) The individual has been correctly assigned one of the case-mix classifiers that CMS designates as representing the required level of care, as provided in § 409.30 of this chapter.

(2) *Special requirement for certifications performed prior to July 1, 2002: A swing-bed hospital with more than 49 beds (but fewer than 100) that does not transfer a swing-bed patient to a SNF within 5 days*

of the availability date. Transfer of the extended care patient to the SNF is not medically appropriate.

(b) *Timing of certification*—(1) *General rule*. The certification must be obtained at the time of admission or as soon thereafter as is reasonable and practicable.

(2) *Special rules for certain swing-bed hospitals*. For swing-bed hospitals with more than 49 beds that are approved after March 31, 1988, the extended care patient's physician has 5 days (excluding weekends and holidays) beginning on the availability date as defined in § 413.114(b), to certify that the transfer of the extended care patient is not medically appropriate.

(c) *Content of recertifications*. (1) The reasons for the continued need for posthospital SNF care:

(2) The estimated time the individual will need to remain in the SNF;

(3) Plans for home care, if any; and

(4) If appropriate, the fact that continued services are needed for a condition that arose after admission to the SNF and while the individual was still under treatment for the condition for which he or she had received inpatient hospital services.

(d) *Timing of recertifications*. (1) The first recertification is required no later than the 14th day of posthospital SNF care.

(2) Subsequent recertifications are required at least every 30 days after the first recertification.

(e) *Signature*. Certification and recertification statements may be signed by—

(1) The physician responsible for the case or, with his or her authorization, by a physician on the SNF staff or a physician who is available in case of an emergency and has knowledge of the case; or

(2) A physician extender (that is, a nurse practitioner, a clinical nurse specialist, or a physician assistant as those terms are defined in section 1861(aa)(5) of the Act) who does not have a direct or indirect employment relationship with the facility but who is working in collaboration with a physician. For purposes of this section—

(i) *Collaboration*. (A) Collaboration means a process whereby a physician extender works with a doctor of medicine or osteopathy to deliver health care services.

(B) The services are delivered within the scope of the physician extender's professional expertise, with medical direction and appropriate supervision as provided for in guidelines jointly developed by the physician extender and the physician or other mechanisms defined by Federal regulations and the law of the State in which the services are performed.

(ii) *Types of employment relationships*. (A) *Direct employment relationship*. A direct employment relationship with the facility is one in which the physician extender meets the common law definition of the facility's ''employee,'' as specified in §§ 404.1005, 404.1007, and 404.1009 of title 20 of the regulations. When a physician extender meets this definition with respect to an entity other than the facility itself, and that entity has an agreement with the facility for the provision of nursing services under § 409.21 of this subchapter, the facility is considered to have an indirect employment relationship with the physician extender.

(B) *Indirect employment relationship*. (*1*) When a physician extender meets the definition of a direct employment relationship in paragraph (e)(2)(ii)(A) of this section with respect to an entity other than the facility itself, and that entity has an agreement with the facility for the provision of nursing services under § 409.21 of this subchapter, the facility is considered to have an indirect employment relationship with the physician extender.

(*2*) An indirect employment relationship does not exist if the agreement between the entity and the facility involves only the performance of delegated physician tasks under § 483.30(e) of this chapter.

(f) *Recertification requirement fulfilled by utilization review*. A SNF may substitute utilization review of extended stay cases for the second and subsequent recertifications, if it includes this procedure in its utilization review plan.

(g) *Description of procedures*. The SNF must have available on file a written description that specifies the certification and recertification time schedule and indicates whether utilization

review is used as an alternative to the second and subsequent recertifications.

[53 FR 6634, Mar. 2, 1988, as amended at 54 FR 37275, Sept. 7, 1989; 58 FR 30671, May 26, 1993; 60 FR 38272, July 26, 1995; 62 FR 46037, Aug. 29, 1997; 63 FR 26311, May 12, 1998; 63 FR 53307, Oct. 5, 1998; 66 FR 39600, July 31, 2001; 70 FR 45055, Aug. 4, 2005; 75 FR 73626, Nov. 29, 2010; 82 FR 36635, Aug. 4, 2017; 83 FR 39290, Aug. 8, 2018]

§ 424.22 Requirements for home health services.

Medicare Part A or Part B pays for home health services only if a physician or allowed practitioner as defined at § 484.2 of this chapter certifies and recertifies the content specified in paragraphs (a)(1) and (b)(2) of this section, as appropriate.

(a) *Certification*—(1) *Content of certification.* As a condition for payment of home health services under Medicare Part A or Medicare Part B, a physician or allowed practitioner must certify the patient's eligibility for the home health benefit, as outlined in sections 1814(a)(2)(C) and 1835(a)(2)(A) of the Act, as follows in paragraphs (a)(1)(i) through (v) of this section. The patient's medical record, as specified in paragraph (c) of this section, must support the certification of eligibility as outlined in paragraph (a)(1)(i) through (v) of this section.

(i) The individual needs or needed intermittent skilled nursing care, or physical therapy or speech-language pathology services as defined in § 409.42(c) of this chapter. If a patient's underlying condition or complication requires a registered nurse to ensure that essential non-skilled care is achieving its purpose, and necessitates a registered nurse be involved in the development, management, and evaluation of a patient's care plan, the physician or allowed practitioner will include a brief narrative describing the clinical justification of this need. If the narrative is part of the certification form, then the narrative must be located immediately prior to the physician or allowed practitioner's signature signature. If the narrative exists as an addendum to the certification form, in addition to the physician or allowed practitioner's signature signature on the certification form, the physician or allowed practitioner must sign immediately following the narrative in the addendum.

(ii) Home health services are or were required because the individual is or was confined to the home, as defined in sections 1835(a) and 1814(a) of the Act, except when receiving outpatient services.

(iii) A plan for furnishing the services has been established and will be or was periodically reviewed by a physician or allowed practitioner and who is not precluded from performing this function under paragraph (d) of this section.

(iv) The services will be or were furnished while the individual was under the care of a physician or allowed practitioner.

(v) A face-to-face patient encounter, which is related to the primary reason the patient requires home health services, occurred no more than 90 days prior to the home health start of care date or within 30 days of the start of the home health care and was performed by physician or non-physician practitioner defined in paragraph (a)(1)(v)(A) of this section. The certifying physician or certifying allowed practitioner must also document the date of the encounter as part of the certification.

(A) The face-to-face encounter must be performed by one of the following:

(*1*) The certifying physician (as defined at § 484.2 of this chapter) or a physician, with privileges, who cared for the patient in an acute or post-acute care facility from which the patient was directly admitted to home health.

(*2*) The certifying nurse practitioner (as defined at § 484.2 of this chapter), certifying clinical nurse specialist (as defined at § 484.2 of this chapter), or a nurse practitioner or a clinical nurse specialist who is working in accordance with State law and in collaboration with a physician or in collaboration with an acute or post-acute care physician with privileges who cared for the patient in the acute or post-acute care facility from which the patient was directly admitted to home health.

(*3*) A certified nurse midwife (as defined in section 1861(gg) of the Act) as authorized by State law, under the supervision of a physician or under the supervision of an acute or post-acute

care physician with privileges who cared for the patient in the acute or post-acute care facility from which the patient was directly admitted to home health.

(*4*) A certifying physician assistant (as defined at § 484.2 of this chapter) or a physician assistant under the supervision of a physician or under the supervision of an acute or post-acute care physician with privileges who cared for the patient in the acute or post-acute care facility from which the patient was directly admitted to home health.

(B) The face-to-face patient encounter may occur through telehealth, in compliance with section 1834(m) of the Act and subject to the list of payable Medicare telehealth services established by the applicable physician fee schedule regulation.

(C) The face-to-face patient encounter must be performed by the certifying physician or allowed practitioner unless the encounter is performed by:

(*1*) A certified nurse midwife as described in paragraph (a)(1)(v)(A)(*4*) of this section.

(*2*) A physician, physician assistant, nurse practitioner, or clinical nurse specialist with privileges who cared for the patient in the acute or post-acute facility from which the patient was directly admitted to home health and who is different from the certifying practitioner.

(2) *Timing and signature.* The certification of need for home health services must be obtained at the time the plan of care is established or as soon thereafter as possible and must be signed and dated by the physician or allowed practitioner who establishes the plan.

(b) *Recertification*—(1) *Timing and signature of recertification.* Recertification is required at least every 60 days when there is a need for continuous home health care after an initial 60-day episode. Recertification should occur at the time the plan of care is reviewed, and must be signed and dated by the physician or allowed practitioner who reviews the plan of care. Recertification is required at least every 60 days unless there is a—

(i) Beneficiary elected transfer; or

(ii) Discharge with goals met and/or no expectation of a return to home health care.

(2) *Content and basis of recertification.* As a condition for payment of home health services under Medicare Part A or Medicare Part B, if there is a continuing need for home health services, a physician or allowed practitioner must recertify the patient's continued eligibility for the home health benefit as outlined in sections 1814(a)(2)(C) and 1835(a)(2)(A) of the Act, as set forth in paragraph (a)(1) of this section, and as specified in paragraphs (b)(2)(i) and (ii) of this section.

(i) Need for occupational therapy may be the basis for continuing services that were initiated because the individual needed skilled nursing care or physical therapy or speech therapy.

(ii) If a patient's underlying condition or complication requires a registered nurse to ensure that essential non-skilled care is achieving its purpose, and necessitates a registered nurse be involved in the development, management, and evaluation of a patient's care plan, the physician or allowed practitioner must include a brief narrative describing the clinical justification of this need. If the narrative—

(A) Is part of the recertification form, then the narrative must be located immediately prior to the physician or allowed practitioner's signature.

(B) Exists as an addendum to the recertification form, in addition to the physician or allowed practitioner's signature on the recertification form, the physician or allowed practitioner must sign immediately following the narrative in the addendum.

(c) *Determining patient eligibility for Medicare home health services.* (1) Documentation in the certifying physician or allowed practitioner's medical record or the acute/post-acute care facility's medical records (if the patient was directly admitted to home health) or both must be used as the basis for certification of the patient's eligibility for home health as described in paragraphs (a)(1) and (b) of this section. Documentation from the HHA may also be used to support the basis for certification of home health eligibility, but only if the following requirements are met:

(i) The documentation from the HHA can be corroborated by other medical record entries in the certifying physician or allowed practitioner's medical record for the patient or the acute/post-acute care facility's medical record for the patient or both, thereby creating a clinically consistent picture that the patient is eligible for Medicare home health services.

(ii)(A) The certifying physician or allowed practitioner signs and dates the HHA documentation demonstrating that the documentation from the HHA was considered when certifying patient eligibility for Medicare home health services.

(B) HHA documentation can include, but is not limited to, the patient's plan of care required under § 409.43 of this chapter, or the initial or comprehensive assessment of the patient required under § 484.55 of this chapter.

(2) The documentation must be provided upon request to review entities or CMS or both. If the documentation used as the basis for the certification of eligibility is not sufficient to demonstrate that the patient is or was eligible to receive services under the Medicare home health benefit, payment is not rendered for home health services provided.

(d) *Limitation of the performance of physician or allowed practitioner's certification and plan of care functions.* The need for home health services to be provided by an HHA may not be certified or recertified, and a plan of care may not be established and reviewed, by any physician or allowed practitioner who has a financial relationship as defined in § 411.354 of this chapter, with that HHA, unless the physician or allowed practitioner's relationship meets one of the exceptions in section 1877 of the Act, which sets forth general exceptions to the referral prohibition related to both ownership/investment and compensation; exceptions to the referral prohibition related to ownership or investment interests; and exceptions to the referral prohibition related to compensation arrangements.

(1) If a physician or allowed practitioner has a financial relationship as defined in § 411.354 of this chapter, with an HHA, the physician or allowed practitioner may not certify or recertify need for home health services provided by that HHA, establish or review a plan of treatment for such services, or conduct the face-to-face encounter required under sections 1814(a)(2)(C) and 1835(a)(2)(A) of the Act unless the financial relationship meets one of the exceptions set forth in § 411.355 through § 411.357 of this chapter.

(2) A Nonphysician practitioner may not perform the face-to-face encounter required under sections 1814(a)(2)(C) and 1835(a)(2)(A) of the Act if such encounter would be prohibited under paragraph (d)(1) if the nonphysician practitioner were a physician.

[53 FR 6638, Mar. 2, 1988; 53 FR 12945, Apr. 20, 1988; 56 FR 8845, Mar. 1, 1991, as amended at 65 FR 41211, July 3, 2000; 66 FR 962, Jan. 4, 2001; 70 FR 70334, Nov. 21, 2005; 72 FR 51098, Sept. 5, 2007; 74 FR 58133, Nov. 10, 2009; 75 FR 70463, Nov. 17, 2010; 76 FR 9503, Feb. 18, 2011; 76 FR 68606, Nov. 4, 2011; 77 FR 67163, Nov. 8, 2012; 79 FR 66116, Nov. 6, 2014; 80 FR 68717, Nov. 5, 2015; 83 FR 56627, Nov. 13, 2018; 85 FR 27624, May 8, 2020]

§ 424.24 Requirements for medical and other health services furnished by providers under Medicare Part B.

(a) *Exempted services.* Certification is not required for the following:

(1) Hospital services and supplies incident to physicians' services furnished to outpatients. The exemption applies to drugs and biologicals that cannot be self-administered, but not to partial hospitalization services, as set forth in paragraph (e) of this section.

(2) Outpatient hospital diagnostic services, including necessary drugs and biologicals, ordinarily furnished or arranged for by a hospital for the purpose of diagnostic study.

(b) *General rule.* Medicare Part B pays for medical and other health services furnished by providers (and not exempted under paragraph (a) of this section) only if a physician certifies the content specified in paragraph (c)(1) or (4), (d)(1), or (e)(1) of this section, as appropriate.

(c) *Outpatient physical therapy, occupational therapy, and speech-language pathology services*—(1) *Content of certification.* (i) The individual needs, or needed, physical therapy, occupational therapy, or speech-language pathology services.

(ii) The services were furnished while the individual was under the care of a physician, nurse practitioner, clinical nurse specialist, or physician assistant.

(iii) The services were furnished under a plan of treatment that meets the requirements of § 410.61 of this chapter.

(2) *Timing.* The initial certification must be obtained as soon as possible after the plan is established.

(3) *Signature.* (i) If the plan of treatment is established by a physician, nurse practitioner, clinical nurse specialist, or physician assistant, the certification must be signed by that physician or nonphysician practitioner.

(ii) If the plan of treatment is established by a physical therapist, occupational therapist, or speech-language pathologist, the certification must be signed by a physician or by a nurse practitioner, clinical nurse specialist, or physician assistant who has knowledge of the case, except as specified in paragraph (c)(5) of this section.

(4) *Recertification*—(i) *Timing.* Recertification is required at least every 90 days.

(ii) *Content.* When it is recertified, the plan or other documentation in the patient's record must indicate the continuing need for physical therapy, occupational therapy or speech-language pathology services.

(iii) *Signature.* The physician, nurse practitioner, clinical nurse specialist, or physician assistant who reviews the plan must recertify the plan by signing the medical record.

(5) *Treatment plan.* If the plan of treatment is established by a physical therapist, occupational therapist, or speech-language pathologist, and there is a written order or referral from the individual's physician, nurse practitioner (NP), physician assistant (PA), or clinical nurse specialist (CNS) in the patient's record and the therapist has documented evidence that the plan of treatment has been delivered to the physician, NP, PA, or CNS within 30 days of completion of the initial evaluation, the certification does not need to be signed by a physician, NP, CNS, or PA who has knowledge of the case. If there is no written order or referral from the individual's physician, NP, CNS, or PA, in the patient's record, the therapist must obtain the signature of the physician, NP, PA, or CNS on the plan of treatment in accordance with paragraph (c)(3) of this section. No references to an order or referral in this subsection shall be construed to require an order or referral for outpatient physical therapy, occupational therapy, or speech-language pathology services.

(d) *Intensive outpatient services: Content of certification and plan of treatment requirements*—

(1) *Content of certification.* (i) The individual requires such services for a minimum of 9 hours per week.

(ii) The services are or were furnished while the individual was under the care of a physician.

(iii) The services were furnished under a written plan of treatment that meets the requirements of paragraph (d)(2) of this section.

(2) *Plan of treatment requirements.* (i) The plan is an individualized plan that is established and is periodically reviewed by a physician in consultation with appropriate staff participating in the program, and that sets forth—

(A) The physician's diagnosis;

(B) The type, amount, duration, and frequency of the services; and

(C) The treatment goals under the plan.

(ii) The physician determines the frequency and duration of the services taking into account accepted norms of medical practice and a reasonable expectation of improvement in the patient's condition.

(3) *Recertification requirements*—(i) *Signature.* The physician recertification must be signed by a physician who is treating the patient and has knowledge of the patient's response to treatment.

(ii) *Timing.* Recertifications are required at intervals established by the provider, but no less frequently than every 60 days.

(iii) *Content.* The recertification must specify that the patient continues to require at least 9 hours of intensive outpatient services and describe the following:

(A) The patient's response to the therapeutic interventions provided by the intensive outpatient program.

(B) The patient's psychiatric symptoms that continue to place the patient at risk of relapse or hospitalization.

(C) Treatment goals for coordination of services to facilitate discharge from the intensive outpatient program.

(e) *Partial hospitalization services: Content of certification and plan of treatment requirements*—(1) *Content of certification.* (i) The individual requires such services for a minimum of 20 hours per week and would require inpatient psychiatric care if the partial hospitalization services were not provided.

(ii) The services are or were furnished while the individual was under the care of a physician.

(iii) The services were furnished under a written plan of treatment that meets the requirements of paragraph (e)(2) of this section.

(2) *Plan of treatment requirements.* (i) The plan is an individualized plan that is established and is periodically reviewed by a physician in consultation with appropriate staff participating in the program, and that sets forth—

(A) The physician's diagnosis;

(B) The type, amount, duration, and frequency of the services; and

(C) The treatment goals under the plan.

(ii) The physician determines the frequency and duration of the services taking into account accepted norms of medical practice and a reasonable expectation of improvement in the patient's condition.

(3) *Recertification requirements*—(i) *Signature.* The physician recertification must be signed by a physician who is treating the patient and has knowledge of the patient's response to treatment.

(ii) *Timing.* The first recertification is required as of the 18th day of partial hospitalization services. Subsequent recertifications are required at intervals established by the provider, but no less frequently than every 30 days.

(iii) *Content.* The recertification must specify that the patient would otherwise require inpatient psychiatric care in the absence of continued stay in the partial hospitalization program and describe the following:

(A) The patient's response to the therapeutic interventions provided by the partial hospitalization program.

(B) The patient's psychiatric symptoms that continue to place the patient at risk of hospitalization.

(C) Treatment goals for coordination of services to facilitate discharge from the partial hospitalization program.

(f) *Blood glucose testing.* For each blood glucose test, the physician must certify that the test is medically necessary. A physician's standing order is not sufficient to order a series of blood glucose tests payable under the clinical laboratory fee schedule.

(g) *All other covered medical and other health services furnished by providers*—(1) *Content of certification.* The services were medically necessary,

(2) *Signature.* The certificate must be signed by a physician, nurse practioner, clinical nurse specialist, or physician assistant who has knowledge of the case.

(3) *Timing.* The physician, nurse practioner, clinical nurse specialist, or physician assistant may provide certification at the time the services are furnished or, if services are provided on a continuing basis, either at the beginning or at the end of a series of visits.

(4) *Recertification.* Recertification of continued need for services is not required.

[53 FR 6638, Mar. 2, 1988; 53 FR 12945, Apr. 20, 1988, as amended at 56 FR 8845, 8853, Mar. 1, 1991; 63 FR 58912, Nov. 2, 1998; 65 FR 18548, Apr. 7, 2000; 71 FR 69788, Dec. 1, 2006; 72 FR 66405, Nov. 27, 2007; 88 FR 82182, Nov. 22, 2023; 89 FR 98565, Dec. 9, 2024]

§ 424.27 Requirements for comprehensive outpatient rehabilitation facility (CORF) services.

Medicare Part B pays for CORF services only if a physician certifies, and the facility physician recertifies, the content specified in paragraphs (a) and (b)(2) of this section, as appropriate.

(a) *Certification: Content.* (1) The services were required because the individual needed skilled rehabilitation services;

(2) The services were furnished while the individual was under the care of a physician; and

(3) A written plan of treatment has been established and is reviewed periodically by a physician.

(b) *Recertification*—(1) *Timing.* Recertification is required at least every 60 days for respiratory therapy services

and every 90 days for physical therapy, occupational therapy, and speech-language pathology services based on review by a facility physician or the referring physician who, when appropriate, consults with the professional personnel who furnish the services.

(2) *Content.* (i) The plan is being followed;

(ii) The patient is making progress in attaining the rehabilitation goals; and,

(iii) The treatment is not having any harmful effect on the patient.

[53 FR 6634, Mar. 2, 1988, as amended at 72 FR 66405, Nov. 27, 2007]

Subpart C—Claims for Payment

§ 424.30 Scope.

This subpart sets forth the requirements, procedures, and time limits for claiming Medicare payments. Claims must be filed in all cases except when services are furnished on a prepaid capitation basis by an MA organization, or through cost settlement with either a health maintenance organization (HMO), a competitive medical plan (CMP), or a health care prepayment plan (HCPP), or as part of a demonstration. Therefore, claims must be filed by hospitals seeking IME payment under § 412.105(g) of this chapter, and/or direct GME payment under § 413.76(c) of this chapter, and/or nursing or allied health education payment under § 413.87 of this chapter associated with inpatient services furnished on a prepaid capitation basis by an MA organization. Hospitals that must report patient data for purposes of the DSH payment adjustment under § 412.106 of this chapter for inpatient services furnished on a prepaid capitation basis by an MA organization, or through cost settlement with an HMO/CMP, or as part of a demonstration, are required to file claims by submitting no pay bills for such inpatients. Special procedures for claiming payment after the beneficiary has died and for certain bills paid by organizations are set forth in subpart E of this part.

[77 FR 53682, Aug. 31, 2012]

§ 424.32 Basic requirements for all claims.

(a) A claim must meet the following requirements:

(1) A claim must be filed with the appropriate intermediary or carrier on a form prescribed by CMS in accordance with CMS instructions.

(2) A claim for physician services, clinical psychologist services, or clinical social worker services must include appropriate diagnostic coding for those services using ICD–9–CM.

(3) A claim must be signed by the beneficiary or on behalf of the beneficiary (in accordance with § 424.36).

(4) A claim must be filed within the time limits specified in § 424.44.

(5) All Part B claims for services furnished to SNF residents (whether filed by the SNF or by another entity) must include the SNF's Medicare provider number and appropriate HCPCS coding.

(b) The prescribed forms for claims are the following:

CMS–1450—Uniform Institutional Provider Bill. (This form is for institutional provider billing for Medicare inpatient, outpatient and home health services.)

CMS–1490S—Request for Medicare payment. (For use by a patient to request payment for medical expenses.)

CMS–1500—Health Insurance Claim Form. (For use by physicians and other suppliers to request payment for medical services.)

CMS–1660—Request for Information-Medicare Payment for Services to a Patient now Deceased. (For use in requesting amounts payable under title XVIII to a deceased beneficiary.)

(c) *Where claims forms are available.* Excluding forms CMS–1450 and CMS–1500, all claims forms prescribed for use in the Medicare program are distributed free-of-charge to the public, institutions, or organizations. The CMS–1450 and CMS–1500 may be obtained only by commercial purchase. All other claims forms can be obtained upon request from CMS or any Social Security branch or district office, or from Medicare intermediaries or carriers. The CMS–1490S is also available at local Social Security Offices.

(d) *Submission of electronic claims*—(1) *Definitions.* For purposes of this paragraph, the following terms have the following meanings:

(i) *Claim* means a transaction defined at 45 CFR 162.1101(a).

(ii) *Electronic claim* means a claim that is submitted via electronic media. A claim submitted via direct data entry is considered to be an electronic claim.

(iii) *Direct data entry* is defined at 45 CFR 162.103.

(iv) *Electronic media* is defined at 45 CFR 160.103.

(v) *Initial Medicare claim* means a claim submitted to Medicare for payment under Part A or Part B of the Medicare Program under title XVIII of the Act for initial processing, including claims sent to Medicare for the first time for secondary payment purposes. Initial Medicare claim excludes any adjustment or appeal of a previously submitted claim, and claims submitted for payment under Part C of the Medicare program under title XVIII of the Act.

(vi) *Physician, practitioner, facility, or supplier* is a Medicare provider or supplier other than a provider of services.

(vii) *Provider of services* means a provider of services as defined in section 1861(u) of the Act.

(viii) *Small provider of services or small supplier* means—

(A) A provider of services with fewer than 25 full-time equivalent employees; or

(B) A physician, practitioner, facility, or supplier with fewer than 10 full-time equivalent employees.

(2) *Submission of electronic claims required.* Except for claims to which paragraph (d)(3) or (d)(4) of this section applies, an initial Medicare claim may be paid only if submitted as an electronic claim for processing by the Medicare fiscal intermediary or carrier that serves the physician, practitioner, facility, supplier, or provider of services. This requirement does not apply to any other transactions, including adjustment or appeal of the initial Medicare claim.

(3) *Exceptions to requirement to submit electronic claims.* The requirement of paragraph (d)(2) of this section is waived for any initial Medicare claim when—

(i) There is no method available for the submission of an electronic claim. This exception includes claims submitted by Medicare beneficiaries and situations in which the standard adopted by the Secretary at 45 FR 162.1102 does not support all of the information necessary for payment of the claim. The Secretary may identify situations coming within this exception in guidance.

(ii) The entity submitting the claim is a small provider of services or small supplier.

(4) *Unusual cases.* The Secretary may waive the requirement of paragraph (d)(2) of this section in unusual cases as the Secretary finds appropriate. Unusual cases are deemed to exist in the following situations:

(i) The submission of dental claims.

(ii) There is a service interruption in the mode of submitting the electronic claim that is outside the control of the entity submitting the claim, for the period of the interruption.

(iii) The entity submitting the claim submits fewer than 10 claims to Medicare per month, on average.

(iv) The entity submitting the claim only furnishes services outside of the U.S. territory.

(v) On demonstration, satisfactory to the Secretary, of other extraordinary circumstances precluding submission of electronic claims.

(5) *Effective date.* This paragraph (d) is effective October 16, 2003, and applies to claims submitted on or after October 16, 2003.

[53 FR 6639, Mar. 2, 1988; 53 FR 12945, Apr. 20, 1988, as amended at 59 FR 10299, Mar. 4, 1994; 63 FR 26311, May 12, 1998; 63 FR 53307, Oct. 5, 1998; 66 FR 39601, July 31, 2001; 68 FR 48813, Aug. 15, 2003; 70 FR 71020, Nov. 25, 2005; 71 FR 48143, Aug. 18, 2006; 72 FR 66405, Nov. 27, 2007]

§ 424.33 Additional requirements: Claims for services of providers and claims by suppliers and nonparticipating hospitals.

All claims for services of providers and all claims by suppliers and nonparticipating hospitals must be—

(a) Filed by the provider, supplier, or hospital; and

(b) Signed by the provider, supplier, or hospital unless CMS instructions waive this requirement.

§ 424.34 Additional requirements: Beneficiary's claim for direct payment.

(a) *Basic rule.* A beneficiary's claim for direct payment for services furnished by a supplier, or by a nonparticipating hospital that has not elected to claim payment for emergency services, must include an itemized bill or a ''report of services'', as specified in paragraphs (b) and (c) of this section.

(b) *Itemized bill from the hospital or supplier.* The itemized bill for the services, which may be receipted or unpaid, must include all of the following information:

(1) The name and address of—

(i) The beneficiary;

(ii) The supplier or nonparticipating hospital that furnished the services; and

(iii) The physician who prescribed the services if they were furnished by a supplier other than the physician.

(2) The place where each service was furnished, e.g., home, office, independent laboratory, hospital.

(3) The date each service was furnished.

(4) A listing of the services in sufficient detail to permit determination of payment under the fee schedule for physicians' services; for itemized bills from physicians, appropriate diagnostic coding using ICD–9–CM must be used.

(5) The charges for each service.

(c) *Report of services furnished by a supplier.* For Medicare Part B services furnished by a supplier, the beneficiary claims may include the ''Report of Services'' portion of the appropriate claims form, completed by the supplier in accordance with CMS instructions, in lieu of an itemized bill.

[53 FR 6634, Mar. 2, 1988, as amended at 59 FR 10299, Mar. 4, 1994; 59 FR 26740, May 24, 1994]

§ 424.36 Signature requirements.

(a) *General rule.* The beneficiary's own signature is required on the claim unless the beneficiary has died or the provisions of paragraphs (b), (c), or (d) of this section apply. For purposes of this section, ''the claim'' includes the actual claim form or such other form that contains adequate notice to the beneficiary or other authorized individual that the purpose of the signature is to authorize a provider or supplier to submit a claim to Medicare for specified services furnished to the beneficiary.

(b) *Who may sign when the beneficiary is incapable.* If the beneficiary is physically or mentally incapable of signing the claim, the claim may be signed on his or her behalf by one of the following:

(1) The beneficiary's legal guardian.

(2) A relative or other person who receives social security or other governmental benefits on the beneficiary's behalf.

(3) A relative or other person who arranges for the beneficiary's treatment or exercises other responsibility for his or her affairs.

(4) A representative of an agency or institution that did not furnish the services for which payment is claimed but furnished other care, services, or assistance to the beneficiary.

(5) A representative of the provider or of the nonparticipating hospital claiming payment for services it has furnished if the provider or nonparticipating hospital is unable to have the claim signed in accordance with paragraph (b)(1), (2), (3), or (4) of this section after making reasonable efforts to locate and obtain the signature of one of the individuals specified in paragraph (b)(1), (2), (3), or (4) of this section.

(6) An ambulance provider or supplier with respect to emergency or nonemergency ambulance transport services, if the following conditions and documentation requirements are met.

(i) None of the individuals listed in paragraph (b)(1), (2), (3), or (4) of this section was available or willing to sign the claim on behalf of the beneficiary at the time the service was provided;

(ii) The ambulance provider or supplier maintains in its files the following information and documentation for a period of at least four years from the date of service:

(A) A contemporaneous statement, signed by an ambulance employee present during the trip to the receiving facility, that, at the time the service was provided, the beneficiary was physically or mentally incapable of signing

the claim and that none of the individuals listed in paragraph (b)(1), (2), (3), or (4) of this section were available or willing to sign the claim on behalf of the beneficiary, and

(B) Documentation with the date and time the beneficiary was transported, and the name and location of the facility that received the beneficiary, and

(C) Either of the following:

(*1*) A signed contemporaneous statement from a representative of the facility that received the beneficiary, which documents the name of the beneficiary and the date and time the beneficiary was received by that facility; or

(*2*) The requested information from a representative of the hospital or facility using a secondary form of verification obtained at a later date, but prior to submitting the claim to Medicare for payment. Secondary forms of verification include a copy of any of the following:

(*i*) The signed patient care/trip report;

(*ii*) The facility or hospital registration/admission sheet;

(*iii*) The patient medical record;

(*iv*) The facility or hospital log; or

(*v*) Other internal facility or hospital records.

(c) *Who may sign if the beneficiary was not present for the service.* If a provider, nonparticipating hospital, or supplier files a claim for services that involved no personal contact between the provider, hospital, or supplier and the beneficiary (for example, a physician sent a blood sample to the provider for diagnostic tests), a representative of the provider, hospital, or supplier may sign the claim on the beneficiary's behalf.

(d) *Claims by entities that provide coverage complementary to Medicare.* A claim by an entity that provides coverage complementary to Medicare Part B may be signed by the entity on the beneficiary's behalf.

(e) *Acceptance of other signatures for good cause.* If good cause is shown, CMS may honor a claim signed by a party other than those specified in paragraphs (a) through (c) of this section.

[53 FR 6640, Mar. 2, 1988; 53 FR 12945, Apr. 20, 1988, as amended at 53 FR 28388, July 28, 1988; 72 FR 66406, Nov. 27, 2007; 73 FR 2432, Jan. 15, 2008; 73 FR 66938, Nov. 19, 2008]

§ 424.37 Evidence of authority to sign on behalf of the beneficiary.

(a) *Beneficiary incapable.* When a party specified in § 424.36(b) signs a claim or request for payment statement, he or she must also submit a brief statement that—

(1) Describes his or her relationship to the beneficiary; and

(2) Explains the circumstances that make it impractical for the beneficiary to sign the claim or statement.

(b) *Beneficiary not present for services.* When a representative of the provider, nonparticipating hospital, or supplier signs a claim or request for payment statement under § 424.36(c), he or she must explain why it was not possible to obtain the beneficiary's signature. (For example: ''Patient not physically present for test.'')

[53 FR 6640, Mar. 2, 1988; 53 FR 12945, Apr. 20, 1988]

§ 424.40 Request for payment effective for more than one claim.

(a) *Basic procedure.* A separate request for payment statement prescribed by CMS and signed by the beneficiary (or by his or her representative) may be included in claims by reference, in the circumstances specified in paragraphs (b) through (d) of this section.

(b) *Claims filed by a provider or nonparticipating hospital*—(1) *Inpatient services.* A signed request for payment statement, included in the first claim for Part A services furnished by a facility (a participating hospital or SNF, or a nonparticipating hospital that has elected to claim payment) during a beneficiary's period of confinement, may be effective for all claims for Part A services the facility furnishes that beneficiary during that confinement.

(2) *Home health services and outpatient physical therapy or speech pathology services.* A signed request for payment statement, included in the first claim for home health services or outpatient physical therapy or speech pathology services furnished by a provider under a plan of treatment, may be effective for all claims for home health services or outpatient physical therapy or speech pathology services furnished by the provider under that plan of treatment.

(c) *Signed statement in the provider record*—(1) *Services to inpatients.* A signed request for payment statement in the files of a participating hospital or SNF may be effective for all claims for services furnished to the beneficiary during a single inpatient stay in that facility—

(i) By the hospital or SNF;

(ii) By physicians, if their services are billed by the hospital or SNF in its name; or

(iii) By physicians who bill separately, if the services were furnished in the hospital or SNF.

(2) *Services to outpatients: Providers and renal dialysis facilities.* A signed request for payment statement retained in the provider's or facility's files may be effective indefinitely, for all claims for services furnished to that beneficiary on an outpatient basis—

(i) By the provider or facility;

(ii) By physicians whose services are billed by the provider or facility in its name; or

(iii) By physicians who bill separately, if the services were furnished in the provider or facility.

(3) *Services to outpatients: Independent rural health clinics and Federally qualified health centers.* A signed request for payment statement retained in the clinic's or center's files may be effective indefinitely for all claims for services furnished to that beneficiary by the clinic.

(d) *Signed statement in the supplier's record.* A signed request for payment statement retained in the supplier's file may be effective indefinitely subject to the following restrictions:

(1) This policy does not apply to unassigned claims for rental of durable medical equipment (DME).

(2) With respect to assigned claims for rental or purchase of DME, a new statement is required if another item of equipment is rented or purchased.

[53 FR 6634, Mar. 2, 1988, as amended at 57 FR 24982, June 12, 1992]

§ 424.44 Time limits for filing claims.

(a) *Time limits.* (1) Except as provided in paragraphs (b) and (e) of this section, for services furnished on or after January 1, 2010, the claim must be filed no later than the close of the period ending 1 calendar year after the date of service.

(2) Except as provided in paragraphs (b) and (e) of this section and except for services furnished during the last 3 months of 2009, for services furnished before January 1, 2010, the claim must be filed—

(i) On or before December 31 of the following year for services that were furnished during the first 9 months of a calendar year; and

(ii) On or before December 31st of the second following year for services that were furnished during the last 3 months of the calendar year.

(3) For services furnished during the last 3 months of CY 2009 all claims must be filed no later than December 31, 2010.

(b) *Exceptions to time limits.* Exceptions to the time limits for filing claims include the following:

(1) The time for filing a claim will be extended if CMS or one of its contractors determines that a failure to meet the deadline in paragraph (a) of this section was caused by error or misrepresentation of an employee, Medicare contractor (including Medicare Administrative Contractor, intermediary, or carrier), or agent of HHS that was performing Medicare functions and acting within the scope of its authority.

(2) The time for filing a claim will be extended if CMS or one of its contractors determines that a failure to meet the deadline in paragraph (a) of this section is caused by all of the following conditions:

(i) At the time the service was furnished the beneficiary was not entitled to Medicare.

(ii) The beneficiary subsequently received notification of Medicare entitlement effective retroactively to or before the date of the furnished service.

(3) The time for filing a claim will be extended if CMS or one of its contractors determines that a failure to meet the deadline in paragraph (a) of this section is caused by all of the following conditions:

(i) At the time the service was furnished the beneficiary was not entitled to Medicare.

(ii) The beneficiary subsequently received notification of Medicare entitlement effective retroactively to or before the date of the furnished service.

(iii) A State Medicaid agency recovered the Medicaid payment for the furnished service from a provider or supplier 6 months or more after the service was furnished.

(4) The time for filing a claim will be extended if CMS or one of its contractors determines that a failure to meet the deadline in paragraph (a) of this section is caused by all of the following conditions:

(i) At the time the service was furnished the beneficiary was enrolled in a Medicare Advantage plan or Program of All-inclusive Care for the Elderly (PACE) provider organization.

(ii) The beneficiary was subsequently disenrolled from the Medicare Advantage plan or Program of All-inclusive Care for the Elderly (PACE) provider organization effective retroactively to or before the date of the furnished service.

(iii) The Medicare Advantage plan or Program of All-inclusive Care for the Elderly (PACE) provider organization recovered its payment for the furnished service from a provider or supplier 6 months or more after the service was furnished.

(5) *Extension of time.* (i) If CMS or one of its contractors determines that a failure to meet the deadline specified in paragraph (a) of this section was caused by error or misrepresentation of an employee, Medicare contractor (including Medicare Administrative Contractor, intermediary, or carrier), or agent of HHS that was performing Medicare functions and acting within the scope of its authority, the time to file a claim will be extended through the last day of the sixth calendar month following the month in which either the beneficiary or the provider or supplier received notification that the error or misrepresentation referenced in paragraph (b)(1) of this section was corrected. No extension of time will be granted for paragraph (b)(1) when the request for that exception is made to CMS or one of its contractors more than 4 years after the date of service.

(ii) If CMS or one of its contractors determines that both of the conditions are met in paragraph (b)(2) of this section but that all of the conditions in paragraph (b)(3) are not satisfied, the time to file a claim will be extended through the last day of the sixth calendar month following the month in which either the beneficiary or the provider or supplier received notification of Medicare entitlement effective retroactively to or before the date of the furnished service.

(iii) If CMS or one of its contractors determines that all of the conditions are met in paragraph (b)(3) of this section, the time to file a claim will be extended through the last day of the sixth calendar month following the month in which the State Medicaid agency recovered the Medicaid payment for the furnished service from the provider or supplier.

(iv) If CMS or one of its contractors determines that all of the conditions are met in paragraph (b)(4) of this section, the time to file a claim will be extended through the last day of the sixth calendar month following the month in which the Medicare Advantage plan or Program of All-inclusive Care for the Elderly (PACE) provider organization recovered its payment for the furnished service from the provider or supplier.

(c) *Extension of period ending on a nonworkday.* If the last day of the period allowed under paragraph (a) or (b) of this section falls on a Federal nonworkday (a Saturday, Sunday, legal holiday, or a day which by statute or Executive Order is declared to be a nonworkday for Federal employees), the time is extended to the next succeeding workday.

(d) *Outpatient diabetes self-management training.* CMS makes payment in half-hour increments to an entity for the furnishing of outpatient diabetes self-management training on or after the approval date CMS approves the entity to furnish the services under part 410, subpart H of this chapter.

(e) As specified in §§ 424.520 and 424.521 of this subpart, there are restrictions on the ability of the following newly-enrolled suppliers to submit claims for items or services furnished prior to the

effective date of their Medicare billing privileges:

(1) Physician or nonphysician practitioner organizations.

(2) Physicians.

(3) Nonphysician practitioners.

(4) Independent diagnostic testing facilities.

[53 FR 6634, Mar. 2, 1988, as amended at 65 FR 83153, Dec. 29, 2000; 73 FR 69939, Nov. 19, 2008; 75 FR 73627, Nov. 29, 2010]

Subpart D—To Whom Payment Is Ordinarily Made

§ 424.50 Scope.

(a) This subpart specifies to whom Medicare payment is ordinarily made for different kinds of services.

(b) Subpart E of this part sets forth provisions applicable in special situations.

(c) Subpart F of this part specifies the exceptional circumstances under which payment may be made to an assignee or reassignee.

§ 424.51 Payment to the provider.

(a) *Basic rule.* Except as specified in paragraph (b) of this section, Medicare pays the provider for services furnished by a provider.

(b) *Exception.* Medicare pays the beneficiary for outpatient hospital services if the hospital has collected an amount in excess of the unmet deductible and coinsurance, as specified in § 489.30(b)(4) of this chapter.

§ 424.52 Payment to a nonparticipating hospital.

Medicare pays a nonparticipating hospital for the following services, if covered, in the specified circumstances:

(a) Emergency inpatient and outpatient services furnished by a U.S. hospital, if the hospital has in effect an election to claim payment in accordance with subpart G of this part.

(b) Certain medical and other health services covered under Medicare Part B and furnished by a U.S. hospital, if the hospital meets the requirements of § 424.55 for payment as a supplier.

(c) Emergency or nonemergency inpatient services furnished by a foreign hospital if the hospital has in effect an election to claim payment in accordance with subpart G of this part.

§ 424.53 Payment to the beneficiary.

Medicare pays the beneficiary for the following services, if covered, in the specified circumstances:

(a) Emergency inpatient and outpatient services furnished by a nonparticipating U.S. hospital that has not elected to claim payment in accordance with subpart G of this part.

(b) Certain medical and other health services covered under Medicare Part B and furnished by a nonparticipating U.S. hospital, if the hospital does not receive assigned payment as a supplier under § 424.55.

(c) Emergency or nonemergency services furnished by a foreign hospital if the hospital does not have in effect an election to claim payment in accordance with subpart H of this part.

(d) Physician and ambulance services furnished outside the United States.

(e) Services furnished by a supplier if the claim has not been assigned to the supplier.

§ 424.54 Payment to the beneficiary's legal guardian or representative payee.

Medicare may pay amounts due a beneficiary to the beneficiary's legal guardian or representative payee.

§ 424.55 Payment to the supplier.

(a) Medicare pays the supplier for covered services if the beneficiary (or the person authorized to request payment on the beneficiary's behalf) assigns the claim to the supplier and the supplier accepts assignment.

(b) In accepting assignment, the supplier agrees to the following:

(1) To accept, as full charge for the service, the amount approved by the carrier as the basis for determining the Medicare Part B payment (the reasonable charge or the lesser of the fee schedule amount and the actual charge).

(2) To limit charges to the beneficiary or any other source as follows:

(i) To collect nothing for those services for which Medicare pays 100 percent of the Medicare approved amount.

(ii) To collect only the difference between the Medicare approved amount

and the Medicare Part B payment (for example, the amount of any reduction in incurred expenses under § 410.155(c), any applicable deductible amount, and any applicable coinsurance amount) for services for which Medicare pays less than 100 percent of the approved amount.

(3) Not to charge the beneficiary when Medicare paid for services determined to be ''not reasonable or necessary'' if—

(i) The beneficiary was without fault in the overpayment; and

(ii) The determination that the payment was incorrect was made by the carrier after the third year following the year in which the carrier sent notice to the beneficiary that it approved the payment.

(c) *Exception.* In situations when payment under the Act can only be made on an assignment-related basis or when payment is for services furnished by a participating physician or supplier, the beneficiary (or the person authorized to request payment on the beneficiary's behalf) is not required to assign the claim to the supplier in order for an assignment to be effective.

(d) For purposes of claims for services submitted by an MDPP supplier (as defined at § 410.79(b) of this chapter), Medicare deems such claims to have been assigned by the beneficiary (or the person authorized to request payment on the beneficiary's behalf) and the assignment accepted by the MDPP supplier.

[53 FR 6634, Mar. 2, 1988, as amended at 63 FR 20130, Apr. 23, 1998; 69 FR 66426, Nov. 15, 2004; 82 FR 53364, Nov. 15, 2017]

§ 424.56 Payment to a beneficiary and to a supplier.

(a) *Conditions for split payment.* If the beneficiary assigns the claim after paying part of the bill, payment may be made partly to the beneficiary and partly to the supplier.

(b) *Payment to the supplier.* Payment to the supplier who submits the assigned claim is for whichever of the following amounts is less:

(1) The reasonable charge minus the amount the beneficiary had already paid to the supplier; or

(2) The full Part B benefit due for the services furnished.

(c) *Payment to the beneficiary.* Any part of the Part B benefit which, on the basis of paragraph (b) of this section, is not payable to the supplier, is paid to the beneficiary.

(d) *Examples.*

Example 1. An assigned bill of $300 on which partial payment of $100 has been made is submitted to the carrier. The carrier determines that $300 is the reasonable charge for the service furnished. Total payment due is 80 percent of $300 or $240. Of this amount, $200 (the difference between the $100 partial payment and the $300 reasonable charge) is paid to the supplier. The remaining $40 is paid to the beneficiary.

Example 2. An assigned bill of $325 on which partial payment of $275 has been made is submitted to the carrier. The carrier determines that $275 is the reasonable charge for the services. Total payment due is 80 percent of $275 or $220. The $220 is paid to the beneficiary, since any payment to the supplier, when added to the $275 partial payment would exceed the reasonable charge for the services furnished.

[53 FR 6641, Mar. 2, 1988; 53 FR 12945, Apr. 20, 1988]

§ 424.57 Special payment rules for items furnished by DMEPOS suppliers and issuance of DMEPOS supplier billing privileges.

(a) *Definitions.* As used in this section, the following definitions apply:

Accredited DMEPOS suppliers means suppliers that have been accredited by a recognized independent accreditation organization approved by CMS in accordance with the requirements at § 424.58.

Affiliate means a person or organization that is related to another person or organization through a compensation arrangement or ownership.

Assessment means a sum certain that CMS or the Office of Inspector General (OIG) may assess against a DMEPOS supplier under Titles XI, XVIII, or XXI of the Social Security Act or as specified in this chapter.

Attended facility-based polysomnogram means a comprehensive diagnostic sleep test including at least electroencephalography, electrooculography, electromyography, heart rate or electrocardiography, airflow, breathing effort, and arterial oxygen saturation furnished in a sleep laboratory facility in which a technologist supervises the recording during sleep

time and has the ability to intervene if needed.

Authorized surety means a surety that has been issued a Certificate of Authority by the U.S. Department of the Treasury as an acceptable surety on Federal bonds and the certificate has neither expired nor been revoked.

Civil money penalty (CMP) means a sum that CMS has the authority, as implemented by 42 CFR 402.1(c); or OIG has the authority, under section 1128A of the Act or 42 CFR part 1003, to impose on a supplier as a penalty.

CMS approved accreditation organization means a recognized independent accreditation organization approved by CMS under § 424.58.

Continuous positive airway pressure (CPAP) device means a machine that introduces air into the breathing passages at pressures high enough to overcome obstructions in the airway in order to improve airflow. The airway pressure delivered into the upper airway is continuous during both inspiration and expiration.

DMEPOS stands for durable medical equipment, prosthetics, orthotics and supplies.

DMEPOS supplier means an entity or individual, including a physician or a Part A provider, which sells or rents Part B covered items to Medicare beneficiaries and which meets the standards in paragraphs (c) and (d) of this section.

Final adverse action means one or more of the following actions:

(i) A Medicare-imposed revocation of any Medicare billing privileges.

(ii) Suspension or revocation of a license to provide health care by any State licensing authority.

(iii) Revocation for failure to meet DMEPOS quality standards.

(iv) A conviction of a Federal or State felony offense (as defined in § 424.535(a)(3)(i) within the last 10 years preceding enrollment, revalidation, or re-enrollment.

(v) An exclusion or debarment from participation in a Federal or State health care program.

Government-operated supplier is a DMEPOS supplier owned or operated by a Federal, State, or Tribal entity.

Independent accreditation organization means an accreditation organization that accredits a supplier of DMEPOS and other items and services for a specific DMEPOS product category or a full line of DMEPOS product categories.

Medicare covered items means medical equipment and supplies as defined in section 1834(j)(5) of the Act.

Penal sum is the maximum obligation of the surety if a loss occurs.

Rider means a notice issued by a surety that a change in the bond has occurred or will occur.

Sleep test means an attended or unattended diagnostic test for a sleep disorder whether performed in or out of a sleep laboratory. The 'provider of the sleep test' is the individual or entity that directly or indirectly administers and/or interprets the sleep test and/or furnishes the sleep test device used to administer the sleep test.

Sufficient evidence means documents CMS may supply to the surety in order to establish that a DMEPOS supplier had received Medicare funds in excess of the amount due and payable under the statute and regulations, the amount of a CMP, or the amount of some other assessment against the DMEPOS supplier.

Surety bond means a bond issued by one or more sureties under 31 U.S.C. 9304 through 9308 and 31 CFR parts 223, 224, and 225.

Unpaid claim means an overpayment made by the Medicare program to the DMEPOS supplier for which the DMEPOS supplier is responsible, plus accrued interest that is effective 90 days after the date of the notice sent to the DMEPOS supplier of the overpayment. If a written agreement for payment, acceptable to CMS, is made, an *unpaid claim* also means a Medicare overpayment for which the DMEPOS supplier is responsible, plus accrued interest after the DME supplier's default on the arrangement.

(b) *General rule.* A DMEPOS supplier must meet the following conditions in order to be eligible to receive payment for a Medicare-covered item:

(1) The supplier has submitted a completed application to CMS to furnish Medicare-covered items including required enrollment forms. (The supplier must enroll separate physical locations it uses to furnish Medicare-covered

DMEPOS, with the exception of locations that it uses solely as warehouses or repair facilities.)

(2) The item was furnished on or after the date CMS issued to the supplier a DMEPOS supplier number conveying billing privileges. (CMS issues only one supplier number for each location.) This requirement does not apply to items furnished incident to a physician's service.

(3) CMS has not revoked or excluded the DMEPOS supplier's privileges during the period which the item was furnished has not been revoked or excluded.

(4) A supplier that furnishes a drug used as a Medicare-covered supply with durable medical equipment or prosthetic devices must be licensed by the State to dispense drugs (A supplier of drugs must bill and receive payment for the drug in its own name. A physician, who is enrolled as a DMEPOS supplier, may dispense, and bill for, drugs under this standard if authorized by the State as part of the physician's license.)

(5) The supplier has furnished to CMS all information or documentation required to process the claim.

(6) The supplier is in compliance with all conditions of payment in paragraph (b) of this section, as well as with paragraph (c)(1)(ii)(A) of this section, at the time the item or service is furnished.

(c) *Application certification standards.* The supplier must meet and must certify in its application for billing privileges that it meets and will continue to meet the following standards:

(1) Operates its business and furnishes Medicare-covered items in compliance with the following applicable laws:

(i) Federal regulatory requirements that specify requirements for the provision of DMEPOS and ensure accessibility for the disabled.

(ii) *State licensure and regulatory requirements.* If a State requires licensure to furnish certain items or services, a DMEPOS supplier—

(A) Must be licensed to provide the item or service; and

(B) May contract with a licensed individual or other entity to provide the licensed services unless expressly prohibited by State law.

(2) Has not made, or caused to be made, any false statement or misrepresentation of a material fact on its application for billing privileges. (The supplier must provide complete and accurate information in response to questions on its application for billing privileges. The supplier must report to CMS any changes in information supplied on the application within 30 days of the change.);

(3) Must have the application for billing privileges signed by an individual whose signature binds a supplier;

(4) Fills orders, frabicates, or fits items from its own inventory or by contracting with other companies for the purchase of items necessary to fill the order. If it does, it must provide, upon request, copies of contracts or other documentation showing compliance with this standard. A supplier may not contract with any entity that is currently excluded from the Medicare program, any State health care programs, or from any other Federal Government Executive Branch procurement or nonprocurement program or activity;

(5) Advises beneficiaries that they may either rent or purchase inexpensive or routinely purchased durable medical equipment, and of the purchase option for capped rental durable medical equipment, as defined in §414.220(a) of this subchapter. (The supplier must provide, upon request, documentation that it has provided beneficiaries with this information, in the form of copies of letters, logs, or signed notices.);

(6) Honors all warranties expressed and implied under applicable State law. A supplier must not charge the beneficiary or the Medicare program for the repair or replacement of Medicare covered items or for services covered under warranty. This standard applies to all purchased and rented items, including capped rental items, as described in §414.229 of this subchapter. The supplier must provide, upon request, documentation that it has provided beneficiaries with information about Medicare covered items covered under warranty, in the form of copies of letters, logs, or signed notices;

(7) Maintains a physical facility on an appropriate site. An appropriate site must meet all of the following:

(i) Must meet the following criteria:

(A)(*1*) Except for orthotic and prosthetic personnel described in paragraph (c)(7)(i)(A)(*2*) of this section, maintains a practice location that is at least 200 square feet beginning—

(*i*) September 27, 2010 for a prospective DMEPOS supplier;

(*ii*) The first day after termination of an expiring lease for an existing DMEPOS supplier with a lease that expires on or after September 27, 2010 and before September 27, 2013; or

(*iii*) September 27, 2013, for an existing DMEPOS supplier with a lease that expires on or after September 27, 2013.

(*2*) Orthotic and prosthetic personnel providing custom fabricated orthotics or prosthetics in private practice do not have to meet the practice location requirements in paragraph (c)(7)(i)(A)(*1*) of this section if the orthotic and prosthetic personnel are—

(*i*) State-licensed; or

(*ii*) Practicing in a State that does not offer State licensure for orthotic and prosthetic personnel.

(B) Is in a location that is accessible to the public, Medicare beneficiaries, CMS, NSC, and its agents. (The location must not be in a gated community or other area where access is restricted.)

(C) Is accessible and staffed during posted hours of operation.

(D) Maintains a permanent visible sign in plain view and posts hours of operation. If the supplier's place of business is located within a building complex, the sign must be visible at the main entrance of the building or the hours can be posted at the entrance of the supplier.

(E) Except for business records that are stored in centralized location as described in paragraph (c)(7)(ii) of this section, is in a location that contains space for storing business records (including the supplier's delivery, maintenance, and beneficiary communication records).

(F) Is in a location that contains space for retaining the necessary ordering and referring documentation specified in § 424.516(f).

(ii) May be the centralized location for all of the business records and the ordering and referring documentation of a multisite supplier.

(iii) May be a ''closed door'' business, such as a pharmacy or supplier providing services only to beneficiaries residing in a nursing home, that complies with all applicable Federal, State, and local laws and regulations. ''Closed door'' businesses must comply with all the requirements in this paragraph.

(8) Permits CMS, the NSC, or agents of CMS or the NSC to conduct on-site inspections to ascertain supplier compliance with the requirements of this section.

(9) Maintains a primary business telephone that is operating at the appropriate site listed under the name of the business locally or toll-free for beneficiaries.

(i) Cellular phones, beepers, or pagers must not be used as the primary business telephone.

(ii) Calls must not be exclusively forwarded from the primary business telephone listed under the name of the business to a cellular phone, beeper, or pager.

(iii) Answering machines, answering services, facsimile machines or combination of these options must not be used exclusively as the primary business telephone during posted operating hours.

(10) Has a comprehensive liability insurance policy in the amount of at least $300,000 that covers both the supplier's place of business and all customers and employees of the supplier. In the case of a supplier that manufactures its own items, this insurance must also cover product liability and completed operations. Failure to maintain required insurance at all times will result in revocation of the supplier's billing privileges retroactive to the date the insurance lapsed;

(11) Must agree not to contact a beneficiary by telephone when supplying a Medicare-covered item unless one of the following applies:

(i) The individual has given written permission to the supplier to contact them by telephone concerning the furnishing of a Medicare-covered item that is to be rented or purchased.

(ii) The supplier has furnished a Medicare-covered item to the individual and the supplier is contacting the individual to coordinate the delivery of the item.

(iii) If the contact concerns the furnishing of a Medicare-covered item other than a covered item already furnished to the individual, the supplier has furnished at least one covered item to the individual during the 15-month period preceding the date on which the supplier makes such contact.

(12) Must be responsible for the delivery of Medicare covered items to beneficiaries and maintain proof of delivery. (The supplier must document that it or another qualified party has at an appropriate time, provided beneficiaries with necessary information and instructions on how to use Medicare-covered items safely and effectively);

(13) Must answer questions and respond to complaints a beneficiary has about the Medicare-covered item that was sold or rented. A supplier must refer beneficiaries with Medicare questions to the appropriate carrier. A supplier must maintain documentation of contacts with beneficiaries regarding complaints or questions;

(14) Must maintain and replace at no charge or repair directly, or through a service contract with another company, Medicare-covered items it has rented to beneficiaries. The item must function as required and intended after being repaired or replaced;

(15) Must accept returns from beneficiaries of substandard (less than full quality for the particular item or unsuitable items, inappropriate for the beneficiary at the time it was fitted and rented or sold);

(16) Must disclose these supplier standards to each beneficiary to whom it supplies a Medicare-covered item;

(17) Must comply with the disclosure provisions in § 420.206 of this subchapter;

(18) Must not convey or reassign a supplier number;

(19) Must have a complaint resolution protocol to address beneficiary complaints that relate to supplier standards in paragraph (c) of this section and keep written complaints, related correspondence and any notes of actions taken in response to written and oral complaints. Failure to maintain such information may be considered evidence that supplier standards have not been met. (This information must be kept at its physical facility and made available to CMS, upon request.);

(20) Must maintain the following information on all written and oral beneficiary complaints, including telephone complaints, it receives:

(i) The name, address, telephone number, and health insurance claim number of the beneficiary.

(ii) A summary of the complaint; the date it was received; the name of the person receiving the complaint, and a summary of actions taken to resolve the complaint.

(iii) If an investigation was not conducted, the name of the person making the decision and the reason for the decision.

(21) Provides to CMS, upon request, any information required by the Medicare statute and implementing regulations.

(22) All suppliers of DMEPOS and other items and services must be accredited by a CMS-approved accreditation organization in order to receive and retain a supplier billing number. The accreditation must indicate the specific products and services, for which the supplier is accredited in order for the supplier to receive payment for those specific products and services.

(23) All DMEPOS suppliers must notify their accreditation organization when a new DMEPOS location is opened. The accreditation organization may accredit the new supplier location for three months after it is operational without requiring a new site visit.

(24) All DMEPOS supplier locations, whether owned or subcontracted, must meet the DMEPOS quality standards and be separately accredited in order to bill Medicare. An accredited supplier may be denied enrollment or their enrollment may be revoked, if CMS determines that they are not in compliance with the DMEPOS quality standards.

(25) All DMEPOS suppliers must disclose upon enrollment all products and services, including the addition of new

product lines for which they are seeking accreditation. If a new product line is added after enrollment, the DMEPOS supplier will be responsible for notifying the accrediting body of the new product so that the DMEPOS supplier can be re-surveyed and accredited for these new products.

(26) Must meet the surety bond requirements specified in paragraph (d) of this section.

(27) Must obtain oxygen from a State-licensed oxygen supplier (applicable only to those suppliers in States that require oxygen licensure.)

(28) Is required to maintain ordering and referring documentation consistent with the provisions found in § 424.516(f)

(29)(i) Except as specified in paragraph (c)(29)(ii) of this section, is prohibited from sharing a practice location with any other Medicare supplier or provider.

(ii) The prohibition specified in paragraph (c)(29)(i) of this section is not applicable at a practice location that meets one of the following:

(A) Where a physician whose services are defined in section 1848(j)(3) of the Act or a nonphysician practitioner, as described in section 1842(b)(18)(C) of the Act, furnishes items to his or her own patient as part of his or her professional service.

(B) Where a physical or occupational therapist whose services are defined in sections 1861(p) and 1861(g) of the Act, furnishes items to his or her own patient as part of his or her professional service.

(C) Where a DMEPOS supplier is colocated with and owned by an enrolled Medicare provider (as described in § 489.2(b) of this chapter). The DMEPOS supplier—

(*1*) Must operate as a separate unit; and

(*2*) Meet all other DMEPOS supplier standards.

(30)(i) Except as specified in paragraph (c)(30)(ii) of this section, is open to the public a minimum of 30 hours per week.

(ii) The provision of paragraph (c)(30)(i) of this section is not applicable at a practice location where a—

(A) Physician whose services are defined in section 1848(j)(3) of the Act furnishes items to his or her own patient(s) as part of his or her professional service;

(B) A physical or occupational therapist whose services are defined in sections 1861(p) and 1861(g) of the Act furnishes items to his or her own patient(s) as part of his or her professional service; or

(C) DMEPOS supplier is working with custom made orthotics and prosthetics.

(d) *Surety bonds requirements*—(1) *Effective date of surety bond requirements*—(i) *DMEPOS suppliers seeking enrollment or with a change in ownership.* Except as provided in paragraph (d)(15) of this section, beginning May 4, 2009, DMEPOS suppliers seeking to enroll or to change the ownership of a supplier of DMEPOS must meet the requirements of paragraph (d) of this section for each assigned NPI for which the DMEPOS supplier is seeking to obtain Medicare billing privileges.

(ii) *Existing DMEPOS suppliers.* Except as provided in paragraph (d)(15) of this section, beginning October 2, 2009, each Medicare-enrolled DMEPOS supplier must meet the requirements of paragraph (d) of this section for each assigned NPI to which Medicare has granted billing privileges.

(2) *Minimum requirements for a DMEPOS supplier.* (i) A DMEPOS supplier enrolling in the Medicare program, making a change in ownership, or responding to a revalidation or reenrollment request must submit to the CMS contractor a surety bond from an authorized surety of $50,000 and, if required by the CMS contractor, an elevated bond amount as described in paragraph (d)(3) of this section with its paper or electronic Medicare enrollment application (CMS–855S, OMB number 0938–1056). The term of the initial surety bond must be effective on the date that the application is submitted to the CMS contractor.

(ii) A supplier that seeks to become an enrolled DMEPOS supplier through a purchase or transfer of assets or ownership interest must submit to the CMS contractor surety bond from an authorized surety of $50,000 and, if required by the CMS contractor, an elevated bond amount as described in paragraph (d)(3) of this section that is effective from the date of the purchase

or transfer in order to exercise billing privileges as of that date. If the bond is effective at a later date, the effective date of the new DMEPOS supplier billing privileges is the effective date of the surety bond as validated by the CMS contractor.

(iii) A DMEPOS supplier enrolling a new practice location must submit to the CMS contractor a new surety bond from an authorized surety or an amendment or rider to the existing bond, showing that the new practice location is covered by an additional base surety bond of $50,000 or, as necessary, an elevated surety bond amount as described in paragraph (d)(3) of this section.

(3) *Elevated surety bond amounts.* (i) If required, a DMEPOS supplier must obtain and maintain a base surety bond in the amount of $50,000 as specified in paragraph (d)(2) of this section and an elevated surety bond in the amount prescribed by the CMS contractor as described in paragraph (d)(3)(ii) of this section.

(ii) The CMS contractor prescribes an elevated surety bond amount of $50,000 per occurrence of an adverse legal action within the 10 years preceding enrollment, revalidation, or reenrollment, as defined in paragraph (a) of this section.

(4) *Type and terms of the surety bond*—(i) *Type of bond.* A DMEPOS supplier must submit a bond that is continuous.

(ii) *Minimum requirements of liability coverage.* (A) The terms of the bond submitted by a DMEPOS supplier for the purpose of complying with this section must meet the minimum requirements of liability coverage ($50,000) and surety and DMEPOS supplier responsibility as set forth in this section.

(B) CMS requires a DMEPOS supplier to submit a bond that on its face reflects the requirements of this section. CMS revokes or denies a DMEPOS supplier's billing privileges based upon the submission of a bond that does not reflect the requirements of paragraph (d) of this section.

(5) *Specific surety bond requirements.* (i) The bond must guarantee that the surety will, within 30 days of receiving written notice from CMS containing sufficient evidence to establish the surety's liability under the bond of unpaid claims, CMPs, or assessments, pay CMS a total of up to the full penal amount of the bond in the following amounts:

(A) The amount of any unpaid claim, plus accrued interest, for which the DMEPOS supplier is responsible.

(B) The amount of any unpaid claims, CMPs, or assessments imposed by CMS or OIG on the DMEPOS supplier, plus accrued interest.

(ii) The bond must provide the following: The surety is liable for unpaid claims, CMPs, or assessments that occur during the term of the bond.

(iii) If the DMEPOS supplier fails to furnish a bond meeting the requirements of paragraph (d) of this section, fails to submit a rider when required, or if the DMEPOS supplier's billing privileges are revoked, the last bond or rider submitted by the DMEPOS supplier remains in effect until the last day of the surety bond coverage period and the surety remains liable for unpaid claims, CMPs, or assessments that—

(A) CMS or the OIG imposes or asserts against the DMEPOS supplier based on overpayments or other events that took place during the term of the bond or rider; and

(B) Were imposed or assessed by CMS or the OIG during the 2 years following the date that the DMEPOS supplier failed to submit a bond or required rider, or the date the DMEPOS supplier's billing privileges were terminated, whichever is later.

(6) *Cancellation of a bond and lapse of surety bond coverage.* (i) A DMEPOS supplier may cancel its surety bond and must provide written notice at least 30 days before the effective date of the cancellation to the CMS contractor and the surety.

(ii) Cancellation of a surety bond is grounds for revocation of the DMEPOS supplier's Medicare billing privileges unless the DMEPOS supplier provides a new bond before the effective date of the cancellation. The liability of the surety continues through the termination effective date.

(iii) If CMS receives notification of a lapse in bond coverage from the surety, the DMEPOS supplier's billing privileges are revoked. During this lapse, Medicare does not pay for items or

services furnished during the gap in coverage, and the DMEPOS supplier is held liable for the items or services (that is, the DMEPOS supplier would not be permitted to charge the beneficiary for the items or services).

(iv) The surety must immediately notify the CMS contractor if there is a lapse in the surety's coverage of the DMEPOS supplier's coverage.

(7) *Actions under the surety bond.* The bond must provide that actions under the bond may be brought by CMS or by CMS contractors.

(8) *Required surety information on the surety bond.* The bond must provide the surety's name, street address or post office box number, city, state, and zip code.

(9) *Change of surety.* A DMEPOS supplier that obtains a replacement surety bond from a different surety to cover the remaining term of a previously obtained bond must submit the new surety bond to the CMS contractor at least 30 days prior to the expiration of the previous surety bond. There must be no gap in the coverage of the surety bond periods. If a gap in coverage exists, the CMS contractor revokes the DMEPOS supplier's billing privileges and does not pay for any items or services furnished by the DMEPOS supplier during the period for which no bond coverage was available. If a DMEPOS supplier changes its surety during the term of the bond, the new surety is responsible for any overpayments, CMPs, or assessments incurred by the DMEPOS supplier beginning with the effective date of the new surety bond. The previous surety is responsible for any overpayments, CMPs, or assessments that occurred up to the date of the change of surety.

(10) *Parties to the surety bond.* The surety bond must name the DMEPOS supplier as Principal, CMS as Obligee, and the surety (and its heirs, executors, administrators, successors and assignees, jointly and severally) as surety.

(11) *Effect of DMEPOS supplier's failure to obtain, maintain, and timely file a surety bond.*

(i) CMS revokes the DMEPOS supplier's billing privileges if an enrolled DMEPOS supplier fails to obtain, file timely, or maintain a surety bond as specified in this subpart and CMS instructions. Notwithstanding paragraph (e) of this section, the revocation is effective the date the bond lapsed and any payments for items furnished on or after that date must be repaid to CMS by the DMEPOS supplier.

(ii) CMS denies billing privileges to a DMEPOS supplier if the supplier seeking to become an enrolled DMEPOS supplier fails to obtain and file timely a surety bond as specified with this subpart and CMS instructions.

(12) *Evidence of DMEPOS supplier's compliance.* CMS may at any time require a DMEPOS supplier to show compliance with the requirements of paragraph (d) of this section.

(13) *Effect of subsequent DMEPOS supplier payment.* If a surety has paid an amount to CMS on the basis of liability incurred under a bond and CMS subsequently collects from the DMEPOS supplier, in whole or in part, on the unpaid claim, CMPs, or assessment that was the basis for the surety's liability, CMS reimburses the surety the amount that it collected from the DMEPOS supplier, up to the amount paid by the surety to CMS, provided the surety has no other liability to CMS under the bond.

(14) *Effect of review reversing determination.* If a surety has paid CMS on the basis of liability incurred under a surety bond and to the extent the DMEPOS supplier that obtained the bond is subsequently successful in appealing the determination that was the basis of the unpaid claim, CMP, or assessment that caused the DMEPOS supplier to pay CMS under the bond, CMS refunds the DMEPOS supplier the amount the DMEPOS supplier paid to CMS to the extent that the amount relates to the matter that was successfully appealed, provided all review, including judicial review, has been completed on the matter.

(15) *Exception to the surety bond requirement*—(i) *Qualifying entities and requirements.* (A) Government-operated DMEPOS suppliers are provided an exception to the surety bond requirement if the DMEPOS supplier has provided CMS with a comparable surety bond under State law.

(B) State-licensed orthotic and prosthetic personnel in private practice making custom made orthotics and

prosthetics are provided an exception to the surety bond requirement if—

(*1*) The business is solely-owned and operated by the orthotic and prosthetic personnel, and

(*2*) The business is only billing for orthotic, prosthetics, and supplies.

(C) Physicians and nonphysician practitioners as defined in section 1842(b)(18) of the Act are provided an exception to the surety bond requirement when items are furnished only to the physician or nonphysician practitioner's own patients as part of his or her physician service.

(D) Physical and occupational therapists in private practice are provided an exception to the surety bond requirement if—

(*1*) The business is solely-owned and operated by the physical or occupational therapist;

(*2*) The items are furnished only to the physical or occupational therapist's own patients as part of his or her professional service; and

(*3*) The business is only billing for orthotics, prosthetics, and supplies.

(ii) *Loss of a DMEPOS supplier exception.* A DMEPOS supplier that no longer qualifies for an exception as described in paragraph (d)(15)(i) of this section must submit a surety bond to the CMS contractor in accordance with requirements of paragraph (d) of this section within 60 days after it knows or has reason to know that it no longer meets the criteria for an exception.

(e) *Failure to meet standards*—(1) *Revocation.* CMS revokes a supplier's billing privileges if it is found not to meet the standards in paragraphs (b) and (c) of this section. Except as otherwise provided in this section, the revocation is effective 30 days after the entity is sent notice of the revocation, as specified in § 405.874 of this subchapter.

(2) *Overpayments associated with final adverse actions.* CMS or a CMS contractor may reopen (in accordance with § 405.980 of this chapter) all Medicare claims paid on or after the date of a final adverse action (as defined in paragraph (a) of this section) in order to establish an overpayment determination.

(f) *Payment prohibition.* No Medicare payment will be made to the supplier of a CPAP device if that supplier, or its affiliate, is directly or indirectly the provider of the sleep test used to diagnose the beneficiary with obstructive sleep apnea. This prohibition does not apply if the sleep test is an attended facility-based polysomnogram.

(g) *Revalidation of billing privileges.* A supplier must revalidate its application for billing privileges every 3 years after the billing privileges are first granted. (Each supplier must complete a new application for billing privileges 3 years after its last revalidation.)

[65 FR 60377, Oct. 11, 2000, as amended at 71 FR 48409, Aug. 18, 2006; 73 FR 69939, Nov. 19, 2008; 75 FR 52648, Aug. 27, 2010; 76 FR 5962, Feb. 2, 2011; 77 FR 14994, Mar. 14, 2012; 79 FR 69773, Nov. 24, 2014; 87 FR 70231, Nov. 18, 2022]

§ 424.58 Accreditation.

(a) *Scope and purpose.* This part implements section 1834(a)(20)(B) of the Act, which requires the Secretary to designate and approve one or more independent accreditation organizations for purposes of enforcing the DMEPOS quality standards for suppliers of DMEPOS and other items or services. Section 1847(b)(2)(A)(i) of the Act requires a DMEPOS supplier to meet the DMEPOS quality standards under section 1834(a)(20) of the Act before being awarded a contract.

(b) *Application and reapplication procedures for accreditation organizations.* (1) An independent accreditation organization applying for approval or re-approval of authority to survey suppliers for compliance with the DMEPOS quality standards is required to furnish the following to CMS:

(i) A list of the types of DMEPOS supplies, and a list of products and services for which the organization is requesting approval.

(ii) A detailed comparison of the organization's accreditation requirements and standards with the applicable DMEPOS quality standards, such as a crosswalk.

(iii) A detailed description of the organization's operational processes, including procedures for performing unannounced surveys, frequency of the surveys performed, copies of the organization's survey forms, guidelines and instructions to surveyors, quality review processes for deficiencies identified with accreditation requirements, and dispute resolution processes and

policies when there is a negative survey finding or decision.

(iv) Procedures used to notify DMEPOS suppliers of compliance or noncompliance with the accreditation requirements.

(v) Procedures used to monitor the correction of deficiencies found during an accreditation survey.

(vi) Procedures for coordinating surveys with another accrediting organization if the organization does not accredit all products the supplier provides.

(vii) Detailed professional information about the individuals who perform surveys for the accreditation organization, including the size and composition of accreditation survey teams for each type of DMEPOS supplier accredited, and the education and experience requirements surveyors must meet. The information must include the following:

(A) The content and frequency of the continuing education training provided to survey personnel.

(B) The evaluation systems used to monitor the performance of individual surveyors and survey teams.

(C) Policies and procedures for a surveyor or institutional affiliate of the independent accrediting organization that participates in a survey or accreditation decision regarding a DMEPOS supplier with which that individual or institution is professionally or financially affiliated.

(viii) A description of the organization's data management, analysis and reporting system for its surveys and accreditation decisions, including the kinds of reports, tables, and other displays generated by that system.

(ix) Procedures for responding to, and investigating complaints against, accredited facilities, including policies and procedures regarding coordination of these activities with appropriate licensing bodies, ombudsman programs, the National Supplier Clearinghouse, and CMS.

(x) The organization's policies and procedures for notifying CMS of facilities that fail to meet the accreditation organization's requirements.

(xi) A description of all types, categories, and durations of accreditations offered by the organization.

(xii) A list of the following:

(A) All currently accredited DMEPOS suppliers.

(B) The types and categories of accreditation currently held by each supplier.

(C) The expiration date of each supplier's current accreditation.

(D) The upcoming survey cycles for all DMEPOS suppliers' accreditation surveys scheduled to be performed by the organization.

(xiii) A written presentation that demonstrates the organization's ability to furnish CMS with electronic data in ASCII comparable code.

(xiv) A resource analysis that demonstrates that the organization's staffing, funding, and other resources are adequate to perform fully the required surveys and related activities.

(xv) An agreement that the accreditation organization will permit its surveyors to serve as witnesses if CMS takes an adverse action based on accreditation findings.

(2) *Validation survey.* CMS surveys suppliers of DMEPOS and other items and services accredited under this section on a representative sample basis, or in response to substantial allegations of noncompliance, in order to validate the accreditation organization's survey process. When conducted—

(i) On a representative sample basis, the CMS survey may be comprehensive or focus on a specific standard;

(ii) In response to a substantial allegation, CMS surveys for any standard that CMS determines is related to the allegations.

(3) *Discovery of a deficiency.* If CMS discovers that a DMEPOS supplier was not in compliance with the DMEPOS supplier quality standards, CMS may revoke the supplier's billing number or require the accreditation organization to perform a subsequent full accreditation survey at the accreditation organization's expense.

(4) *Authorization.* A supplier selected for a validation survey must authorize the—

(i) Validation survey to take place; and

(ii) CMS survey team to monitor the correction of any deficiencies found through the validation survey.

(5) *Refusal to cooperate with survey.* If a supplier selected for a validation survey fails to comply with the requirements specified at paragraph (b)(4) of this section, it is deemed to no longer meet the DMEPOS supplier quality standards and may have its supplier billing number revoked.

(6) *Validation survey findings.* If a validation survey results in a finding that the supplier was not in compliance with one or more DMEPOS supplier quality standards, the supplier no longer meets the DMEPOS quality standards and may have its supplier billing number revoked.

(c) *Ongoing responsibilities of a CMS-approved accreditation organization.* An accreditation organization approved by CMS must undertake the following activities on an ongoing basis:

(1) Provide to CMS all of the following in written format (either electronic or hard copy) and on a monthly basis all of the following:

(i) Copies of all accreditation surveys, together with any survey-related information that CMS may require (including corrective action plans and summaries of findings with respect to unmet CMS requirements).

(ii) Notice of all accreditation decisions.

(iii) Notice of all complaints related to suppliers of DMEPOS and other items and services.

(iv) Information about any supplier of DMEPOS and other items and services against which the CMS-approved accreditation organization has taken remedial or adverse action, including revocation, withdrawal, or revision of the supplier's accreditation.

(v) Notice of any proposed changes in its accreditation standards or requirements or survey process. If the organization implements the changes before or without CMS' approval, CMS may withdraw its approval of the accreditation organization.

(2) Within 30 calendar days of a change in CMS requirements, submit to CMS:

(i) An acknowledgment of CMS's notification of the change.

(ii) A revised cross walk reflecting the new requirements.

(iii) An explanation of how the accreditation organization plans to alter its standards to conform to CMS's new requirements, within the timeframes specified in the notification of change it receives from CMS.

(3) Permit its surveyors to serve as witnesses if CMS takes an adverse action based on accreditation findings.

(4) Within 2 calendar days of identifying a deficiency of an accredited DMEPOS supplier that poses immediate jeopardy to a beneficiary or to the general public, provide CMS with written notice of the deficiency and any adverse action implemented by the accreditation organization.

(5) Within 10 calendar days after CMS's notice to a CMS-approved accreditation organization that CMS intends to withdraw approval of the accreditation organization, provide written notice of the withdrawal to all of the CMS-approved accreditation organization's accredited suppliers.

(6) Provide, on an annual basis, summary data specified by CMS that relate to the past year's accreditation activities and trends.

(d) *Continuing Federal oversight of approved accreditation organizations.* This paragraph establishes specific criteria and procedures for continuing oversight and for withdrawing approval of a CMS-approved accreditation organization.

(1) *Equivalency review.* CMS compares the accreditation organization's standards and its application and enforcement of those standards to the comparable CMS requirements and processes when—

(i) CMS imposes new requirements or changes its survey process;

(ii) An accreditation organization proposes to adopt new standards or changes in its survey process; or

(iii) The term of an accreditation organization's approval expires.

(2) *Validation survey.* CMS or its designated survey team may conduct a survey of an accredited DMEPOS supplier, examine the results of a CMS-approved accreditation organization's survey of a supplier, or observe a CMS-approved accreditation organization's onsite survey of a DMEPOS supplier, in order to validate the CMS-approved accreditation organization's accreditation process. At the conclusion of the

review, CMS identifies any accreditation programs for which validation survey results indicate—

(i) A 10 percent rate of disparity between findings by the accreditation organization and findings by CMS or its designated survey team on standards that do not constitute immediate jeopardy to patient health and safety if unmet;

(ii) Any disparity between findings by the accreditation organization and findings by CMS on standards that constitute immediate jeopardy to patient health and safety if unmet; or

(iii) That, irrespective of the rate of disparity, there are widespread or systemic problems in an organization's accreditation process such that accreditation by that accreditation organization no longer provides CMS with adequate assurance that suppliers meet or exceed the Medicare requirements.

(3) *Notice of intent to withdraw approval.* CMS provides the organization written notice of its intent to withdraw approval if an equivalency review, validation review, onsite observation, or CMS's daily experience with the accreditation organization suggests that the accreditation organization is not meeting the requirements of this section.

(4) *Withdrawal of approval.* CMS may withdraw its approval of an accreditation organization at any time if CMS determines that—

(i) Accreditation by the organization no longer adequately assures that the suppliers of DMEPOS and other items and services are meeting the DMEPOS quality standards, and that failure to meet those requirements could jeopardize the health or safety of Medicare beneficiaries and could constitute a significant hazard to the public health; or

(ii) The accreditation organization has failed to meet its obligations with respect to application or reapplication procedures.

(e) *Reconsideration.* (1) An accreditation organization dissatisfied with a determination that its accreditation requirements do not provide or do not continue to provide reasonable assurance that the entities accredited by the accreditation organization meet the applicable supplier quality standards is entitled to a reconsideration. CMS reconsiders any determination to deny, remove, or not renew the approval of deeming authority to accreditation organizations if the accreditation organization files a written request for reconsideration by its authorized officials or through its legal representative.

(2) The request must be filed within 30 calendar days of the receipt of CMS notice of an adverse determination or non-renewal.

(3) The request for reconsideration must specify the findings or issues with which the accreditation organization disagrees and the reasons for the disagreement.

(4) A requestor may withdraw its request for reconsideration at any time before the issuance of a reconsideration determination.

(5) In response to a request for reconsideration, CMS provides the accreditation organization the opportunity for an informal hearing to be conducted by a hearing officer appointed by the Administrator of CMS and provide the accreditation organization the opportunity to present, in writing and in person, evidence or documentation to refute the determination to deny approval, or to withdraw or not renew deeming authority.

(6) CMS provides written notice of the time and place of the informal hearing at least 10 calendar days before the scheduled date.

(7) The informal reconsideration hearing is open to CMS and the organization requesting the reconsideration, including authorized representatives; technical advisors (individuals with knowledge of the facts of the case or presenting interpretation of the facts); and legal counsel.

(i) The hearing is conducted by the hearing officer who receives testimony and documents related to the proposed action.

(ii) Testimony and other evidence may be accepted by the hearing officer even though it is inadmissible under the rules of court procedures.

(iii) The hearing officer does not have the authority to compel by subpoena the production of witnesses, papers, or other evidence.

(8) Within 45 calendar days of the close of the hearing, the hearing officer

presents the findings and recommendations to the accreditation organization that requested the reconsideration.

(9) The written report of the hearing officer includes separate numbered findings of fact and the legal conclusions of the hearing officer. The hearing officer's decision is final.

[71 FR 48409, Aug. 18, 2006]

Subpart E—To Whom Payment is Made in Special Situations

§ 424.60 Scope.

(a) This subpart sets forth provisions applicable to payment after the beneficiary's death and payment to entities that provide coverage complementary to Medicare Part B.

(b) The provisions applicable to payment for services excluded as custodial care or services not reasonable and necessary are set forth in §§ 405.332 through 405.336 of this chapter.

[53 FR 6634, Mar. 2, 1988, as amended at 53 FR 28388, July 28, 1988]

§ 424.62 Payment after beneficiary's death: Bill has been paid.

(a) *Scope.* This section specifies the persons whom Medicare pays, and the conditions for payments, when the beneficiary has died and the bill has been paid.

(b) *Situation.* (1) The beneficiary has received covered services for which he could receive direct payment under § 424.53.

(2) The beneficiary died without receiving Medicare payment.

(3) The bill has been paid.

(c) *Persons whom Medicare pays.* In the situation described in paragraph (b) of this section, Medicare pays the following persons in the specified circumstances:

(1) The person or persons who, without a legal obligation to do so, paid for the services with their own funds, before or after the beneficiary's death.

(2) The legal representative of the beneficiary's estate if the services were paid for by the beneficiary before he or she died, or with funds from the estate.

(3) If the deceased beneficiary or his or her estate paid for the services and no legal representative of the estate has been appointed, the survivors, in the following order of priority:

(i) The person found by SSA to be the surviving spouse, if he or she was either living in the same household with the deceased at the time of death, or was, for the month of death, entitled to monthly social security or railroad retirement benefits on the basis of the same earnings record as the deceased beneficiary;

(ii) The child or children, who were, for the month of death, entitled to monthly social security or railroad retirement benefits on the basis of the same earnings record as the deceased (and, if there is more than one child, in equal parts to each child);

(iii) The parent or parents, who were, for the month of death, entitled to monthly social security or railroad retirement benefits on the basis of the same earnings record as the deceased (and, if there is more than one parent, in equal parts to each parent);

(iv) The person found by SSA to be the surviving spouse who was not living in the same household with the deceased at the time of death and was not, for the month of death, entitled to monthly social security or railroad retirement benefits on the basis of the same earnings record as the deceased beneficiary;

(v) The child or children who were not entitled to monthly social security or railroad retirement benefits on the basis of the same earnings record as the deceased (and, if there is more than one child, in equal parts to each child);

(vi) The parent or parents who were not entitled to monthly social security or railroad retirement benefits on the basis of the same earnings record as the deceased (and, if there is more than one parent, in equal parts to each parent).

(4) If none of the listed relatives survive, no payment is made.

(5) If the services were paid for by a person other than the deceased beneficiary, and that person died before payment was completed, Medicare does not pay that person's estate. Medicare pays a surviving relative of the deceased beneficiary in accordance with the priorities in paragraph (c)(3) of this

section. If none of those relatives survive. Medicare pays the legal representative of the deceased beneficiary's estate. If there is no legal representative of the estate, no payment is made.

(d) *Amount of payment.* The amount of payment is the amount due, including unnegotiated checks issued for the purpose of making direct payment to the beneficiary.

(e) *Conditions for payment.* For payment to be made under this section—

(1) The person who claims payment must meet the following requirements:

(i) Submit a claim on a CMS-prescribed form and an itemized bill in accordance with the requirements of this subpart. (See paragraph (g) of this section for an exception.)

(ii) Provide evidence that the services were furnished if the intermediary or carrier requests it.

(iii) Provide evidence of payment of the bill and of the identity of the person who paid it.

(2) If a person claims payment as the legal representative of the deceased beneficiary's estate, he or she must also submit a copy of the papers showing appointment as legal representative.

(3) If a person claims payment as a survivor of the beneficiary, he or she must also submit evidence, if the intermediary or carrier requests it, that he or she is highest on the priority list of paragraph (c)(3) of this section.

(f) *Evidence of payment.* Evidence of payment may be—

(1) A receipted bill, or a properly completed ''Report of Services'' section of a claim form, showing who paid the bill;

(2) A cancelled check;

(3) A written statement from the provider or supplier or an authorized staff member; or

(4) Other probative evidence.

(g) *Exception: Claim submitted before beneficiary died.* If a claim and itemized bill has been submitted by or on behalf of the beneficiary before he or she died, submission of another claim form and itemized bill is not required; any written request by the person seeking payment is sufficient.

§ 424.64 Payment after beneficiary's death: Bill has not been paid.

(a) *Scope.* This section specifies whom Medicare pays, and the conditions for payment when the beneficiary has died and the bill has not been paid.

(b) *Situation.* (1) The beneficiary has received covered Part B services furnished by a physician or other supplier.

(2) The beneficiary died without making an assignment to the physician or other supplier or receiving Medicare payment.

(3) The bill has not been paid.

(c) *To whom payment is made.* In the situation described in paragraph (b) of this section, Medicare pays as follows:

(1) *Payment to the supplier.* Medicare pays the physician or other supplier if he or she—

(i) Files a claim on a CMS-prescribed form in accordance with the applicable requirements of this subpart;

(ii) Upon request from the carrier, provides evidence that the services for which it claims payment were, in fact, furnished; and

(iii) Agrees in writing to accept the reasonable charge as the full charge for the services.

(2) *Payment to a person who assumes legal obligation to pay for the services.* If the physician or other supplier does not agree to accept the reasonable charge as full charge for the service, Medicare pays any person who submits to the carrier all of the following:

(i) A statement indicating that he or she has assumed legal obligation to pay for the services.

(ii) A claim on a CMS-prescribed form in accordance with the requirements of this subpart. (If a claim had been submitted by or on behalf of the beneficiary before he or she died, submission of another claim form is not required; a written request by the person seeking payment meets the requirement for a claim.)

(iii) An itemized bill that identifies the claimant as the person to whom the physician or other supplier holds responsible for payment. (If such an itemized bill had been submitted by or on behalf of the beneficiary before he or she died, submission of another itemized bill is not required.)

(iv) If the intermediary or carrier requests it, evidence that the services were actually furnished.

[53 FR 6634, Mar. 2, 1988, as amended at 53 FR 28388, July 28, 1988]

§ 424.66 Payment to entities that provide coverage complementary to Medicare Part B.

(a) *Conditions for payment.* Medicare may pay an entity for Part B services furnished by a physician or other supplier if the entity meets all of the following requirements:

(1) Provides coverage of the service under a complementary health benefit plan (this is, the coverage that the plan provides is complementary to Medicare benefits and covers only the amount by which the Part B payment falls short of the approved charge for the service under the plan).

(2) Has paid the person who provided the service an amount (including the amount payable under the Medicare program) that the person accepts as full payment.

(3) Has the written authorization of the beneficiary (or of a person authorized to sign claims on his behalf under § 424.36) to receive the Part B payment for the services for which the entity pays.

(4) Relieves the beneficiary of liability for payment for the service and will not seek any reimbursement from the beneficiary, his or her survivors or estate.

(5) Submits any information CMS or the carrier may request, including an itemized physician or supplier bill, in order to apply the requirements under the Medicare program.

(6) Identifies and excludes from its requests for payment all services for which Medicare is the secondary payer.

(b) *Services paid for by the entity.* An entity is not required to pay and claim reimbursement for all Part B services furnished to members of its plans. However, if it does not pay and claim reimbursement for all those services, it must establish in advance precise criteria for identifying the services for which it will pay and claim reimbursement.

[53 FR 28388, July 28, 1988; 53 FR 40231, Oct. 14, 1988]

§ 424.67 Enrollment requirements for opioid treatment programs (OTP).

(a) *General enrollment requirement.* In order for a program or eligible professional (as that term is defined in section 1848(k)(3)(B) of the Act) to receive Medicare payment for the provision of opioid use disorder treatment services, the provider must qualify as an OTP (as that term is defined in § 8.2 of this title) and enroll in the Medicare program under the provisions of this section and of subpart P of this part.

(b) *Specific requirements and standards for enrollment.* To enroll in the Medicare program, an OTP must meet all of the following requirements and standards:

(1) Fully complete and submit, as applicable, the Form CMS–855A or Form CMS–855B application (or their successor applications) and any applicable supplement or attachment thereto to its applicable Medicare contractor. This includes, but is not limited to, the following:

(i) Maintain and submit to CMS (via the applicable supplement or attachment) a list of all physicians, other eligible professionals, and pharmacists (regardless of whether the individual is a W–2 employee of the OTP) who are legally authorized to prescribe, order, or dispense controlled substances on behalf of the OTP. The list must include the physician's, other eligible professional's, or pharmacist's:

(A) First and last name, and middle initial.

(B) Social Security Number.

(C) National Provider Identifier.

(D) License number (if applicable).

(ii) Certifying via the Form CMS–855A or Form CMS–855B (as applicable) and/or the applicable supplement or attachment thereto that the OTP meets and will continue to meet the specific requirements and standards for enrollment described in paragraphs (b) and (e) of this section.

(2) Comply with the application fee requirements in § 424.514. (This includes OTPs enrolling under the circumstances described in paragraph (c)(2) of this section.)

(3)(i) Except as stated in paragraph (b)(3)(ii) of this section, successfully complete the assigned categorical risk

level screening required under, as applicable, § 424.518(b) and (c).

(ii) For currently enrolled OTPs that are changing their OTP enrollment from a Form CMS–855B enrollment to a Form CMS–855A enrollment, or vice versa, successfully complete the limited level of categorical screening under § 424.518(a) if the OTP has already completed, as applicable, the moderate or high level of categorical screening under § 424.518(b) or (c), respectively.

(4)(i) Have a current, valid certification by SAMHSA for an opioid treatment program consistent with the provisions and requirements of § 8.11 of this title.

(ii) A provisional certification under § 8.11(e) of this title does not meet the requirements of paragraph (b)(4)(i) of this section.

(5) Report on the Form CMS–855A or Form CMS–855B (as applicable) and/or any applicable supplement all OTP staff who meet the definition of ''managing employee'' in § 424.502. Such individuals include, but are not limited to, the following:

(i) Medical director (as described in § 8.2 of this title).

(ii) Program sponsor (as described in § 8.2 of this title).

(6)(i)(A) Must not employ or contract with a prescribing or ordering physician or eligible professional or with any individual legally authorized to dispense narcotics who, within the preceding 10 years, has been convicted (as that term is defined in 42 CFR 1001.2) of a Federal or State felony that CMS deems detrimental to the best interests of the Medicare program and its beneficiaries based on the same categories of detrimental felonies, as well as case by case detrimental determinations, found at § 424.535(a)(3).

(B) Paragraph (b)(6)(i)(A) of this section applies regardless of whether the individual in question is:

(*1*) Currently dispensing narcotics at or on behalf of the OTP; or

(*2*) A W–2 employee of the OTP.

(ii) Must not employ or contract with any personnel (regardless of whether the individual is a W–2 employee of the OTP) who is revoked from Medicare under § 424.535 or any other applicable section in Title 42, or who is on the preclusion list under § 422.222 or § 423.120(c)(6) of this chapter.

(iii) Must not employ or contract with any personnel (regardless of whether the individual is a W–2 employee of the OTP) who has a prior adverse action by a State oversight board, including, but not limited to, a reprimand, fine, or restriction, for a case or situation involving patient harm that CMS deems detrimental to the best interests of the Medicare program and its beneficiaries. CMS will consider the factors enumerated at § 424.535(a)(22) in each case of patient harm that potentially applies to this paragraph.

(7)(i) Sign (and adhere to the term of) a provider agreement in accordance with the provisions of part 489 of this chapter.

(ii) An OTP's appeals under part 498 of a Medicare revocation (under § 424.535) and a provider agreement termination (under § 489.53 of this chapter) must be filed jointly and, as applicable, considered jointly by CMS under part 498 of this chapter.

(8) Comply with all other applicable requirements for enrollment specified in this section and in subpart P of this part.

(c) *Clarification of required enrollment forms.* (1) An OTP may only be enrolled as an OTP via the Form CMS–855A or Form CMS–855B but not both.

(2) If a currently enrolled OTP is changing its OTP enrollment from a Form CMS–855B enrollment to a Form CMS–855A enrollment, or vice versa, the effective date of billing that was established for the OTP's prior enrollment under §§ 424.520(d) and 424.521(a) is applied to the OTP's new enrollment.

(d) *Denial of enrollment.* CMS may deny an OTP's enrollment application on any of the following grounds:

(1)(i) The provider does not have a current, valid certification by SAMHSA as required under paragraph (b)(4)(i) of this section or fails to meet any other applicable requirement in this section.

(ii) Any of the denial reasons in § 424.530 applies.

(2) An OTP may appeal the denial of its enrollment application under part 498 of this chapter.

(e) *Continued compliance, standards, and reasons for revocation.* (1) Upon and after enrollment, an OTP—

(i) Must remain validly certified by SAMHSA as required under §8.11 of this title.

(ii) Remains subject to, and must remain in full compliance with, the provisions of this section and of subpart P of this part. This includes, but is not limited to, the provisions of paragraph (b)(6) of this section, the revalidation provisions in §424.515, and the deactivation and reactivation provisions in §424.540.

(iii) Upon revalidation, successfully complete the moderate categorical risk level screening required under §424.518(b).

(2) CMS may revoke an OTP's enrollment on any of the following grounds:

(i) The provider does not have a current, valid certification by SAMHSA as required under paragraph (b)(4)(i) of this section or fails to meet any other applicable requirement or standard in this section, including, but not limited to, the OTP standards in paragraphs (b)(6) and (e)(1) of this section.

(ii) Any of the revocation reasons in §424.535 applies.

(3) An OTP may appeal the revocation of its enrollment under part 498 of this title.

(f) *Claim payment.* For an OTP to receive payment for furnished drugs:

(1) The prescribing or medication ordering physician's or other eligible professional's National Provider Identifier must be listed on Field 17 of the Form CMS–1500; and

(2) All other applicable requirements of this section, this part, and part 8 of this title must be met.

(g) *Relation to part 8 of this title.* Nothing in this section shall be construed as:

(1) Supplanting any of the provisions in part 8 of this title; or

(2) Eliminating an OTP's obligation to maintain compliance with all applicable provisions in part 8 of this title.

[84 FR 63202, Nov. 15, 2019, as amended at 85 FR 85038, Dec. 28, 2020]

§424.68 Enrollment requirements for home infusion therapy suppliers.

(a) *Definition.* For purposes of this section, a home infusion therapy supplier means a supplier of home infusion therapy that meets all of the following requirements:

(1) Furnishes infusion therapy to individuals with acute or chronic conditions requiring administration of home infusion drugs.

(2) Ensures the safe and effective provision and administration of home infusion therapy on a 7-day-a-week, 24-hour-a-day basis.

(3) Is accredited by an organization designated by the Secretary in accordance with section 1834(u)(5) of the Act.

(4) Is enrolled in Medicare as a home infusion therapy supplier consistent with the provisions of this section and subpart P of this part.

(b) *General requirement.* For a supplier to receive Medicare payment for the provision of home infusion therapy supplier services, the supplier must qualify as a home infusion therapy supplier (as defined in this section) and be in compliance with all applicable provisions of this section and of subpart P of this part.

(c) *Specific requirements for enrollment.* To enroll in the Medicare program as a home infusion therapy supplier, a home infusion therapy supplier must meet all of the following requirements:

(1)(i) Fully complete and submit the Form CMS–855B application (or its electronic or successor application) to its applicable Medicare contractor.

(ii) Certify via the Form CMS–855B that the home infusion therapy supplier meets and will continue to meet the specific requirements and standards for enrollment described in this section and in subpart P of this part.

(2) Comply with the application fee requirements in §424.514.

(3) Be currently and validly accredited as a home infusion therapy supplier by a CMS-recognized home infusion therapy supplier accreditation organization.

(4) Comply with §414.1515 of this chapter and all provisions of part 486, subpart I of this chapter.

(5) Successfully complete the limited categorical risk level of screening under §424.518.

(d) *Denial of enrollment.* (1) Enrollment denial by CMS. CMS may deny a supplier's enrollment application as a

home infusion therapy supplier on either of the following grounds:

(i) The supplier does not meet all of the requirements for enrollment outlined in § 424.68 and in subpart P of this part.

(ii) Any of the applicable denial reasons in § 424.530.

(2) Appeal of an enrollment denial. A supplier may appeal the denial of its enrollment application as a home infusion therapy supplier under part 498 of this chapter.

(e) *Continued compliance, standards, and reasons for revocation.* (1) Upon and after enrollment, a home infusion therapy supplier—

(i) Must remain currently and validly accredited as described in paragraph (c)(3) of this section.

(ii) Remains subject to, and must remain in full compliance with, all of the provisions of—

(A) This section;

(B) Subpart P of this part;

(C) Section 414.1515 of this chapter; and

(D) Part 486, subpart I of this chapter.

(2) CMS may revoke a home infusion therapy supplier's enrollment on any of the following grounds:

(i) The supplier does not meet the accreditation requirements as described in paragraph (c)(3) of this section.

(ii) The supplier does not comply with all of the provisions of—

(A) This section;

(B) Subpart P of this part;

(C) Section 414.1515 of this chapter; and

(D) Part 486, subpart I of this chapter; or

(iii) Any of the revocation reasons in § 424.535 applies.

(3) A home infusion therapy supplier may appeal the revocation of its enrollment under part 498 of this chapter.

[85 FR 70355, Nov. 4, 2020]

Subpart F—Limitations on Assignment and Reassignment of Claims

§ 424.70 Basis and scope.

(a) *Statutory basis.* This subpart implements sections 1815(c) and 1842(b)(6) of the Act, which establish limitations on who may receive payments due a provider or supplier of services or a beneficiary.

(b) *Scope.* This subpart—

(1) Prohibits the assignment, reassignment, or other transfer of the right to Medicare payments except under specified conditions;

(2) Sets forth the sanctions that CMS may impose on a provider or supplier that violates this prohibition, or on a supplier that violates the conditions to which it agreed in accepting assignment from the individual; and

(3) Specifies the conditions for payment under court-ordered assignments or reassignments.

§ 424.71 Definitions.

As used in this subpart, unless the context indicates otherwise—

Court of competent jurisdiction means a court that has jurisdiction over the subject matter and the parties before it.

Facility means a hospital or other institution that furnishes health care services to inpatients.

Entity means a person, group, or facility that is enrolled in the Medicare program.

Power of attorney means any written documents by which a principal authorizes an agent to—

(1) Receive, in the agent's name, any payments due the principal;

(2) Negotiate checks payable to the principal; or

(3) Receive, in any other manner, direct payment of amounts due the principal.

[53 FR 6634, Mar. 2, 1988, as amended at 69 FR 66426, Nov. 15, 2004]

§ 424.73 Prohibition of assignment of claims by providers.

(a) *Basic prohibition.* Except as specified in paragraph (b) of this section, Medicare does not pay amounts that are due a provider to any other person under assignment, or power of attorney, or any other direct payment arrangement.

(b) *Exceptions to the prohibition*—(1) *Payment to a government agency or entity.* Subject to the requirements of the Assignment of Claims Act (31 U.S.C. 3727), Medicare may pay a government

agency or entity under an assignment by the provider.

(2) *Payment under assignment established by court order.* Medicare may pay under an assignment established by, or in accordance with, the order of a court of competent jurisdiction if the assignment meets the conditions set forth in § 424.90.

(3) *Payment to an agent.* Medicare may pay an agent who furnishes billing and collection services to the provider if the following conditions are met:

(i) The agent receives the payment under an agency agreement with the provider;

(ii) The agent's compensation is not related in any way to the dollar amounts billed or collected;

(iii) The agent's compensation is not dependent upon the actual collection of payment;

(iv) The agent acts under payment disposition instructions that the provider may modify or revoke at any time; and

(v) The agent, in receiving the payment, acts only on behalf of the provider.

Payment to an agent will always be made in the name of the provider.

§ 424.74 Termination of provider agreement.

CMS may terminate a provider agreement, in accordance with § 489.53(a)(1) of this chapter, if the provider—

(a) Executes or continues a power of attorney, or enters into or continues any other arrangement, that authorizes or permits payment contrary to the provisions of this subpart; or

(b) Fails to furnish, upon request by CMS or the intermediary, evidence necessary to establish compliance with the requirements of this subpart.

§ 424.80 Prohibition of reassignment of claims by suppliers.

(a) *Basic prohibition.* Except as specified in paragraph (b) of this section, Medicare does not pay amounts that are due a supplier under an assignment to any other person under reassignment, power of attorney, or any other direct arrangement. Nothing in this section alters a party's obligations under the anti-kickback statute (section 1128B(b) of the Act), the physician self-referral prohibition (section 1877 of the Act), the rules regarding physician billing for purchased diagnostic tests (§ 414.50 of this chapter), the rules regarding payment for services and supplies incident to a physician's professional services (§ 410.26 of this chapter), or any other applicable Medicare laws, rules, or regulations.

(b) *Exceptions to the basic rule*—(1) *Payment to employer.* Medicare may pay the supplier's employer if the supplier is required, as a condition of employment, to turn over to the employer the fees for his or her services.

(2) *Payment to an entity under a contractual arrangement.* Medicare may pay an entity enrolled in the Medicare program if there is a contractual arrangement between the entity and the supplier under which the entity bills for the supplier's services, subject to the provisions of paragraph (d) of this section.

(3) *Payment to a government agency or entity.* Subject to the requirements of the Assignment of Claims Act (31 U.S.C. 3727), Medicare may pay a government agency or entity under a reassignment by the supplier.

(4) *Payment under a reassignment established by court order.* Medicare may pay under a reassignment established by, or in accordance with, the order of a court competent jurisdiction, if the reassignment meets the conditions set forth in § 424.90.

(5) *Payment to an agent.* Medicare may pay an agent who furnishes billing and collection services to the supplier, or to the employer, facility, or system specified in paragraphs (b) (1), (2) and (3) of this section, if the conditions of § 424.73(b)(3) for payment to a provider's agent are met by the agent of the supplier or of the employer, facility, or system. Payment to an agent will always be made in the name of the supplier or the employer, facility, or system.

(c) *Rules applicable to an employer or entity.* An employer or entity that may receive payment under paragraph (b)(1) or (b)(2) of this section is considered the supplier of those services for purposes of subparts C, D, and E of this part, subject to the provisions of paragraph (d) of this section.

(d) *Reassignment to an entity under an employer-employee relationship or under a contractual arrangement: Conditions and limitations*—(1) *Liability of the parties.* An entity enrolled in the Medicare program that receives payment under a contractual arrangement under paragraph (b)(2) of this section and the supplier that otherwise receives payment are jointly and severally responsible for any Medicare overpayment to that entity.

(2) *Access to records.* The supplier who furnishes the service has unrestricted access to claims submitted by an entity for services provided by that supplier. This paragraph applies irrespective of whether the supplier is an employee or whether the service is provided under a contractual arrangement. If an entity refuses to provide, upon request, the billing information to the supplier performing the service, the entity's right to receive reassigned benefits may be revoked under § 424.82(c)(3).

(3) *Reassignment of the technical or professional component of a diagnostic test.* If a physician or other supplier bills for the technical or professional component of a diagnostic test covered under section 1861(s)(3) of the Act and paid for under part 414 of this chapter (other than clinical diagnostic laboratory tests paid under section 1833(a)(2)(D) of the Act, which are subject to the special rules set forth in section 1833(h)(5)(A) of the Act) following a reassignment from a physician or other supplier who performed the technical or professional component, the amount payable to the billing physician or other supplier may be subject to the limits specified in § 414.50 of this chapter.

[53 FR 6634, Mar. 2, 1988, as amended at 54 FR 4027, Jan. 27, 1989; 69 FR 66426, Nov. 15, 2004; 70 FR 16722, Apr. 1, 2005; 71 FR 69788, Dec. 1, 2006; 72 FR 66406, Nov. 27, 2007]

§ 424.82 Revocation of right to receive assigned benefits.

(a) *Scope.* This section sets forth the conditions and procedures for revocation of the right of a supplier or other party to receive Medicare payments.

(b) *Definition.* As used in this section, *other party* means an employer, facility, or health care delivery system to which Medicare may make payment under § 424.80(b) (1), (2), or (3).

(c) *Basis for revocation.* CMS may revoke the right of a supplier or other party to receive Medicare payments if the supplier or other party, after warning by CMS or the carrier—

(1) Violates the terms of assignment in § 424.55(b).

(2) Continues collection efforts or fails to refund moneys incorrectly collected, in violation of the terms of assignment in § 424.55(b).

(3) Executes or continues in effect a reassignment or power of attorney or any other arrangement that seeks to obtain payment contrary to the provisions of § 424.80; or

(4) Fails to furnish evidence necessary to establish its compliance with the requirements of § 424.80.

(d) *Proposed revocation: Notice and opportunity for review.* If CMS proposes to revoke the right to payment in accordance with paragraph (c) of this section, it will send the supplier or other party a written notice that—

(1) States the reasons for the proposed revocation; and

(2) Provides an opportunity for the supplier or other party to submit written argument and evidence against the proposed revocation. CMS usually allows 15 days from the date on the notice, but may extend or reduce the time as circumstances require.

(e) *Actual revocation: Timing, notice, and opportunity for hearing*—(1) *Timing.* CMS determines whether to revoke after considering any written argument or evidence submitted by the supplier or other party or, if none is submitted, at the expiration of the period specified in the notice of proposed revocation.

(2) *Notice and opportunity for hearing.* The notice of revocation specifies—

(i) The reasons for the revocation;

(ii) That the revocation is effective as of the date on the notice;

(iii) That the supplier or other party may, within 60 days from the date on the notice (or a longer period if the notice so specifies), request an administrative hearing and may be represented by counsel or other qualified representative.

(iv) That the carrier will withhold payment on any claims submitted by

the supplier or other party until the period for requesting a hearing expires or, if a hearing is requested, until the hearing officer issues a decision;

(v) That if the hearing decision reverses the revocation, the carrier will pay the supplier's or other party's claims; and

(vi) That if a hearing is not requested or the hearing decision upholds the revocation, payment will be made to the beneficiary or to another person or agency authorized to receive payment on his or her behalf.

[53 FR 6644, Mar. 2, 1988; 53 FR 12945, Apr. 20, 1988]

§ 424.83 Hearings on revocation of right to receive assigned benefits.

If the supplier or other party requests a hearing under § 424.82(e)(2)—

(a) The hearing is conducted—

(1) By a CMS hearing official who was not involved in the decision to revoke; and

(2) In accordance with the procedures set forth in §§ 405.824 through 405.833 (but excepting § 405.832(d)) and 405.860 through 405.872 of this chapter. In applying those procedures, ''CMS'' is substituted for ''carrier''; and ''hearing official'', for ''hearing officer''.

(b) As soon as practicable after the close of the hearing, the official who conducted it issues a hearing decision that—

(1) Is based on all the evidence presented at the hearing and included in the hearing record; and

(2) Contains findings of fact and a statement of reasons.

§ 424.84 Final determination on revocation of right to receive assigned benefits.

(a) *Basis of final determination*—(1) *Final determination without a hearing.* If the supplier or other party does not request a hearing, CMS's revocation determination becomes final at the end of the period specified in the notice of revocation.

(2) *Final determination following a hearing.* If there is a hearing, the hearing decision constitutes CMS's final determination.

(b) *Notice of final determination.* CMS sends the supplier or other party a written notice of the final determination and, if there was a hearing, includes a copy of the hearing decision.

(c) *Application of the final determination*—(1) A final determination not to revoke is the final administrative decision by CMS on the matter.

(2) A final determination to revoke remains in effect until CMS finds that the reason for the revocation has been removed and that there is reasonable assurance that it will not recur.

(d) *Effect of revocation when supplier or other party has a financial interest in another entity.* Revocation of the party's right to accept assignment also applies to any corporation, partnership, or other entity in which the party, directly or indirectly, has or acquires all or all but a nominal part of the financial interest.

[53 FR 6644, Mar. 2, 1988; 53 FR 12945, Apr. 20, 1988]

§ 424.86 Prohibition of assignment of claims by beneficiaries.

(a) *Basic prohibition.* Except as specified in paragraph (b) of this section, Medicare does not pay amounts that are due a beneficiary under § 424.53 to any other person under assignment, power of attorney, or any other direct payment arrangement.

(b) *Exceptions*—(1) *Payment to a government agency or entity.* Subject to the requirements of the Assignment of Claims Act (31 U.S.C. 3727), Medicare may pay a government agency or entity under an assignment by a beneficiary (or by the beneficiary's legal guardian or representative payee).

(2) *Payment under an assignment established by court order.* Medicare may pay under an assignment established by, or in accordance with, a court order if the assignment meets the conditions set forth in § 424.90.

§ 424.90 Court ordered assignments: Conditions and limitations.

(a) *Conditions for acceptance.* An assignment or reassignment established by or in accordance with a court order is effective for Medicare payments only if—

(1) Someone files a certified copy of the court order and of the executed assignment or reassignment (if it was necessary to execute one) with the

intermediary or carrier responsible for processing the claim; and

(2) The assignment or reassignment—

(i) Applies to all Medicare benefits payable to a particular person or entity during a specified or indefinite time period; or

(ii) Specifies a particular amount of money, payable to a particular person or entity by a particular intermediary or carrier.

(b) *Retention of authority to reduce interim payments to providers.* A court-ordered assignment does not preclude the intermediary or carrier from reducing interim payments, as set forth in § 413.64(i) of this chapter, if the provider or assignee is in imminent danger of insolvency or bankruptcy.

(c) *Liability of the parties.* The party that receives payments under a court-ordered assignment or reassignment that meets the conditions of paragraph (a) of this section and the party that would have received payment if the court order had not been issued are jointly and severally responsible for any Medicare overpayment to the former.

Subpart G—Special Conditions: Emergency Services Furnished by a Nonparticipating Hospital

§ 424.100 Scope.

This subpart sets forth procedures and criteria that are followed in determining whether Medicare will pay for emergency services furnished by a hospital that is located in the United States and does not have in effect a provider agreement, that is, an agreement to participate in Medicare.

§ 424.101 Definitions.

As used in this subpart, unless the context indicates otherwise—

Emergency services means inpatient or outpatient hospital services that are necessary to prevent death or serious impairment of health and, because of the danger to life or health, require use of the most accessible hospital available and equipped to furnish those services.

Hospital means a facility that—

(1) Is primarily engaged in providing, by or under the supervision of doctors of medicine or osteopathy, inpatient services for the diagnosis, treatment, and care or rehabilitation of persons who are sick, injured, or disabled;

(2) Is not primarily engaged in providing skilled nursing care and related services for patients who require medical or nursing care, as described in section 1861(j)(1)(A) of the Act;

(3) Provides 24-hour nursing service in accordance with section 1861(e)(5) of the Act; and

(4) Is licensed, or is approved as meeting the standards for licensing, by the State or local licensing agency.

Reasonable charges means customary charges insofar as they are reasonable.

§ 424.102 Situations that do not constitute an emergency.

Without additional evidence of a threat to life or health, the following situations do not in themselves indicate a need for emergency services:

(a) Lack of care at home.

(b) Lack of transportation to a participating hospital.

(c) Death of the patient in the hospital.

§ 424.103 Conditions for payment for emergency services.

Medicare pays for emergency services furnished to a beneficiary by a nonparticipating hospital or under arrangements made by such a hospital if the conditions of this section are met.

(a) *General requirements.* (1) The services are of the type that Medicare would pay for if they were furnished by a participating hospital.

(2) The hospital has in effect an election to claim payment for all emergency services furnished in a calendar year in accordance with § 424.104.

(3) The need for emergency services arose while the beneficiary was not an inpatient in a hospital.

(4) In the case of inpatient hospital services, the services are furnished during a period in which the beneficiary could not be safely discharged or transferred to a participating hospital or other institution.

(5) The determination that the hospital was the most accessible hospital available and equipped to furnish the

services is made in accordance with § 424.106.

(b) *Medical information requirements.* A physician (or, if appropriate, the hospital) submits medical information that—

(1) Describes the nature of the emergency and specifies why it required that the beneficiary be treated in the most accessible hospital;

(2) Establishes that all the conditions in paragraph (a) of this section are met; and

(3) Indicates when the emergency ended, which, for inpatient hospital services, is the earliest date on which the beneficiary could be safely discharged or transferred to a participating hospital or other institution.

§ 424.104 Election to claim payment for emergency services furnished during a calendar year.

(a) *Terms of the election.* The hospital agrees to the following:

(1) To comply with the provisions of subpart C of part 489 of this chapter relating to charges for items and services the hospital may make to the beneficiary, or any other person on his or her behalf.

(2) To comply with the provisions of subpart D of part 489 of this chapter relating to proper disposition of monies incorrectly collected from, or on behalf of a beneficiary.

(3) To request payment under the Medicare program based on amounts specified in § 413.74 of this chapter.

(b) *Filing of election statement.* An election statement must be filed on a form designated by CMS, signed by an authorized official of the hospital, and either received by CMS, or postmarked, before the close of the calendar year of election.

(c) *Acceptance and effective date of election.* If CMS accepts the election statement, the election is effective as of the earliest day of the calendar year of election from which CMS determines the hospital has been in continuous compliance with the requirements of section 1814(d) of the Act.

(d) *Appeal by hospital.* Any hospital dissatisfied with a determination that it does not qualify to claim reimbursement shall be entitled to appeal the determination as provided in part 498 of this chapter.

(e) *Conditions for reinstatement after notice of failure to continue to qualify.* If CMS has notified a hospital that it no longer qualifies to receive reimbursement for a calendar year, CMS will not accept another election statement from that hospital until CMS finds that—

(1) The reason for its failure to qualify has been removed; and

(2) There is reasonable assurance that it will not recur.

§ 424.106 Criteria for determining whether the hospital was the most accessible.

(a) *Basic requirement.* (1) The hospital must be the most accessible one available and equipped to furnish the services.

(2) CMS determines accessibility based on the factors specified in paragraphs (b) and (c) of this section and the conditions set forth in paragraph (d) of this section.

(b) *Factors that are considered.* CMS considers the following factors in determining whether a nonparticipating hospital in a rural area meets the accessibility requirements:

(1) The relative distances of participating and nonparticipating hospitals in the area.

(2) The transportation facilities available to these hospitals.

(3) The quality of the roads to each hospital.

(4) The availability of beds at each hospital.

(5) Any other factors that bear on whether or not the services could be provided sooner in the nonparticipating hospitals than in a participating hospital in the general area.

In urban and suburban areas where both participating and nonparticipating hospitals are similarly available, CMS presumes that the services could have been provided in a participating hospital unless clear and convincing evidence shows that there was a medical or practical need to use the nonparticipating hospital.

(c) *Factors that are not considered.* CMS gives no consideration to the following factors in determining whether

the nonparticipating hospital was the most accessible hospital:

(1) The personal preference of the beneficiary, the physician, or members of the family.

(2) The fact that the attending physician did not have staff privileges in a participating hospital which was available and the most accessible to the beneficiary.

(3) The location of previous medical records.

(d) *Conditions under which the accessibility requirement is met.* If a beneficiary must be taken to a hospital immediately for required diagnosis and treatment, the nonparticipating hospital meets the accessibility requirement if—

(1) It was the nearest hospital to the point where the emergency occurred, it was medically equipped to handle the type of emergency, and it was the most accessible, on the basis of the factors specified in paragraph (b) of this section; or

(2) There was a closer participating hospital equipped to handle the emergency, but the participating hospital did not have a bed available or would not accept the individual.

§ 424.108 Payment to a hospital.

(a) *Conditions for payment.* Medicare pays the hospital for emergency services if the hospital—

(1) Has in effect a statement of election to claim payment for all covered emergency services furnished during a calendar year, in accordance with § 424.104;

(2) Claims payment in accordance with § 424.32; and

(3) Submits evidence requested by CMS to establish that the services meet the requirements of this subpart.

(b) *Subsequent claims.* If the hospital files subsequent claims because the initial claim did not include all the services furnished, those claims must include physicians' statements that—

(1) Contain sufficient information to clearly establish that, when the additional services were furnished, the emergency still existed; and

(2) Indicate when the emergency ended, which, for inpatient hospital services, is the earliest date on which the beneficiary could be safely discharged or transferred to a participating hospital or other institution.

§ 424.109 Payment to the beneficiary.

Medicare pays the beneficiary for emergency services if the following conditions are met:

(a) The hospital does not have in effect an election to claim payment.

(b) The beneficiary, or someone on his or her behalf, submits—

(1) A claim that meets the requirements of § 424.32;

(2) An itemized hospital bill; and

(3) Evidence requested by CMS to establish that the services meet the requirements of this subpart.

Subpart H—Special Conditions: Services Furnished in a Foreign Country

§ 424.120 Scope.

This subpart sets forth the conditions for payment for services furnished in a foreign country.

§ 424.121 Scope of payments.

Subject to the conditions set forth in this subpart—

(a) Medicare Part A pays, in the amounts specified in § 413.74 of this chapter, for emergency and nonemergency inpatient hospital services furnished by a foreign hospital.

(b) Medicare Part B pays for certain physicians' services and ambulance services furnished in connection with covered inpatient care in a foreign hospital, as specified in § 424.124.

(c) All other services furnished outside the United States are excluded from Medicare coverage, as specified in § 411.9 of this chapter.

[53 FR 6634, Mar. 2, 1988, as amended at 71 FR 48143, Aug. 18, 2006]

§ 424.122 Conditions for payment for emergency inpatient hospital services.

Medicare Part A pays for emergency inpatient hospital services furnished by a foreign hospital if the following conditions are met:

(a) At the time of the emergency that required the inpatient hospital services, the beneficiary was—

(1) In the United States; or

(2) In Canada traveling between Alaska and another State without unreasonable delay and by the most direct route.

(b) The foreign hospital was closer to, or more accessible from, the site of the emergency than the nearest United States hospital equipped to deal with, and available to treat, the individual's illness or injury.

(c) The conditions for payment for emergency services set forth in § 424.103 are met.

(d) The hospital is a hospital as defined in § 424.101, and is licensed, or approved as meeting the conditions for licensing, by the appropriate agency of the country in which it is located.

(e) The determination of whether the hospital was more accessible is made in accordance with § 424.106.

§ 424.123 Conditions for payment for nonemergency inpatient services furnished by a hospital closer to the individual's residence.

Medicare Part A pays for inpatient hospital services furnished by a foreign hospital if the following conditions are met:

(a) The beneficiary is a resident of the United States.

(b) The foreign hospital is closer or more accessible to the beneficiary's residence than the nearest United States hospital equipped to deal with, and available to treat, the individual's illness or injury.

(c) The foreign hospital is—

(1) A hospital as defined in § 424.101 and, it is licensed, or approved as meeting the conditions for licensing, by the appropriate agency of the country in which it is located; and

(2) Accredited by the Joint Commission on Accreditation of Healthcare Organizations (JCAHO) or accredited or approved by a program of the country where it is located under standards the CMS finds to be essentially equivalent to those of the JCAHO.

(d) The services are covered services that Medicare would pay for if they were furnished by a participating hospital.

[53 FR 6634, Mar. 2, 1988, as amended at 71 FR 48143, Aug. 18, 2006]

§ 424.124 Conditions for payment for physician services and ambulance services.

(a) *Basic rules.* Medicare Part B pays for physician and ambulance services if—

(1) They are furnished—

(i) To an individual who is entitled to Part B benefits; and

(ii) In connection with covered inpatient hospital services; and

(2) They meet the conditions set forth in paragraphs (b) and (c) of this section.

(b) *Physician services.* (1) The physician services are services covered under Medicare Part B and are furnished—

(i) In the hospital, during a period of covered inpatient services; or

(ii) Outside the hospital, on the day of admission and for the same condition that required inpatient admission; and

(2) The physician is legally authorized to practice in the country where he or she furnishes the services.

(c) *Ambulance services.* The ambulance services are—

(1) Necessary because the use of other means of transportation is contraindicated by the beneficiary's condition; and

(2) Furnished by an ambulance that meets the definition in § 410.41 of this chapter.

[53 FR 6646, Mar. 2, 1988; 53 FR 12945, Apr. 20, 1988; 64 FR 3649, Jan. 25, 1999]

§ 424.126 Payment to the hospital.

(a) *Conditions for payment.* Medicare pays the hospital if it—

(1) Has in effect an election that—

(i) Meets the requirements set forth in § 424.104; and

(ii) Reflects the hospital's intent to claim for all covered services furnished during a calendar year.

(2) Claims payment in accordance with §§ 424.32 and 413.74 of this chapter; and

(3) Submits evidence requested by CMS to establish that the services meet the requirements of this subpart.

(b) *Amount of payment.* Payment is made (in accordance with § 413.74 of this chapter) on the basis of 100 percent of the hospital's customary charges, subject to the applicable deductible

and coinsurance provisions set forth elsewhere in this chapter.

§ 424.127 Payment to the beneficiary.

(a) *Conditions for payment of inpatient hospital services.* Medicare pays the beneficiary if—

(1) The hospital does not have in effect an election to claim payment; and

(2) The beneficiary, or someone on his or her behalf, submits—

(i) A claim in accordance with § 424.32;

(ii) An itemized hospital bill; and

(iii) Evidence requested by CMS to establish that the services meet the requirements of this subpart.

(b) *Amount payable for inpatient hospital services.* The amount payable to the beneficiary is determined in accordance with § 424.109(b).

(c) *Conditions for payment for Part B services.* Medicare pays the beneficiary for physicians' services and ambulance services as specified in § 424.121, if an itemized bill for the services is submitted by the beneficiary or someone on his or her behalf and the conditions of § 424.126(a) (2) and (3) are met.

(d) The amount payable to the beneficiary is determined in accordance with § 410.152 of this chapter.

Subpart I—Requirements for Medicare Diabetes Prevention Program Suppliers and Beneficiary Engagement Incentives Under the Medicare Diabetes Prevention Program Expanded Model

SOURCE: 82 FR 53364, Nov. 15, 2017, unless otherwise noted.

§ 424.200 Scope.

This subpart specifies the requirements for Medicare Diabetes Prevention Program suppliers and beneficiary engagement incentives under the Medicare Diabetes Prevention Program expanded model.

§ 424.205 Requirements for Medicare Diabetes Prevention Program suppliers.

(a) *Definitions.* In addition to the definitions specified at § 410.79(b) and § 414.84(a) of this subchapter, the following definitions apply to this section:

Administrative location means a physical location associated with the MDPP supplier's operations where they are the primary operator in the space, from where coaches are dispatched or based, and where MDPP services may or may not be furnished.

Coach means an individual who furnishes MDPP services on behalf of an MDPP supplier as an employee, contractor, or volunteer.

Coach eligibility end date means the end date indicated by the MDPP supplier in submitting a change to the supplier's MDPP enrollment application in accordance with paragraph (d)(5) of this section that removed the coach's information, or the date the supplier itself was revoked from or withdrew its Medicare enrollment as an MDPP supplier.

Coach eligibility start date, means the start date indicated by the MDPP supplier when submitting the coach's information on the MDPP enrollment application.

Community setting means a location where the MDPP supplier furnishes MDPP services outside of their administrative locations. A community setting is a location open to the public not primarily associated with the supplier. Community settings may include, for example, church basements or multipurpose rooms in recreation centers.

Eligible coach means an individual who CMS has screened and has determined can provide MDPP services on behalf of an MDPP supplier in accordance with paragraph (e) of this section.

Ineligible coach means an individual whom CMS has screened and has determined cannot provide MDPP services on behalf of an MDPP supplier in accordance with paragraph (e) of this section.

(b) *Conditions for MDPP supplier enrollment.* An entity may enroll as an MDPP supplier only if it satisfies the following requirements and all other applicable Medicare enrollment requirements:

(1) Has either preliminary, full, full plus CDC DPRP recognition.

(2) Maintains an active and valid TIN and NPI at the organizational level.

(3) Has passed screening requirements as follows:

(i) Upon initial enrollment, at a ''high'' categorical risk in accordance with § 424.518(c)(2); and

(ii) Upon revalidation, at a ''moderate'' categorical risk in accordance with § 424.518(b)(2).

(4) Maintains, and submits to CMS through the CMS-approved enrollment application, a roster of all coaches who will be furnishing MDPP services on the entity's behalf that includes each coach's first and last names, middle initial (if applicable), date of birth, Social Security Number (SSN), active and valid NPI, coach eligibility start date, and coach eligibility end date (if applicable). This roster must be updated in accordance with paragraph (d)(5) of this section.

(5) The Medicare provider enrollment application fee does not apply to all Medicare Diabetes Prevention Program (MDPP) suppliers that submit an enrollment application on or after January 1, 2022.

(6) Meets and certifies in its CMS-approved enrollment application that it meets and will continue to meet the supplier enrollment standards described in paragraph (d) of this section.

(7) Revalidates its Medicare enrollment every 5 years after the effective date of enrollment.

(c) *Medicare Diabetes Prevention Program supplier standards.* An MDPP supplier must meet and must certify in its CMS-approved enrollment application that it meets and will continue to meet the following standards.

(1) The MDPP supplier must have and maintain preliminary, full, or full plus CDC DPRP recognition.

(2) The MDPP supplier must not currently have its billing privileges terminated for-cause or be excluded by a State Medicaid agency.

(3) The MDPP supplier must not include on the roster of coaches, described in paragraph (b)(4) of this section and updated in accordance with paragraph (d)(5) of this section, nor permit MDPP services to be furnished by, any individual coach who meets any of ineligibility criteria outlined in paragraph (e)(1) of this section.

(4) The MDPP supplier must maintain at least one administrative location. All administrative locations maintained by the MDPP supplier must be located at an appropriate site and be reported on the CMS-approved enrollment application. An appropriate site for such an administrative location would include all of the following characteristics:

(i) Signage posted on the exterior of the building or suite, in a building directory, or on materials located inside of the building. Such signage may include, for example, the MDPP supplier's legal business name or DBA, as well as hours of operation.

(ii) Open for business during stated operational hours.

(iii) Employees, staff, or volunteers present during operational hours; and

(iv) Not a private residence.

(5) The MDPP supplier must update its enrollment application within 30 days of any changes of ownership, changes to the coach roster (including due to coach ineligibility or because the coach is no longer an employee, contractor, or volunteer of the MDPP supplier), and final adverse action history, and report all other changes, including but not limited to changes in the MDPP supplier's administrative location(s), to CMS within 90 days of the reportable event.

(6) The MDPP supplier must maintain a primary business telephone that operates either at administrative locations described in paragraph (d)(4) of this section or directly where services are furnished, if services are furnished in community settings. The associated telephone number must be listed with either the legal or doing business as name of the supplier in public view, including on Web sites, flyers, and materials.

(7) The MDPP supplier must not knowingly sell to or allow another individual or entity to use its supplier billing number.

(8) Subject to paragraph (d)(8)(i) of this section, the MDPP supplier must not deny an MDPP beneficiary access to MDPP services during the MDPP services period described in § 410.79(c)(2) of this chapter, including on the basis of the beneficiary's weight, health status, or achievement of performance goals.

(i) Suppliers may deny an MDPP beneficiary access to MDPP services during the MDPP services period only under one of the following conditions:

(A) The MDPP beneficiary no longer meets the eligibility criteria for MDPP services under § 410.79(c)(1) of this chapter.

(B) The MDPP supplier lacks the self-determined publicly-posted capacity to furnish MDPP services to a given MDPP beneficiary.

(C) The MDPP supplier determines that the MDPP beneficiary significantly disrupts the session for other MDPP beneficiaries or becomes abusive.

(ii) MDPP suppliers must maintain a record of the number of MDPP beneficiaries for whom it declined access away for the reasons outlined in paragraphs (d)(8)(i)(B) and (C) of this section, to include the date each such beneficiary was declined access. For beneficiaries who were declined access for the reasons described in paragraph (d)(8)(i)(C) of this section, the MDPP supplier must document details of the occurrence(s), including date(s) of the behavior, any remediation efforts taken by the MDPP supplier, and final action (for example, dismissal from an MDPP session or denial from future sessions) in the beneficiary's MDPP records.

(9) The MDPP supplier and other individuals or entities performing functions or services related to MDPP services on the MDPP supplier's behalf must not unduly coerce an MDPP beneficiary's decision to change or not to change to a different MDPP supplier, including through the use of pressure, intimidation, or bribery.

(10) Except as allowed under paragraph (d)(8) of this section, the MDPP supplier must offer an MDPP beneficiary no fewer than all of the following:

(i) 16 in-person or distance learning core sessions no more frequently than weekly for the first 6 months of the MDPP services period, which begins on the date of attendance at the first such core session.

(ii) 1 in-person or distance learning core maintenance session each month during months 7 through 12 (6 months total) of the MDPP services period.

(11) Before the initial core session is furnished, the MDPP supplier must disclose detailed information about the set of MDPP services to each MDPP beneficiary to whom it wishes to begin furnishing MDPP services. Such information must include all of the following:

(i) Eligibility requirements under § 410.79(c)(1) of this chapter, including the once-per-lifetime nature of MDPP services.

(ii) Minimum coverage requirements under § 410.79(c)(2).

(iii) The MDPP supplier standards as specified in paragraph (d) of this section.

(12) The MDPP supplier must answer MDPP beneficiaries' questions about MDPP services and respond to MDPP-related complaints within a reasonable timeframe. An MDPP supplier must implement a complaint resolution protocol and maintain documentation of all beneficiary contact regarding such complaints, including the name and Medicare Beneficiary Identifier of the beneficiary, a summary of the complaint, related correspondences, notes of actions taken, and the names and/or NPIs of individuals who took such actions on behalf of the MDPP supplier. Failure to maintain a complaint resolution protocol or to retain information regarding MDPP related complaints in accordance with paragraph (g) of this section may be considered evidence that the MPPP supplier standards have not been met. This information must be kept at each administrative location and made available to CMS or its contractors upon request.

(13) The MDPP supplier must maintain a crosswalk file which indicates how beneficiary identifications for the purposes of CDC performance data requirements correspond to corresponding beneficiary health insurance claims numbers or Medicare Beneficiary Identifiers for each MDPP beneficiary receiving MDPP services from the MDPP supplier. The MDPP supplier must submit the crosswalk file to CMS or its contractor.

(14) The MDPP supplier must submit performance data for MDPP beneficiaries who ever attended ongoing

maintenance sessions with data elements consistent with the CDC's DPRP standards for data elements required for the core services period.

(15) The MDPP supplier must allow CMS or its agents to conduct onsite inspections or recordkeeping reviews in order to ascertain the MDPP supplier's compliance with these standards, and must adhere to the documentation requirements as outlined in paragraph (g) of this section.

(d) *Coach eligibility*—(1) *Criteria.* To furnish MDPP services to a beneficiary, an MDPP coach must not:

(i) Currently have Medicare billing privileges revoked and be currently subject to the reenrollment bar.

(ii) Currently have its Medicaid billing privileges terminated for-cause or be excluded by a State Medicaid agency.

(iii) Currently be excluded from any other Federal health care program, as defined in 42 CFR 1001.2, in accordance with section 1128, 1128A, 1156, 1842, 1862, 1867 or 1892 of the Act.

(iv) Currently be debarred, suspended, or otherwise excluded from participating in any other Federal procurement or nonprocurement program or activity in accordance with the Federal Acquisition Streamlining Act implementing regulations and the Department of Health and Human Services nonprocurement common rule at 45 CFR part 76.

(v) Have, in the previous 10 years, one of the following State or Federal felony convictions:

(A) Crimes against persons, such as murder, rape, assault, and other similar crimes for which the individual was convicted, as defined under 42 CFR 1001.2, had a guilty plea or adjudicated pretrial diversion.

(B) Financial crimes, such as extortion, embezzlement, income tax evasion, insurance fraud and other similar crimes for which the individual was convicted, as defined under 42 CFR 1001.2, had a guilty plea or adjudicated pretrial diversion.

(C) Any felony that placed Medicare or its beneficiaries at immediate risk, such as a malpractice suit that results in the individual being convicted, as defined under 42 CFR 1001.2, had a guilty plea or adjudicated pretrial diversion of criminal neglect or misconduct.

(D) Any felonies for which the individual was convicted, as defined under 42 CFR 1001.2, had a guilty plea or adjudicated pretrial diversion that would result in mandatory exclusion under section 1128(a) of the Act.

(2) *CMS determination of coach eligibility.* CMS will screen each individual identified on the roster of coaches included with the supplier's enrollment application described in paragraph (b)(4) of this section and updated in accordance with paragraph (d)(5) of this section to verify that the individual coach does not meet any of the conditions specified in paragraph (e)(1) of this section and that the coach can provide MDPP services on behalf of an MDPP supplier. For each individual coach successfully screened by CMS, his or her eligibility start date becomes effective and remains effective until an MDPP supplier or CMS takes action that results in an eligibility end date.

(e) *Effective date for billing privileges.* (1) For MDPP suppliers initially enrolling and for newly established administrative locations that result in a new enrollment record or Provider Transaction Access Number, the effective date for Medicare billing privileges for MDPP suppliers is—

(i) The later of—

(A) The date of filing of a Medicare enrollment application that was subsequently approved by a Medicare contractor;

(B) The date of filing of a corrective action plan that was subsequently approved by a Medicare contractor; or

(C) The date that the supplier first began furnishing services at a new administrative location that resulted in a new enrollment record or Provider Transaction Access Number.

(ii) Under no circumstances should the effective date of billing privileges for any MDPP supplier be prior to April 1, 2018.

(2) For any newly established administrative locations that do not result in a new enrollment record or Provider Transaction Access Number, the existing billing privilege effective date for their Provider Transaction Access

Number will apply, but not earlier than April 1, 2018.

(f) *Documentation retention and provision requirements.* An MDPP supplier must maintain all documentation related to participation in the MDPP in accordance with all applicable Federal and State laws. The MDPP supplier must provide to CMS, a contractor acting on CMS' behalf, the Office of the Inspector General, and the Comptroller General or their designee(s) scheduled and unscheduled access to the MDPP supplier's records, including, but not limited to, all books, contracts, records, documents, and other evidence sufficient to enable the audit, evaluation, inspection, or investigation of the MDPP supplier's compliance with the MDPP expanded model's requirements, including the MDPP expanded model requirements for in-kind beneficiary incentive engagements in § 424.210 of this chapter in the event that the MDPP supplier chooses to offer such incentives to any MDPP beneficiary.

(1) The documentation for the first core session must be established contemporaneous with the furnishing of MDPP services and must include at least all of the following:

(i) Organizational information, including MDPP supplier name, CDC DPRP number, and NPI.

(ii) Basic beneficiary information for each MDPP beneficiary in attendance, including but not limited to beneficiary name, Medicare Beneficiary Identifier (MBI), and age.

(iii) Evidence that each such beneficiary satisfied the eligibility requirements under § 410.79(c) of this chapter at the time of service.

(2) The documentation for each MDPP session attended by an MDPP must be established contemporaneous with the furnishing of MDPP services and must include at least all of the following:

(i) Documentation of the type of session (in-person or distance learning).

(ii) Identification of which CDC-approved DPRP curriculum was associated with the session.

(iii) The NPI of the coach who furnished the session.

(iv) The date and place of service of the session.

(v) Each MDPP's beneficiary's weight and date weight taken, in a form and manner as specified by CMS.

(3) If an MDPP supplier chooses to offer in-kind beneficiary engagement incentives to MDPP beneficiaries as permitted under § 424.210, the records maintained by the MDPP supplier in accordance with this section must also include the information required by § 424.210(e).

(4) An MDPP supplier is required to maintain and handle any beneficiary information related to MDPP, including Personally Identifiable Information (PII) and Protected Health Information (PHI), as would be required under HIPAA, other applicable state and federal privacy laws, and CMS standards.

(5) The MDPP supplier's records must include an attestation from the MDPP supplier that, as applicable, the MDPP beneficiary for which it is submitting a claim—

(i) Has achieved the required minimum 5-percent weight loss as measured in accordance with § 410.79(e)(3)(iii) of this chapter during a core session or core maintenance session furnished by that supplier, if the claim submitted is for a performance payment under § 414.84(b)(1) of this chapter.

(ii) Has achieved the required minimum 5-percent weight loss as measured in-person during a core session or core maintenance session furnished by that supplier, if the claim submitted is for a performance payment under § 414.84(b)(1) of this chapter.

(iii) Has achieved at least a 9-percent weight loss percentage as measured in accordance with § 410.79(e)(3)(iii) of this chapter during a core session or core maintenance session furnished by that supplier, if the claim submitted is for a performance payment under § 414.84(b)(2) of this chapter.

(iv) Has achieved at least a 9-percent weight loss percentage as measured in-person during a core session or core maintenance session furnished by that supplier, if the claim submitted is for a performance payment under § 414.84(b)(2) of this chapter.

(6) The MDPP supplier must maintain all records required under this section for a period of 10 years from the

last day of the MDPP beneficiary's receipt of MDPP services provided by the MDPP supplier or from the date of completion of any audit, evaluation, inspection, or investigation, whichever is later, unless either of the following apply:

(i) CMS determines that there is a special need to retain a particular record or group of records for a longer period and notifies the MDPP supplier at least 30 calendar days before the normal disposition rate; or

(ii) There has been a dispute or allegation of fraud or similar fault against the MDPP supplier, in which case the records must be maintained for an additional 6 years from the date of any resulting final resolution of the dispute or allegation of fraud or similar fault, as defined at § 405.902 of this chapter.

(g) *Denial or revocation of MDPP supplier enrollment.* (1) An MDPP supplier is subject to enrollment denial or revocation of its MDPP supplier enrollment for one or more of the following reasons:

(i) *Failure to meet enrollment requirements.* The MDPP supplier does not satisfy the conditions specified in paragraph (b) of this section.

(A) An enrollment denial under this paragraph (h)(1)(i) is considered an enrollment denial under § 424.530(a)(1).

(B) A revocation under this paragraph (h)(1)(i) is considered a revocation under § 424.535(a)(1).

(C) An MDPP supplier that does not satisfy the requirements in paragraph (b)(1) of this section may become eligible to bill for MDPP services again if it successfully achieves preliminary, full, or full plus CDC DPRP recognition, and successfully enrolls again in Medicare as an MDPP supplier after any applicable reenrollment bar has expired.

(ii) *Failure to meet MDPP supplier standards.* The MDPP supplier fails to meet the standards specified in paragraph (d) of this section.

(A) An enrollment denial under this paragraph (h)(1)(ii) is considered an enrollment denial under § 424.530(a)(1).

(B) A revocation under this paragraph (h)(1)(ii) is considered a revocation under § 424.535(a)(1).

(iii) *Application of existing enrollment denial reasons.* One of the enrollment denial reasons specified in § 424.530(a) applies.

(iv) *Application of existing revocation reasons.* One of the revocation reasons specified in § 424.535(a) applies.

(v) *Use of an ineligible coach.* (A) The MDPP supplier knowingly allows an ineligible coach to furnish MDPP services to Medicare beneficiaries. Knowingly means that the MDPP supplier received an enrollment denial or revocation notice based on failing to meet the standard specified in § 424.205(d)(3), was provided notice by CMS or contractors working on its behalf of this coach's ineligibility including the reason(s) for ineligibility, submitted a corrective action plan (CAP) to remove the coach and become compliant therefore maintaining its enrollment, but continued to allow the coach to provide MDPP services in violation of the CAP.

(B) Revocation under this paragraph (h)(1)(v) is subject to the following requirements:

(*1*) The revocation becomes effective 30 days after CMS or the CMS contractor mails notice of its determination to the MDPP supplier.

(*2*) For the revocation authority under this paragraph (h)(1)(v), MDPP suppliers are barred from participating in the Medicare program from the date of the revocation, which begins 30 days after CMS or its contractor mails notice of the revocation, until the end of the reenrollment bar, which lasts a minimum of 1 year, but not greater than 3 years, depending on the severity of the basis for revocation.

(*3*) A revoked MDPP supplier must, within 60 calendar days after the effective date of revocation, submit all claims for items and services furnished before the date of the revocation letter.

(2) An MDPP supplier may appeal an enrollment denial or revocation decision in accordance with the procedures specified in part 498 of this chapter. References to suppliers in that section apply to MDPP suppliers.

[82 FR 53364, Nov. 15, 2017,as amended at 86 FR 65682, Nov. 19, 2021; 88 FR 79540, Nov. 16, 2023; 89 FR 98565, Dec. 9, 2024]

§ 424.210 Beneficiary engagement incentives under the Medicare Diabetes Prevention Program expanded model.

(a) *Definitions.* In addition to the definitions specified at § 410.79(b) and § 424.205(a) of this chapter, the following definition applies to this section:

Engagement incentive period means the period of time during which an MDPP supplier may furnish in-kind beneficiary engagement incentives to a given MDPP beneficiary to whom the MDPP supplier is furnishing MDPP services. This period begins when an MDPP supplier furnishes any MDPP service to an MDPP eligible beneficiary and ends when one of the following occurs, whichever occurs first:

(i) The MDPP beneficiary's MDPP services period ends as described in § 410.79(c)(3) of this chapter.

(ii) The MDPP supplier knows the MDPP beneficiary will no longer be receiving MDPP services from the MDPP supplier.

(iii) The MDPP supplier has not had direct contact, either in-person, by telephone, or via other telecommunications technology, with the MDPP beneficiary for more than 90 consecutive calendar days during the MDPP services period.

(b) *General.* An MDPP supplier may choose to furnish an item or service as an in-kind beneficiary engagement incentive to an MDPP beneficiary only during the engagement incentive period, subject to the following conditions:

(1) The item or service must be furnished directly to an MDPP beneficiary by an MDPP supplier or by an agent of the MDPP supplier, such as a coach, under the MDPP supplier's direction and control.

(2) The item or service must be reasonably connected to the CDC-approved National Diabetes Prevention Program curriculum furnished to the MDPP beneficiary during a core session or core maintenance session furnished by the MDPP supplier.

(3) The item or service must be a preventive care item or service or an item or service that advances a clinical goal, as specified in paragraph (d) of this section, for an MDPP beneficiary by engaging him or her in better managing his or her own health.

(4) The item or service must not be tied to the receipt of items or services outside of the MDPP services.

(5) The item or service must not be tied to the receipt of items or services from a particular provider, supplier, or coach.

(6) The availability of the item or service must not be advertised or promoted as an in-kind beneficiary engagement incentive available to an MDPP beneficiary receiving MDPP services from the MDPP supplier except that an MDPP beneficiary may be made aware of the availability of the item or service at the time the MDPP beneficiary could reasonably benefit from it during the engagement incentive period.

(7) The cost of the item or service must not be shifted to another Federal health care program, as defined at section 1128B(f) of the Act.

(8) The cost of the item or service must not be shifted to an MDPP beneficiary.

(c) *Technology furnished to an MDPP beneficiary.* In-kind beneficiary engagement incentives involving technology furnished by an MDPP supplier to an MDPP beneficiary are subject to the following conditions:

(1) Items or services involving technology may not, in the aggregate, exceed $1,000 in retail value for any one MDPP beneficiary.

(2) Items or services involving technology must be the minimum necessary to advance a clinical goal, as specified in paragraph (d) of this section, for an MDPP beneficiary.

(3) Items involving technology exceeding $100 in retail value must—

(i) Remain the property of the MDPP supplier; and

(ii) Be retrieved from the MDPP beneficiary at the end of the engagement incentive period. The MDPP supplier must document all retrieval attempts, including the ultimate date of retrieval, in accordance with paragraph (e)(3) of this section. Documented diligent, good faith attempts to retrieve items of technology will be deemed to meet the retrieval requirement.

(d) *Clinical goals of the MDPP expanded model.* The following are the

clinical goals for MDPP beneficiaries that may be advanced through in-kind beneficiary engagement incentives:

(1) Attendance at core sessions or core maintenance sessions.

(2) Weight loss.

(3) Long-term dietary change.

(4) Adherence to long-term health behavior changes.

(e) *Documentation of beneficiary engagement incentives.* In addition to the documentation requirements at § 424.205(g), an MDPP supplier must maintain documentation of items and services furnished as in-kind beneficiary engagement incentives that exceed $25 in retail value.

(1) The documentation must be established contemporaneous with the furnishing of the in-kind items and services and must include at least the following:

(i) The date the item or service is furnished.

(ii) The identity of the MDPP beneficiary to whom the item or service is furnished.

(iii) The agent of the MDPP supplier that furnished the item or service, if applicable.

(iv) A description of the item or service.

(v) The retail value of the item or service.

(vi) Documentation establishing that the item or service was furnished to the MDPP beneficiary during the engagement incentive period.

(2) Documentation regarding items or services that are furnished to the MDPP beneficiary for use on an ongoing basis during the engagement incentive period, including items involving technology exceeding $100 in retail value, must also include contemporaneous documentation establishing that the MDPP beneficiary is in the engagement incentive period throughout the time period that the MDPP beneficiary possesses or has access to the item or service furnished by the MDPP supplier.

(3) The documentation regarding items involving technology exceeding $100 in retail value must also include contemporaneous documentation of any attempt to retrieve the item as required by paragraph (c)(3)(ii) of this section.

(4) The MDPP supplier must retain and provide access to the documentation required in this section in accordance with § 424.205(g).

[82 FR 53364, Nov. 15, 2017, as amended at 88 FR 79540, Nov. 16, 2023]

Subparts J–L [Reserved]

Subpart M—Replacement and Reclamation of Medicare Payments

§ 424.350 Replacement of checks that are lost, stolen, defaced, mutilated, destroyed, or paid on forged endorsements.

(a) *U.S. Government checks*—(1) *Responsibility.* The Treasury Department is responsible for the investigation and settlement of claims in connection with Treasury checks issued on behalf of CMS.

(2) *Action by CMS.* CMS forwards reports of lost, stolen, defaced, mutilated, destroyed, or forged Treasury checks to the Treasury Department disbursing center responsible for issuing checks.

(3) *Action by the Treasury Department.* The Treasury Department will replace and begin reclamation of Treasury checks in accordance with Treasury Department regulations (31 CFR parts 235, 240, and 245).

(b) *Intermediary and carrier benefit checks.* Checks issued by intermediaries and carriers are drawn on commercial banks and are not subject to the Federal laws and Treasury Department regulations that govern Treasury checks. Replacement procedures are carried out in accordance with § 424.352 under applicable State law (including any Federal banking laws or regulations that may affect the relevant State proceedings).

[58 FR 65129, Dec. 13, 1993]

§ 424.352 Intermediary and carrier checks that are lost, stolen, defaced, mutilated, destroyed or paid on forged endorsements.

(a) When an intermediary or carrier is notified by a payee that a check has been lost, stolen, defaced, mutilated,

destroyed, or paid on forged endorsement, the intermediary or carrier contacts the commercial bank on whose paper the check was drawn and determines whether the check has been negotiated.

(b) If the check has been negotiated—

(1) The intermediary or carrier provides the payee with a copy of the check and other pertinent information (such as a claim form, affidavit or questionnaire to be completed by the payee) required to pursue his or her claim in accordance with State law and commercial banking regulations.

(2) To pursue the claim, the payee must examine the check and certify (by completing the claim form, questionnaire or affidavit) that the endorsement is not the payee's.

(3) The claim form and other pertinent information is sent to the intermediary or carrier for review and processing of the claim.

(4) The intermediary or carrier reviews the payee's claim. If the intermediary or carrier determines that the claim appears to be valid, it forwards the claim and a copy of the check to the issuing bank. The intermediary or carrier takes further action to recover the proceeds of the check in accordance with the State law and regulations.

(5) Once the intermediary or carrier recovers the proceeds of the initial check, the intermediary or carrier issues a replacement check to the payee.

(6) If the bank of first deposit refuses to settle on the check for good cause, the payee must pursue the claim on his or her own and the intermediary or carrier will not reissue the check to the payee.

(c) If the check has not been negotiated—

(1) The intermediary or carrier arranges with the bank to stop payment on the check; and

(2) Except as provided in paragraph (d), the intermediary or carrier reissues the check to the payee.

(d) No check may be reissued under (c)(2) unless the claim for a replacement check is received by the intermediary or carrier no later than 1 year from the date of issuance of the original check, unless State law (including any applicable Federal banking laws or regulations that may affect the relevant State proceeding) provides a longer period which will control.

[58 FR 65130, Dec. 13, 1993]

Subparts N–O [Reserved]

Subpart P—Requirements for Establishing and Maintaining Medicare Billing Privileges

SOURCE: 71 FR 20776, Apr. 21, 2006, unless otherwise noted.

§ 424.500 Scope.

The provisions of this subpart contain the requirements for enrollment, periodic resubmission and certification of enrollment information for revalidation, and timely reporting of updates and changes to enrollment information. These requirements apply to all providers and suppliers except for physicians and practitioners who have entered into a private contract with a beneficiary as described in part 405, subpart D of this chapter. Providers and suppliers must meet and maintain these enrollment requirements to bill either the Medicare program or its beneficiaries for Medicare covered services or supplies.

§ 424.502 Definitions.

As used in this subpart, unless the context indicates otherwise—

Additional disclosable party means, with respect to a skilled nursing facility defined at section 1819(a) of the Act, any person or entity who does any of the following:

(1)(i) Exercises operational, financial, or managerial control over the facility or a part thereof;

(ii) Provides policies or procedures for any of the operations of the facility; or

(iii) Provides financial or cash management services to the facility.

(2)(i) Leases or subleases real property to the facility; or

(ii) Owns a whole or part interest equal to or exceeding 5 percent of the total value of such real property.

(3) Provides—

(i) Management or administrative services;

(ii) Management or clinical consulting services; or

(iii) Accounting or financial services to the facility.

Affiliation means, for purposes of applying § 424.519, any of the following:

(1) A 5 percent or greater direct or indirect ownership interest that an individual or entity has in another organization.

(2) A general or limited partnership interest (regardless of the percentage) that an individual or entity has in another organization.

(3) An interest in which an individual or entity exercises operational or managerial control over, or directly or indirectly conducts, the day-to-day operations of another organization (including, for purposes of this paragraph (3), sole proprietorships), either under contract or through some other arrangement, regardless of whether or not the managing individual or entity is a W–2 employee of the organization.

(4) An interest in which an individual is acting as an officer or director of a corporation.

(5) Any reassignment relationship under § 424.80.

Approve/Approval means the enrolling provider or supplier has been determined to be eligible under Medicare rules and regulations to receive a Medicare billing number and be granted Medicare billing privileges.

Authorized official means an appointed official (for example, chief executive officer, chief financial officer, general partner, chairman of the board, or direct owner) to whom the organization has granted the legal authority to enroll it in the Medicare program, to make changes or updates to the organization's status in the Medicare program, and to commit the organization to fully abide by the statutes, regulations, and program instructions of the Medicare program. For purposes of this definition only, the term ''organization'' means the enrolling entity as identified by its legal business name and tax identification number.

Change in majority ownership occurs when an individual or organization acquires more than a 50 percent direct ownership interest in an HHA or hospice during the 36 months following the HHA's or hospice's initial enrollment into the Medicare program or the 36 months following the HHA's or hospice's most recent change in majority ownership (including asset sale, stock transfer, merger, and consolidation). This includes an individual or organization that acquires majority ownership in an HHA or hospice through the cumulative effect of asset sales, stock transfers, consolidations, or mergers during the 36-month period after Medicare billing privileges are conveyed or the 36-month period following the HHA's or hospice's most recent change in majority ownership.

Deactivate means that the provider or supplier's billing privileges were stopped, but can be restored upon the submission of updated information.

Delegated official means an individual who is delegated by the ''Authorized Official,'' the authority to report changes and updates to the enrollment record. The delegated official must be an individual with ownership or control interest in, or be a W–2 managing employee of the provider or supplier.

Deny/Denial means the enrolling provider or supplier has been determined to be ineligible to receive Medicare billing privileges for Medicare covered items or services provided to Medicare beneficiaries.

Director means a director of a corporation, regardless of whether the provider or supplier is a non-profit entity. This includes any member of the corporation's governing body irrespective of the precise title of either the board or the member.

Disclosable event means, for purposes of § 424.519, any of the following:

(1) Currently has an uncollected debt to Medicare, Medicaid, or CHIP, regardless of—

(i) The amount of the debt;

(ii) Whether the debt is currently being repaid (for example, as part of a repayment plan); or

(iii) Whether the debt is currently being appealed;

(2) Has been or is subject to a payment suspension under a federal health care program (as that latter term is defined in section 1128B(f) of the Act), regardless of when the payment suspension occurred or was imposed;

(3) Has been or is excluded by the OIG from participation in Medicare, Medicaid, or CHIP, regardless of whether the exclusion is currently being appealed or when the exclusion occurred or was imposed; or

(4) Has had its Medicare, Medicaid, or CHIP enrollment denied, revoked, or terminated, regardless of—

(i) The reason for the denial, revocation, or termination;

(ii) Whether the denial, revocation, or termination is currently being appealed; or

(iii) When the denial, revocation, or termination occurred or was imposed.

Enroll/Enrollment means the process that Medicare uses to establish eligibility to submit claims for Medicare-covered items and services, and the process that Medicare uses to establish eligibility to order or certify Medicare-covered items and services. The process includes—

(1) Identification of a provider or supplier;

(2) Except for those suppliers that complete the CMS–855O form, CMS-identified equivalent, successor form or process for the sole purpose of obtaining eligibility to order or certify Medicare-covered items and services, validating the provider or supplier's eligibility to provide items or services to Medicare beneficiaries;

(3) Identification and confirmation of the provider or supplier's practice location(s) and owner(s); and

(4) Except for those suppliers that complete the CMS–855O form, CMS-identified equivalent, successor form or process for the sole purpose of obtaining eligibility to order or certify Medicare-covered items and services, granting the Medicare provider or supplier Medicare billing privileges.

Enrollment application means a CMS-approved paper enrollment application or an electronic Medicare enrollment process approved by OMB.

Final adverse action means one or more of the following actions:

(1) A Medicare-imposed revocation of any Medicare billing privileges;

(2) Suspension or revocation of a license to provide health care by any State licensing authority;

(3) Revocation or suspension by an accreditation organization;

(4) A conviction of a Federal or State felony offense (as defined in § 424.535(a)(3)(i)) within the last 10 years preceding enrollment, revalidation, or re-enrollment; or

(5) An exclusion or debarment from participation in a Federal or State health care program.

Indirect ownership interest means as follows:

(1)(i) Any ownership interest in an entity that has an ownership interest in the enrolling or enrolled provider or supplier.

(ii) Any ownership interest in an indirect owner of the enrolling or enrolled provider or supplier.

(2) The amount of indirect ownership interest is determined by multiplying the percentages of ownership in each entity. For example, if A owns 10 percent of the stock in a corporation that owns 80 percent of the provider or supplier, A's interest equates to an 8 percent indirect ownership interest in the provider or supplier and must be reported on the enrollment application. Conversely, if B owns 80 percent of the stock of a corporation that owns 5 percent of the stock of the provider or supplier, B's interest equates to a 4 percent indirect ownership interest in the provider or supplier and need not be reported.

Institutional provider means any provider or supplier that submits a paper Medicare enrollment application using the CMS–855A, CMS–855B (not including physician and nonphysician practitioner organizations), CMS–855S, or an associated internet-based PECOS enrollment application.

Managing employee means—

(1) A general manager, business manager, administrator, director, or other individual that exercises operational or managerial control over, or who directly or indirectly conducts, the day-to-day operation of the provider or supplier, either under contract or through some other arrangement, whether or not the individual is a W–2 employee of the provider or supplier. For purposes of this definition, this includes, but is not limited to, a hospice or skilled nursing facility administrator and a hospice or skilled nursing facility medical director.

(2) With respect to the additional requirements at § 424.516(g) for a skilled nursing facility defined at section 1819(a) of the Act, an individual, including a general manager, business manager, administrator, director, or consultant, who directly or indirectly manages, advises, or supervises any element of the practices, finances, or operations of the facility.

Managing organization means an entity that exercises operational or managerial control over, or that directly or indirectly conducts, the day-to-day operations of the provider or supplier, either under contract or through some other arrangement.

NPI stands for National Provider Identifier.

Officer means an officer of a corporation, regardless of whether the provider or supplier is a non-profit entity.

Operational means the provider or supplier has a qualified physical practice location, is open to the public for the purpose of providing health care related services, is prepared to submit valid Medicare claims, and is properly staffed, equipped, and stocked (as applicable, based on the type of facility or organization, provider or supplier specialty, or the services or items being rendered), to furnish these items or services.

Organizational structure means, with respect to a skilled nursing facility defined at section 1819(a) of the Act, in the case of any of the following:

(1) *A corporation*. The officers, directors, and shareholders of the corporation who have an ownership interest in the corporation which is equal to or exceeds 5 percent.

(2) *A limited liability company*. The members and managers of the limited liability company including, as applicable, what percentage each member and manager has of the ownership interest in the limited liability company.

(3) *A general partnership*. The partners of the general partnership.

(4) *A limited partnership*. The general partners and any limited partners of the limited partnership who have an ownership interest in the limited partnership which is equal to or exceeds 10 percent.

(5) *A trust*. The trustees of the trust.

(6) *An individual*. Contact information for the individual.

Owner means any individual or entity that has any partnership interest in, or that has 5 percent or more direct or indirect ownership of the provider or supplier as defined in sections 1124 and 1124A(A) of the Act.

PECOS stands for Internet-based Provider Enrollment, Chain, and Ownership System.

Physician or nonphysician practitioner organization means any physician or nonphysician practitioner entity that enrolls in the Medicare program as a sole proprietorship or organizational entity.

Private equity company means, for purposes of this subpart only, a publicly traded or non-publicly traded company that collects capital investments from individuals or entities and purchases a direct or indirect ownership share of a provider.

Real estate investment trust means, for purposes of this subpart only, a real estate investment trust as defined in 26 U.S.C. 856.

Reject/Rejected means that the provider or supplier's enrollment application was not processed due to incomplete information, or that additional information or corrected information was not received from the provider or supplier in a timely manner.

Revoke/Revocation means that the provider or supplier's billing privileges are terminated.

State oversight board means, for purposes of §§ 424.530(a)(15) and 424.535(a)(22) only, any State administrative body or organization, such as (but not limited to) a medical board, licensing agency, or accreditation body, that directly or indirectly oversees or regulates the provision of health care within the State.

Supplier means, for purposes of this subpart, all of the following:

(1) The individuals and entities that qualify as suppliers under § 400.202.

(2) Physical therapists in private practice.

(3) Occupational therapists in private practice.

(4) Speech-language pathologists.

Voluntary termination means that a provider or supplier, including an individual physician or nonphysician practitioner, submits written confirmation to CMS of its decision to discontinue enrollment in the Medicare program.

[71 FR 20776, Apr. 21, 2006, as amended at 73 FR 69939, Nov. 19, 2008; 75 FR 70464, Nov. 17, 2010; 75 FR 73628, Nov. 29, 2010; 76 FR 5962, Feb. 2, 2011; 79 FR 72531, Dec. 5, 2014; 82 FR 53368, Nov. 15, 2017; 84 FR 47852, Sept. 10, 2019; 84 FR 63203, Nov. 15, 2019; 86 FR 65682, Nov. 19, 2021; 87 FR 70231, Nov. 18, 2022; 88 FR 77877, Nov. 13, 2023; 88 FR 79540, Nov. 16, 2023; 88 FR 80168, Nov. 17, 2023]

§ 424.505 Basic enrollment requirement.

To receive payment for covered Medicare items or services from either Medicare (in the case of an assigned claim) or a Medicare beneficiary (in the case of an unassigned claim), a provider or supplier must be enrolled in the Medicare program. Except for those suppliers that complete the CMS–855O form or CMS-identified equivalent, successor form or process for the sole purpose of obtaining eligibility to order or certify Medicare-covered items and services; once enrolled the provider or supplier receives billing privileges and is issued a valid billing number effective for the date a claim was submitted for an item that was furnished or a service that was rendered. (See 45 CFR part 162 for information on the National Provider Identifier and its use as the Medicare billing number.)

[71 FR 20776, Apr. 21, 2006, as amended at 79 FR 72531, Dec. 5, 2014]

§ 424.506 National Provider Identifier (NPI) on all enrollment applications and claims.

(a) *Definition. Eligible professional* means any of the professionals specified in section 1848(k)(3)(B) of the Act.

(b) *Enrollment requirements.* (1) A provider or a supplier that is eligible for an NPI must do the following:

(i) Report its NPI on its Medicare enrollment application.

(ii) If the provider or supplier was in the Medicare program before obtaining an NPI and the provider's or the supplier's NPI is not in the provider's or supplier's Medicare enrollment record, the provider or supplier must update its Medicare enrollment record by submitting its NPI using either of the following:

(A) The applicable paper CMS–855 form.

(B) Internet-based PECOS.

(2) A physician or eligible professional who has validly opted-out of the Medicare program is not required to submit a Medicare enrollment application for any reason, including to order or certify.

(c) *Claims reporting requirements.* (1) A provider or supplier that is enrolled in Medicare and submits a paper or an electronic claim must include its NPI and the NPI(s) of any other provider(s) or supplier(s) identified on the claim.

(2) A Medicare beneficiary who submits a claim for service to Medicare—

(i) Must include the legal name of any provider or supplier who is required to be identified in that claim; and

(ii) May, if known to the beneficiary, include the National Provider Identifier (NPI) of any provider or supplier who is required to be identified in that claim.

(3) A Medicare contractor will reject a claim from a provider or a supplier if the required NPI(s) is not reported.

[75 FR 24448, May 5, 2010, as amended at 77 FR 25317, Apr. 27, 2012]

§ 424.507 Ordering covered items and services for Medicare beneficiaries.

(a) *Conditions for payment of claims for ordered covered imaging and clinical laboratory services and items of durable medical equipment, prosthetics, orthotics, and supplies (DMEPOS)*—(1) *Ordered covered imaging, clinical laboratory services, and DMEPOS item claims.* To receive payment for ordered imaging, clinical laboratory services, and DMEPOS items (excluding home health services described in § 424.507(b), and Part B drugs), a provider or supplier must meet all of the following requirements:

(i) The ordered covered imaging, clinical laboratory services, and DMEPOS items (excluding home health services described in paragraph (b) of this section, and Part B drugs) must have been ordered by a physician or, when permitted, an eligible professional (as defined in § 424.506(a) of this part).

(ii) The claim from the provider or supplier must contain the legal name and the National Provider Identifier (NPI) of the physician or the eligible professional (as defined in § 424.506(a) of this part) who ordered the item or service.

(iii) The physician or, when permitted, other eligible professional, as defined in § 424.506(a), who ordered the item or service must—

(A) Be identified by his or her legal name;

(B) Be identified by his or her NPI; and

(C)(*1*) Be enrolled in Medicare in an approved status; or

(*2*) Have validly opted-out of the Medicare program.

(iv) If the item or service is ordered by—

(A) An unlicensed resident (as defined in § 413.75), or by a non-enrolled licensed resident (as defined in § 413.75), the claim must identify a teaching physician, who must be enrolled in Medicare in an approved status, as follows:

(*1*) As the ordering supplier.

(*2*) By his or her legal name.

(*3*) By his/her NPI.

(B) A licensed resident (as defined in § 413.75), he or she must have a provisional license or be otherwise permitted by State law, where the resident is enrolled in an approved graduate medical education program, to practice or order such items and services, the claim must identify by legal name and NPI the—

(*1*) Resident, who is enrolled in Medicare in an approved status to order; or

(*2*) Teaching physician, who is enrolled in Medicare in an approved status.

(2) *Part B beneficiary claims.* To receive payment for ordered covered items and services listed at § 424.507(a), a beneficiary's claim must meet all of the following requirements:

(i) The physician or, when permitted, other eligible professional (as defined § 424.506(a)) who ordered the item or service must—

(A) Be identified by his or her legal name; and

(B)(*1*) Be enrolled in Medicare in an approved status; or

(*2*) Have validly opted out of the Medicare program.

(ii) If the item or service is ordered by—

(A) An unlicensed resident (as defined in § 413.75) or a non-enrolled licensed resident, (as defined in § 413.75) the claim must identify a teaching physician, who must be enrolled in Medicare in an approved status as follows:

(*1*) As the ordering supplier.

(*2*) By his or her legal name.

(B) A licensed resident (as defined in § 413.75), he or she must have a provisional license or are otherwise permitted by State law, where the resident is enrolled in an approved graduate medical education program, to practice or to order such items and services, the claim must identify by legal name the—

(*1*) Resident, who is enrolled in Medicare in an approved status to order; or

(*2*) Teaching physician, who is enrolled in Medicare in an approved status.

(b) *Conditions for payment of claims for covered home health and hospice services.* To receive payment for covered Part A or Part B home health services or for covered hospice services, a provider's home health or hospice services claim must meet all of the following requirements:

(1) The ordering/certifying physician for hospice or home health services, or, for home health services, the ordering/certifying physician assistant, nurse practitioner, or clinical nurse specialist working in accordance with State law, must meet all of the following requirements:

(i) Be identified by his or her legal name.

(ii) Be identified by his or her NPI.

(iii)(A) Be enrolled in Medicare in an approved status; or

(B) Have validly opted-out of the Medicare program.

(2) If the services were ordered/certified by—

(i) An unlicensed resident, as defined in § 413.75, or by a non-enrolled licensed resident, as defined in § 413.75, the claim must identify a teaching physician who must be enrolled in Medicare in an approved status—

(A) As the ordering/certifying supplier;

(B) By his or her legal name; and

(C) By his or her NPI.

(ii) A licensed resident (as defined in §413.75), he or she must have a provisional license or are otherwise permitted by State law, where the resident is enrolled in an approved graduate medical education program, to practice or to order/certify such items and services, the claim must identify by legal name and NPI the—

(A) Resident, who is enrolled in Medicare in an approved status to order; or

(B) Teaching physician, who is enrolled in Medicare in an approved status.

(3) For claims for hospice services, the requirements of this paragraph (b) apply with respect to any physician described in §418.22(c) of this chapter who made the applicable certification described in §418.22(c) of this chapter.

(c) *Denial of provider- or supplier-submitted claims.* Notwithstanding §424.506(c)(3), a Medicare contractor denies a claim from a provider or a supplier for covered items and services described in paragraph (a) or (b) of this section if the claim does not meet the requirements of paragraphs (a)(1) and (b) of this section, respectively.

(d) *Denial of beneficiary-submitted claims.* A Medicare contractor denies a claim from a Medicare beneficiary for covered items or services described in paragraphs (a) and (b) of this section if the claim does not meet the requirements of paragraph (a)(2) of this section.

[77 FR 25317, Apr. 27, 2012, as amended at 85 FR 27625, May 8, 2020; 88 FR 51199, Aug. 2, 2023]

§424.510 Requirements for enrolling in the Medicare program.

(a)(1) Providers and suppliers must submit enrollment information on the applicable enrollment application. Once the provider or supplier successfully completes the enrollment process, including, if applicable, a State survey and certification or accreditation process, CMS enrolls the provider or supplier into the Medicare program.

(2) To be enrolled to furnish Medicare-covered items and services, a provider or supplier must meet the requirements specified in paragraphs (d) and (e) of this section.

(3) To be enrolled solely to order and certify Medicare items or services, a physician or non-physician practitioner must meet the requirements specified in paragraph (d) of this section except for paragraphs (d)(2)(iii)(B), (d)(2)(iv), (d)(3)(ii), and (d)(5), (6), and (9) of this section.

(b) The effective dates for reimbursement are specified in §489.13 of this chapter for providers and suppliers requiring State survey or certification or accreditation, §424.5 and §424.44 for non-surveyed or certified/accredited suppliers, and §424.57 and section 1834(j)(1)(A) of the Act for DMEPOS suppliers.

(c) The effective date for reimbursement for providers and suppliers seeking accreditation from a CMS-approved accreditation organization as specified in §489.13.

(d) Providers and suppliers must meet the following enrollment requirements:

(1) *Submittal of the enrollment application.* A provider or supplier must submit a complete enrollment application and supporting documentation to the designated Medicare fee-for-service contractor.

(2) *Content of the enrollment application.* Each submitted enrollment application must include the following:

(i) Complete, accurate, and truthful responses to all information requested within each section as applicable to the provider or supplier type.

(ii) Submission of all documentation required by CMS under this or other statutory or regulatory authority, or under the Paperwork Reduction Act of 1995, to uniquely identify the provider or supplier. This documentation may include, but is not limited to, proof of the legal business name, practice location, social security number (SSN), tax identification number (TIN), National Provider Identifier (NPI), if issued, and owners of the business.

(iii) Submission of all documentation, including—

(A) All applicable Federal and State licenses, certifications including, but not limited to Federal Aviation Administration; and

(B) Documentation associated with regulatory and statutory requirements necessary to establish a provider's or

supplier's eligibility to furnish Medicare covered items or services to beneficiaries in the Medicare program.

(iv) At the time of enrollment, an enrollment change request, revalidation or change of Medicare contractors where the provider or supplier was already receiving payments via EFT, providers and suppliers must agree to receive Medicare payments via EFT, if not already receiving payment through EFT. In order to receive Medicare payments via EFT, providers and suppliers must submit the CMS–588 form.

(3) *Signature(s) required on the enrollment application.* The certification statement found on the enrollment application must be signed by an individual who has the authority to bind the provider or supplier, both legally and financially, to the requirements set forth in this chapter. This person must also have an ownership or control interest in the provider or supplier, as that term is defined in section 1124(a)(3) of the Act, such as, the general partner, chairman of the board, chief financial officer, chief executive officer, president, or hold a position of similar status and authority within the provider or supplier organization. The signature attests that the information submitted is accurate and that the provider or supplier is aware of, and abides by, all applicable statutes, regulations, and program instructions.

(i) *Requirements.* The signature requirements specified in paragraphs (d)(3)(i)(A) through (C) of this section outline who must sign the enrollment application for an enrolling provider or supplier. In the case of—

(A) An individual practitioner, the applying practitioner.

(B) A sole proprietorship, the applying sole proprietor.

(C) A corporation, partnership, group, limited liability company, or other organization (hereafter referred to collectively in this section as an organization), an authorized official, as defined in § 424.502. When an authorized official signs the certification statement on behalf of an organization, the signed statement is considered legally binding upon the organization.

(ii) *Delegation of authority.* The original enrollment application submitted for an organization's initial enrollment and all subsequent enrollment applications submitted for periodic revalidation of the organization's enrollment data (as required to maintain enrollment in the Medicare program) must be signed by an authorized official. Any updates or changes reported outside of the initial enrollment or periodic revalidation process may be signed by a delegated official(s) of the organization. The delegated official's signature binds the organization both legally and financially, as if the signature was that of the authorized official. Before the delegation of authority is established, the only acceptable signature on the enrollment application to report updates or changes to the enrollment information is that of the authorized official currently on file with Medicare. Once the delegation of authority is established, the only acceptable signatures on correspondence to report updates or changes to the enrollment information are those of the authorized official and the person(s) to whom this authority is delegated in accordance with the requirements described in this section. Individual practitioners and sole proprietors cannot delegate signature authority when submitting an enrollment application for any reason. All enrollment applications submitted by individual practitioners and sole proprietors must be signed by the enrolling or enrolled individual. Each delegation of authority to a delegated official must—

(A) Be assigned by the authorized official currently on file with CMS;

(B) Be submitted to CMS using the appropriate enrollment application or CMS established electronic enrollment process;

(C) Include the title and SSN of each person delegated authority to update or change the organization's enrollment information;

(D) Be an individual that has an ownership or control interest in the organization or is a W–2 managing employee as defined in section 1126(b) of the Act; and

(E) Be signed by the authorized official and the delegated official(s) of the organization.

(4) *Verification of information.* The information submitted by the provider or supplier on the applicable enrollment

application must be such that CMS can validate it for accuracy at the time of submission.

(5) *Completion of any applicable State surveys, certifications, and provider agreements.* The providers or suppliers who are mandated under the provision in part 488 of this chapter to be surveyed or certified by the State survey and certification agency, and to also enter into and sign a provider agreement as outlined in part 489 of this chapter, must also meet those requirements as part of the process to obtain Medicare billing privileges.

(6) *Ability to furnish Medicare covered items or services.* The provider or supplier must be operational to furnish Medicare covered items or services before being granted Medicare billing privileges.

(7) *Additional requirements.* Providers and suppliers must meet the provisions of §424.520 regarding additional compliance and reporting requirements.

(8) *On-site review.* CMS reserves the right, when deemed necessary, to perform on-site inspections of a provider or supplier to verify that the enrollment information submitted to CMS or its agents is accurate and to determine compliance with Medicare enrollment requirements. Site visits for enrollment purposes do not affect those site visits performed for establishing compliance with conditions of participation.

(i) *Medicare Part A providers.* CMS determines, upon on-site review, that the provider is no longer operational to furnish Medicare covered items or services, or the provider fails to satisfy any of the Medicare enrollment requirements.

(ii) *Medicare Part B suppliers.* CMS determines, upon review that the supplier is no longer operational to furnish Medicare covered items or services, or the supplier has failed to satisfy any or all of the Medicare enrollment requirements, or has failed to furnish Medicare covered items or services as required by the statute or regulations.

(9) In order to obtain enrollment and to maintain enrollment for the first three months after Medicare billing privileges are conveyed, a home health agency must satisfy the home health ''initial reserve operating funds'' requirement as set forth in §489.28 of this chapter.

(e) Providers and suppliers must—

(1) Agree to receive Medicare payment via electronic funds transfer (EFT) at the time of enrollment, revalidation, change of Medicare contractors where the provider or supplier was already receiving payments via EFT or submission of an enrollment change request; and

(2) Submit the CMS–588 form to receive Medicare payment via electronic funds transfer.

[71 FR 20776, Apr. 21, 2006, as amended at 73 FR 36461, June 27, 2008; 75 FR 50418, Aug. 16, 2010; 75 FR 70464, Nov. 17, 2010; 75 FR 73628, Nov. 29, 2010; 77 FR 29030, July 16, 2012; 79 FR 72531, Dec. 5, 2014]

§424.514 Application fee.

(a) *Application fee requirements for prospective institutional providers.* Beginning on or after March 25, 2011, prospective institutional providers that are submitting an initial application or currently enrolled institutional providers that are submitting an application to establish a new practice location must submit either or both of the following:

(1) The applicable application fee.

(2) A request for a hardship exception to the application fee at the time of filing a Medicare enrollment application.

(b) *Application fee requirements for revalidating institutional providers.* Beginning March 25, 2011, institutional providers that are subject to CMS revalidation efforts must submit either or both of the following:

(1) The applicable application fee.

(2) A request for a hardship exception to the application fee at the time of filing a Medicare enrollment application.

(c) *Hardship exception for disaster areas.* CMS will assess on a case-by-case basis whether institutional providers enrolling in a geographic area that is a Presidentially-declared disaster under the Robert T. Stafford Disaster Relief and Emergency Assistance Act, 42 U.S.C. 5121–5206 (Stafford Act) should receive an exception to the application fee.

(d) *Application fee.* The application fee and associated requirements are as follows:

(1) For 2010, $500.00.

(2) For 2011 and subsequent years—

(i) Is adjusted by the percentage change in the consumer price index for all urban consumers (all items; United States city average) for the 12-month period ending with June of the previous year;

(ii) Is effective from January 1 to December 31 of a calendar year;

(iii) Is based on the submission of an initial application, application to establish a new practice location or the submission of an application in response to a CMS revalidation request;

(iv) Must be in the amount calculated by CMS in effect for the year during which the application for enrollment is being submitted;

(v) Is nonrefundable, except if submitted with one of the following:

(A) A request for hardship exception that is subsequently approved;

(B) An application that is rejected prior to initiation of screening processes;

(C) An application that is subsequently denied as a result of the imposition of a temporary moratorium;

(e) *Denial or revocation based on application fee.* A Medicare contractor may deny or revoke Medicare billing privileges of a provider or supplier based on noncompliance if, in the absence of a written request for a hardship exception from the application fee that accompanies a Medicare enrollment application, the bank account on which the check that is submitted with the enrollment application is drawn does not contain sufficient funds to pay the application fee.

(f) *Information needed for submission of a hardship exception request.* A provider or supplier requesting an exception from the application fee must include with its enrollment application a letter that describes the hardship and why the hardship justifies an exception.

(g) *Failure to submit application fee or hardship exception request.* A Medicare contractor may—

(1) Reject an enrollment application from a newly-enrolling institutional provider that, with the exceptions described in §424.514(b), is not accompanied by the application fee or by a letter requesting a hardship exception from the application fee.

(2) Revoke the billing privileges of a currently enrolled institutional provider that, with the exceptions described in §424.514(b), is not accompanied by the application fee or by a letter requesting a hardship exception from the application fee.

(3)(i) Notwithstanding the foregoing, the contractor must first inform the provider that the application fee was not submitted in accordance with this section.

(ii) Within 30 days after the date of the notification, the contractor may reject the application of the newly-enrolling institutional provider or revoke the billing privileges of the currently enrolled institutional provider that has not submitted the fee.

(h) *Consideration of hardship exception request.* CMS has 60 days in which to approve or disapprove a hardship exception request. If a provider submits a request for hardship exception to the fee and the provider or supplier has not already submitted the fee consistent with provisions in §424.514(a) and (b), and the request for hardship exception is not approved, CMS notifies the provider or supplier that the hardship exception request was not approved and allows the provider or supplier 30 days from the date of notification to submit the application fee.

(1) A Medicare contractor does not—

(i) Begin processing an enrollment application that is accompanied by a hardship exception request until CMS has made a decision to approve or disapprove the hardship exception request; and

(ii) Deny an enrollment application that is accompanied by a hardship exception request unless the hardship exception request is denied by CMS and the provider or supplier fails to submit the required application fee within 30 days of being notified that the request for a hardship exception was denied.

(2) A hardship exception determination made by CMS is appealable using §405.874 of this chapter.

[76 FR 5962, Feb. 2, 2011]

§ 424.515 Requirements for reporting changes and updates to, and the periodic revalidation of Medicare enrollment information.

To maintain Medicare billing privileges, a provider or supplier (other than a DMEPOS supplier) must resubmit and recertify the accuracy of its enrollment information every 5 years. All providers and suppliers currently billing the Medicare program or initially enrolling in the Medicare program are required to complete the applicable enrollment application. The provider or supplier then enters a 5-year revalidation cycle once a completed enrollment application is submitted and validated. (Ambulance service providers must continue to resubmit enrollment information in accordance with § 410.41(c)(2) of this chapter and DMEPOS suppliers must continue to renew enrollment in accordance with § 424.57(g)). The requirements for the resubmission, recertification and reverification of enrollment information include the following:

(a) *Submission of the enrollment application and supporting documentation.* The provider or supplier must meet the submission, content, signature, verification, operational, inspection, and other requirements outlined in § 424.510.

(1) CMS contacts each provider or supplier directly when it is time to revalidate their enrollment information.

(2) A provider or supplier must submit to CMS the applicable enrollment application with complete and accurate information and applicable supporting documentation within 60 calendar days of our notification to resubmit and certify to the accuracy of its enrollment information.

(b) *Completion of any applicable State surveys, certifications and provider agreements.* A new certification and a new provider agreement are not required for the purpose of resubmission and certification for revalidation of enrollment information. Providers and suppliers must continue to meet the requirements of parts 488 and 489 of this chapter, or any currently established supplier agreement, if applicable.

(c) *On-site inspections.* CMS reserves the right to perform on-site inspections of a provider or supplier to verify that the information submitted to CMS or its agents is accurate and to determine compliance with Medicare enrollment requirements. Site visits for enrollment purposes do not affect those site visits performed for establishing compliance with conditions of participation.

(1) *Medicare Part A providers.* CMS determines, upon on-site review, that the provider is no longer operational to furnish Medicare covered items or services, or the provider fails to satisfy any of the Medicare enrollment requirements.

(2) *Medicare Part B suppliers.* CMS determines, upon review that the supplier is no longer operational to furnish Medicare covered items or services, or the supplier has failed to satisfy any or all of the Medicare enrollment requirements, or has failed to furnish Medicare covered items or services as required by the statute or regulations.

(d) *Off Cycle revalidations.* (1) CMS reserves the right to perform off cycle revalidations in addition to the regular 5-year revalidations and may request that a provider or supplier recertify the accuracy of the enrollment information when warranted to assess and confirm the validity of the enrollment information maintained by CMS. Off cycle revalidations may be triggered as a result of random checks, information indicating local health care fraud problems, national initiatives, complaints, or other reasons that cause CMS to question the compliance of the provider or supplier with Medicare enrollment requirements. Off cycle revalidations may be accompanied by site visits.

(2) CMS reserve the right to adjust the routine 5-year revalidation schedule if we determine that revalidation should occur on a more frequent basis due to complaints or evidence we receive indicating noncompliance with the statute or regulations by specific provider or supplier types. The schedule may also be on a less frequent basis if we determine that the integrity of and compliance with the statute and regulations by specific provider or supplier types indicates that less frequent

validation is justified. If a change occurs, CMS notifies all affected providers and suppliers at least 90 days in advance of implementing the change.

(3) CMS revalidates enrollment information for ambulance service suppliers in accordance with § 410.41(c)(2) of this chapter (Requirements for ambulance suppliers), and DMEPOS suppliers renews enrollment in accordance with § 424.57(g) (Special payment rules for items furnished by DMEPOS suppliers and issuance of DMEPOS supplier billing numbers).

(e) *Additional off-cycle revalidation.* On or after March 23, 2012, Medicare providers and suppliers, including DMEPOS suppliers, may be required to revalidate their enrollment outside the routine 5-year revalidation cycle (3-year DMEPOS supplier revalidation cycle).

(1) CMS will contact providers or suppliers to revalidate their enrollment for off-cycle revalidation.

(2) As with all revalidations, revalidations described in this paragraph are conducted in accordance with the screening procedures specified at § 424.518.

[71 FR 20776, Apr. 21, 2006, as amended at 76 FR 5963, Feb. 2, 2011; 79 FR 69775, Nov. 24, 2014]

§ 424.516 Additional provider and supplier requirements for enrolling and maintaining active enrollment status in the Medicare program.

(a) *Certifying compliance.* CMS enrolls and maintains an active enrollment status for a provider or supplier when that provider or supplier certifies that it meets, and continues to meet, and CMS verifies that it meets, and continues to meet, all of the following requirements:

(1) Compliance with title XVIII of the Act and applicable Medicare regulations.

(2) Compliance with Federal and State licensure, certification, and regulatory requirements, as required, based on the type of services or supplies the provider or supplier type will furnish and bill Medicare.

(3) Not employing or contracting with individuals or entities that meet either of the following conditions:

(i) Excluded from participation in any Federal health care programs, for the provision of items and services covered under the programs, in violation of section 1128A(a)(6) of the Act.

(ii) Debarred by the General Services Administration (GSA) from any other Executive Branch procurement or nonprocurement programs or activities, in accordance with the Federal Acquisition and Streamlining Act of 1994, and with the HHS Common Rule at 45 CFR part 76.

(b) *Reporting requirements Independent Diagnostic Testing Facilities (IDTFs).* IDTF reporting requirements are specified in § 410.33(g)(2) of this chapter.

(c) *Reporting requirements DMEPOS suppliers.* DMEPOS reporting requirements are specified in § 424.57(c)(2).

(d) *Reporting requirements for physicians, nonphysician practitioners, and physician and nonphysician practitioner organizations.* Physicians, nonphysician practitioners, and physician and nonphysician practitioner organizations must report the following reportable events to their Medicare contractor within the specified timeframes:

(1) Within 30 days—

(i) A change of ownership;

(ii) Any adverse legal action; or

(iii) A change, addition, or deletion of a practice location.

(2) All other changes in enrollment must be reported within 90 days.

(e) *Reporting requirements for all other providers and suppliers.* Reporting requirements for all other providers and suppliers not identified in paragraphs (a) through (d) of this section, with the exception of MDPP suppliers whose reporting requirements are established at § 424.205(d), must report to CMS the following information within the specified timeframes:

(1) Within 30 days for a change of ownership or control (including changes in authorized official(s) or delegated official(s)) or a change, addition, or deletion of a practice location;

(2) All other changes to enrollment must be reported within 90 days.

(3) Within 30 days of any revocation or suspension of a Federal or State license or certification including Federal Aviation Administration certifications, an air ambulance supplier must report a revocation or suspension

of its license or certification to the applicable Medicare contractor. The following FAA certifications must be reported:

(i) Specific pilot certifications including but not limited to instrument and medical certifications.

(ii) Airworthiness certification.

(f) *Maintaining and providing access to documentation.* (1)(i) A provider or a supplier that furnishes covered ordered, certified, referred, or prescribed Part A or B services, items or drugs is required to—

(A) Maintain documentation (as described in paragraph (f)(1)(ii) of this section) for 7 years from the date of service; and

(B) Upon the request of CMS or a Medicare contractor, to provide access to that documentation (as described in paragraph (f)(1)(ii) of this section).

(ii) The documentation includes written and electronic documents (including the NPI of the physician or, when permitted, other eligible professional who ordered, certified, referred, or prescribed the Part A or B service, item, or drug) relating to written orders, certifications, referrals, prescriptions, and requests for payments for Part A or B services, items or drugs.

(2)(i) A physician or, when permitted, an eligible professional who orders, certifies, refers, or prescribes Part A or B services, items or drugs is required to—

(A) Maintain documentation (as described in paragraph (f)(2)(ii) of this section) for 7 years from the date of the service; and

(B) Upon request of CMS or a Medicare contractor, to provide access to that documentation (as described in paragraph (f)(2)(ii) of this section).

(ii) The documentation includes written and electronic documents (including the NPI of the physician or, when permitted, other eligible professional who ordered, certified, referred, or prescribed the Part A or B service, item, or drug) relating to written orders, certifications, referrals, prescriptions or requests for payments for Part A or B services, items, or drugs.

(g) *Skilled nursing facilities.* (1) In addition to all other applicable reporting requirements in this subpart, a skilled nursing facility (as defined in section 1819(a) of the Act) must disclose upon initial enrollment (which, for purposes of this paragraph (g), also includes a change of ownership under 42 CFR 489.18) and revalidation the following information:

(i) Each member of the governing body of the facility, including the name, title, and period of service for each such member.

(ii) Each person or entity who is an officer, director, member, partner, trustee, or managing employee (as defined in §424.502) of the facility, including the name, title, and period of service of each such person or entity.

(iii) Each person or entity who is an additional disclosable party of the facility (as defined in §424.502).

(iv) The organizational structure (as defined in §424.502) of each additional disclosable party of the facility and a description of the relationship of each such additional disclosable party to the facility and to one another.

(2) The skilled nursing facility need not disclose the same information described in paragraph (g)(1) of this section more than once on the same enrollment application submission.

(3) The skilled nursing facility must report any change to any of the information described in paragraph (g)(1) of this section consistent with the applicable timeframes in paragraph (e) of this section.

[73 FR 69939, Nov. 19, 2008; 73 FR 80304, Dec. 31, 2008, as amended at 75 FR 24449, May 5, 2010; 75 FR 73628, Nov. 29, 2010; 77 FR 25318, Apr. 27, 2012; 82 FR 53368, Nov. 15, 2017; 84 FR 47852, Sept. 10, 2019; 88 FR 79541, Nov. 16, 2023; 88 FR 80168, Nov. 17, 2023]

§424.517 Onsite review.

(a) CMS reserves the right, when deemed necessary, to perform onsite review of a provider or supplier to verify that the enrollment information submitted to CMS or its agents is accurate and to determine compliance with Medicare enrollment requirements. Site visits for enrollment purposes do not affect those site visits performed for establishing compliance with conditions of participation. Based upon the results of CMS's onsite review, the provider may be subject to denial or revocation of Medicare billing privileges

as specified in § 424.530 or § 424.535 of this part.

(1) *Medicare Part A providers.* CMS determines, upon on-site review, that the provider meets either of the following conditions:

(i) Is unable to furnish Medicare-covered items or services.

(ii) Has failed to satisfy any of the Medicare enrollment requirements.

(2) *Medicare Part B providers.* CMS determines, upon review, that the supplier meets any of the following conditions:

(i) Is unable to furnish Medicare-covered items or services.

(ii) Has failed to satisfy any or all of the Medicare enrollment requirements.

(iii) Has failed to furnish Medicare covered items or services as required by the statute or regulations.

(b) [Reserved]

[73 FR 66940, Nov. 19, 2008]

§ 424.518 Screening levels for Medicare providers and suppliers.

A Medicare contractor is required to screen all initial applications, revalidation applications, change of ownership applications pursuant to 42 CFR 489.18, applications to add a new practice location, and applications to report any new owner (regardless of ownership percentage) pursuant to a change of information or other enrollment transaction under title 42, based on a CMS assessment of risk and assignment to a level of ''limited,'' ''moderate,'' or ''high.''

(a) *Limited categorical risk*—(1) *Limited categorical risk: Provider and supplier categories.* CMS has designated the following providers and suppliers as ''limited'' categorical risk:

(i) Physician or nonphysician practitioners (including nurse practitioners, CRNAs, occupational therapists, speech/language pathologists, and audiologists) and medical groups or clinics.

(ii) Ambulatory surgical centers.

(iii) Competitive Acquisition Program/Part B Vendors.

(iv) End-stage renal disease facilities.

(v) Federally qualified health centers.

(vi) Histocompatibility laboratories.

(vii) Home infusion therapy suppliers.

(viii) Hospitals, including critical access hospitals, rural emergency hospitals, Department of Veterans Affairs hospitals, and other federally owned hospital facilities.

(ix) Health programs operated by an Indian Health Program (as defined in section 4(12) of the Indian Health Care Improvement Act) or an urban Indian organization (as defined in section 4(29) of the Indian Health Care Improvement Act) that receives funding from the Indian Health Service pursuant to Title V of the Indian Health Care Improvement Act.

(x) Mammography screening centers.

(xi) Mass immunization roster billers

(xii) Opioid treatment programs (if § 424.67(b)(3)(ii) applies).

(xiii) Organ procurement organizations.

(xiv) Pharmacies newly enrolling or revalidating via the CMS–855B application.

(xv) Radiation therapy centers.

(xvi) Religious non-medical health care institutions.

(xvii) Rural health clinics.

(2) *Limited screening level: Screening requirements.* When CMS designates a provider or supplier as a ''limited'' categorical level of risk, the Medicare contractor does all of the following:

(i) Verifies that a provider or supplier meets all applicable Federal regulations and State requirements for the provider or supplier type prior to making an enrollment determination.

(ii) Conducts license verifications, including licensure verifications across State lines for physicians or nonphysician practitioners and providers and suppliers that obtain or maintain Medicare billing privileges as a result of State licensure, including State licensure in States other than where the provider or supplier is enrolling.

(iii) Conducts database checks on a pre- and post-enrollment basis to ensure that providers and suppliers continue to meet the enrollment criteria for their provider/supplier type.

(b) *Moderate categorical risk*—(1) *Moderate categorical risk: Provider and supplier categories.* CMS has designated the following providers and suppliers as ''moderate'' categorical risk:

(i) Ambulance service suppliers.

(ii) Community mental health centers.

(iii) Comprehensive outpatient rehabilitation facilities.

(iv) Independent clinical laboratories.

(v) Independent diagnostic testing facilities.

(vi) Physical therapists enrolling as individuals or as group practices.

(vii) Portable x-ray suppliers.

(viii) Prospective (newly enrolling) and revalidating opioid treatment programs that have been fully and continuously certified by the Substance Abuse and Mental Health Services Administration (SAMHSA) since October 23, 2018.

(ix) Revalidating opioid treatment programs that have not been fully and continuously certified by SAMHSA since October 23, 2018, revalidating DMEPOS suppliers, revalidating MDPP suppliers, revalidating HHAs, revalidating SNFs, and revalidating hospices to which CMS applied the fingerprinting requirements outlined in paragraph (c)(2)(ii) of this section upon the provider's or supplier's—

(A) New/initial enrollment; or

(B) Revalidation after CMS waived the fingerprinting requirements, under the circumstances described in paragraph (c)(1)(viii) of this section, when the provider or supplier initially enrolled in Medicare.

(2) *Moderate screening level: Screening requirements.* When CMS designates a provider or supplier as a ''moderate'' categorical level of risk, the Medicare contractor does all of the following:

(i) Performs the ''limited'' screening requirements described in paragraph (a)(2) of this section.

(ii) Conducts an on-site visit.

(c) *High categorical risk*—(1) *High categorical risk: Provider and supplier categories.* CMS has designated the following provider and supplier types as ''high'' categorical risk:

(i) Prospective (newly enrolling) home health agencies.

(ii) Prospective (newly enrolling) DMEPOS suppliers.

(iii) Prospective (newly enrolling) MDPP suppliers

(iv) Prospective (newly enrolling) opioid treatment programs that have not been fully and continuously certified by SAMHSA since October 23, 2018.

(v) Prospective (newly enrolling) (SNFs).

(vi) Prospective (newly enrolling) hospices.

(vii) Enrolled opioid treatment programs that have not been fully and continuously certified by SAMHSA since October 23, 2018, DMEPOS suppliers, MDPP suppliers, HHAs, SNFs, and hospices that are submitting a change of ownership application pursuant to 42 CFR 489.18 or reporting any new owner (regardless of ownership percentage) pursuant to a change of information or other enrollment transaction under title 42.

(viii) Except as stated in paragraph (b)(1)(ix) of this section, revalidating opioid treatment programs that have not been fully and continuously certified by SAMHSA since October 23, 2018, revalidating DMEPOS suppliers, revalidating MDPP suppliers, revalidating HHAs, revalidating SNFs, and revalidating hospices for which, upon their new/initial enrollment, CMS waived the fingerprinting requirements outlined in paragraph (c)(2)(ii) of this section in accordance with applicable legal authority due to a national, state, or local emergency declared under existing law.

(2) *High screening level: Screening requirements.* When CMS designates a provider or supplier as a ''high'' categorical level of risk, the Medicare contractor does all of the following:

(i) Performs the ''limited'' and ''moderate'' screening requirements described in paragraphs (a)(2) and (b)(2) of this section.

(ii)(A) Requires the submission of a set of fingerprints for a national background check from all individuals who maintain a 5 percent or greater direct or indirect ownership interest in the provider or supplier; and

(B) Conducts a fingerprint-based criminal history record check of the Federal Bureau of Investigation's Integrated Automated Fingerprint Identification System on all individuals who maintain a 5 percent or greater direct or indirect ownership interest in the provider or supplier.

(3) *Adjustment in the categorical risk.* CMS adjusts the screening level from

''limited'' or ''moderate'' to ''high'' if any of the following occur:

(i) CMS imposes a payment suspension on a provider or supplier at any time in the last 10 years.

(ii) The provider or supplier—

(A) Has been excluded from Medicare by the OIG; or

(B) Had billing privileges revoked by a Medicare contractor within the previous 10 years and is attempting to establish additional Medicare billing privileges by—

(*1*) Enrolling as a new provider or supplier; or

(*2*) Billing privileges for a new practice location;

(C) Has been terminated or is otherwise precluded from billing Medicaid;

(D) Has been excluded from any Federal health care program; or

(E) Has been subject to any final adverse action, as defined at §424.502, within the previous 10 years.

(iii) CMS lifts a temporary moratorium for a particular provider or supplier type and a provider or supplier that was prevented from enrolling based on the moratorium, applies for enrollment as a Medicare provider or supplier at any time within 6 months from the date the moratorium was lifted.

(4) Any screening level adjustment under paragraph (c)(3) of this section also applies to all other enrolled and prospective providers and suppliers that have the same legal business name and tax identification number as the provider or supplier for which the screening level under paragraph (c)(3) of this section was originally raised.

(d) *Fingerprinting requirements.* An individual subject to the fingerprint-based criminal history record check requirement specified in paragraph (c)(2)(ii)(B) of this section—

(1) Must submit a set of fingerprints for a national background check.

(i) Upon submission of a Medicare enrollment application; or

(ii) Within 30 days of a Medicare contractor request.

(2) In the event the individual(s) required to submit fingerprints under paragraph (c)(2) of this section fail to submit such fingerprints in accordance with paragraph (d)(1) of this section, the provider or supplier will have its billing privileges—

(i) Denied under §424.530(a)(1); or

(ii) Revoked under §424.535(a)(1).

[76 FR 5963, Feb. 2, 2011, as amended at 82 FR 53368, Nov. 15, 2017; 84 FR 63203, Nov. 15, 2019; 85 FR 70355, Nov. 4, 2020; 85 FR 85038, Dec. 28, 2020; 87 FR 70231, Nov. 18, 2022; 87 FR 72293, Nov. 23, 2022; 88 FR 77877, Nov. 13, 2023]

§424.519 Disclosure of affiliations.

(a) *Definitions.* For purposes of this section only, the following terms apply to the definition of disclosable event in §424.502:

(1) ''Uncollected debt'' only applies to the following:

(i) Medicare, Medicaid, or CHIP overpayments for which CMS or the state has sent notice of the debt to the affiliated provider or supplier.

(ii) Civil money penalties imposed under this title.

(iii) Assessments imposed under this title.

(2) ''Revoked,'' ''Revocation,'' ''Terminated,'' and ''Termination'' include situations where the affiliated provider or supplier voluntarily terminated its Medicare, Medicaid, or CHIP enrollment to avoid a potential revocation or termination.

(b) *General.* Upon a CMS request, an initially enrolling or revalidating provider or supplier must disclose any and all affiliations that it or any of its owning or managing employees or organizations (consistent with the terms ''owner'' and ''managing employee'' as defined in §424.502) has or, within the previous 5 years, had with a currently or formerly enrolled Medicare, Medicaid, or CHIP provider or supplier that has a disclosable event (as defined in §424.502). CMS will request such disclosures when it has determined that the initially enrolling or revalidating provider or supplier may have at least one such affiliation.

(c) *Information.* The provider or supplier must disclose the following information about each reported affiliation:

(1) General identifying data about the affiliated provider or supplier. This includes the following:

(i) Legal name as reported to the Internal Revenue Service or the Social

Security Administration (if the affiliated provider or supplier is an individual).

(ii) ''Doing business as'' name (if applicable).

(iii) Tax identification number.

(iv) NPI.

(2) Reason for disclosing the affiliated provider or supplier.

(3) Specific data regarding the affiliation relationship, including the following:

(i) Length of the relationship.

(ii) Type of relationship.

(iii) Degree of affiliation.

(4) If the affiliation has ended, the reason for the termination.

(d) *Mechanism.* The information required to be disclosed under paragraphs (b) and (c) of this section must be furnished to CMS or its contractors via the Form CMS–855 application (paper or the internet-based PECOS enrollment process).

(e) *Denial or revocation.* The failure of the provider or supplier to fully and completely disclose the information specified in paragraphs (b) and (c) of this section when the provider or supplier knew or should reasonably have known of this information may result in either of the following:

(1) The denial of the provider's or supplier's initial enrollment application under § 424.530(a)(1) and, if applicable, § 424.530(a)(4).

(2) The revocation of the provider's or supplier's Medicare enrollment under § 424.535(a)(1) and, if applicable, § 424.535(a)(4).

(f) *Undue risk.* Upon receiving the information described in paragraphs (b) and (c) of this section, CMS determines whether any of the disclosed affiliations poses an undue risk of fraud, waste, or abuse by considering the following factors:

(1) The duration of the affiliation.

(2) Whether the affiliation still exists and, if not, how long ago it ended.

(3) The degree and extent of the affiliation.

(4) If applicable, the reason for the termination of the affiliation.

(5) Regarding the affiliated provider's or supplier's disclosable event under paragraph (b) of this section:

(i) The type of disclosable event.

(ii) When the disclosable event occurred or was imposed.

(iii) Whether the affiliation existed when the disclosable event occurred or was imposed.

(iv) If the disclosable event is an uncollected debt:

(A) The amount of the debt.

(B) Whether the affiliated provider or supplier is repaying the debt.

(C) To whom the debt is owed.

(v) If a denial, revocation, termination, exclusion, or payment suspension is involved, the reason for the disclosable event.

(6) Any other evidence that CMS deems relevant to its determination.

(g) *Determination of undue risk.* A determination by CMS that a particular affiliation poses an undue risk of fraud, waste, or abuse will result in, as applicable, the denial of the provider's or supplier's initial enrollment application under § 424.530(a)(13) or the revocation of the provider's or supplier's Medicare enrollment under § 424.535(a)(19).

(h) *Duplicate data.* A provider or supplier is not required to report affiliation data in that portion of the Form CMS–855 application that collects affiliation information if the same data is being reported in the ''owning or managing control'' (or its successor) section of the Form CMS–855 application.

(i) *Undisclosed affiliations.* CMS may apply § 424.530(a)(13) or § 424.535(a)(19) to situations where a disclosable affiliation (as described in § 424.519(b) and (c)) poses an undue risk of fraud, waste or abuse, but the provider or supplier has not yet reported or is not required at that time to report the affiliation to CMS.

[84 FR 47853, Sept. 10, 2019]

§ 424.520 Effective date of Medicare billing privileges.

(a) *Surveyed, certified or accredited providers and suppliers.* The effective date for billing privileges for providers and suppliers requiring State survey, certification or accreditation is specified in § 489.13 of this chapter. If a provider or supplier is seeking accreditation from a CMS-approved accreditation organization, the effective date is specified in § 489.13.

(b) *Independent Diagnostic Testing Facilities.* The effective date for billing privileges for IDTFs is specified in § 410.33(i) of this chapter.

(c) *DMEPOS suppliers.* The effective date for billing privileges for DMEPOS suppliers is specified in § 424.57(b) of this subpart and section 1834(j)(1)(A) of the Act.

(d) *Additional provider and supplier types.* (1) The effective date of billing privileges for the provider and supplier types identified in paragraph (d)(2) of this section is the later of—

(i) The date of filing of a Medicare enrollment application that was subsequently approved by a Medicare contractor; or

(ii) The date that the provider or supplier first began furnishing services at a new practice location.

(2) The provider and supplier types to which paragraph (d)(1) of this section applies are as follows:

(i) Physicians.

(ii) Non-physician practitioners.

(iii) Physician organizations.

(iv) Non-physician practitioner organizations.

(v) Ambulance suppliers.

(vi) Opioid treatment programs.

(vii) Part B hospital departments.

(viii) Clinical Laboratory Improvement Amendment labs.

(ix) Intensive cardiac rehabilitation facilities.

(x) Mammography centers.

(xi) Mass immunizers/pharmacies.

(xii) Radiation therapy centers.

(xiii) Home infusion therapy suppliers.

(xiv) Physical therapists.

(xv) Occupational therapists.

(xvi) Speech language pathologists.

[73 FR 69940, Nov. 19, 2008, as amended at 75 FR 50418, Aug. 16, 2010; 79 FR 72531, Dec. 5, 2014; 84 FR 63203, Nov. 15, 2019; 85 FR 70355, Nov. 4, 2020; 86 FR 62419, Nov. 9, 2021]

§ 424.521 Request for payment by certain provider and supplier types.

(a) *Request for payment by certain provider and supplier types.* (1) The providers and suppliers identified in paragraph (a)(2) of this section may retrospectively bill for services when the provider or supplier has met all program requirements (including State licensure requirements), and services were provided at the enrolled practice location for up to—

(i) Thirty days prior to their effective date if circumstances precluded enrollment in advance of providing services to Medicare beneficiaries; or

(ii) Ninety days prior to their effective date if a Presidentially-declared disaster under the Robert T. Stafford Disaster Relief and Emergency Assistance Act, 42 U.S.C. 5121–5206 (Stafford Act) precluded enrollment in advance of providing services to Medicare beneficiaries.

(2) The provider and supplier types to which paragraph (a)(1) of this section applies are as follows:

(i) Physicians.

(ii) Non-physician practitioners.

(iii) Physician organizations.

(iv) Non-physician practitioner organizations.

(v) Ambulance suppliers.

(vi) Opioid treatment programs.

(vii) Part B hospital departments.

(viii) Clinical Laboratory Improvement Amendment labs.

(ix) Intensive cardiac rehabilitation facilities.

(x) Mammography centers.

(xi) Mass immunizers/pharmacies.

(xii) Radiation therapy centers.

(xiii) Home infusion therapy suppliers.

(xiv) Physical therapists.

(xv) Occupational therapists.

(xvi) Speech language pathologists.

(b) [Reserved]

[79 FR 72531, Dec. 5, 2014, as amended at 84 FR 63203, Nov. 15, 2019; 85 FR 70355, Nov. 4, 2020; 86 FR 62419, Nov. 9, 2021]

§ 424.522 Additional effective dates.

(a) *Reassignments.* A reassignment of benefits under § 424.80 is effective beginning 30 days before the Form CMS–855R is submitted if all applicable requirements during that period were otherwise met.

(b) *Form CMS–855O enrollment.* The effective date of a Form CMS–855O enrollment is the date on which the Medicare contractor received the Form CMS–855O application if all other requirements are met.

[86 FR 62419, Nov. 9, 2021]

§ 424.525 Rejection of a provider's or supplier's application for Medicare enrollment.

(a) *Reasons for rejection.* CMS may reject a provider's or supplier's enrollment application for any of the following reasons:

(1) The provider or supplier fails to furnish complete information on the provider/supplier enrollment application within 30 calendar days from the date of the Medicare contractor's request for the missing information. This includes the following situations:

(i) The application is missing data required by CMS or the Medicare contractor to process the application (such as, but not limited to, names, Social Security Number, contact information, and practice location information).

(ii) The application is unsigned or undated.

(iii) The application contains a copied or stamped signature.

(iv) The application is signed more than 120 days prior to the date on which the Medicare contractor received the application.

(v) The application is signed by a person unauthorized to do so under this subpart.

(vi) For paper applications, the required certification statement is missing.

(vii) The paper application is completed in pencil.

(viii) The application is submitted via fax or e-mail when the provider or supplier was not otherwise permitted to do so.

(ix) The provider or supplier failed to submit all of the forms needed to process a Form CMS–855 reassignment package within 30 days of receipt.

(x) The provider or supplier submitted the incorrect Form CMS–855 application.

(2) The provider or supplier fails to furnish all required supporting documentation within 30 calendar days of submitting the enrollment application.

(3) The Prospective institutional provider or supplier does not submit the application fee in the designated amount or a hardship waiver request with the Medicare enrollment application at the time of filing.

(b) *Extension of 30-day period.* CMS, at its discretion, may choose to extend the 30 day period if CMS determines that the provider or supplier is actively working with CMS to resolve any outstanding issues.

(c) *Resubmission after rejection.* To enroll in Medicare and obtain Medicare billing privileges after notification of a rejected enrollment application, the provider or supplier must complete and submit a new enrollment application and submit all supporting documentation for CMS review and approval.

(d) *Additional review.* Enrollment applications that are rejected are not afforded appeal rights.

(e) *Applicability.* Except as otherwise specified in the applicable reason for rejection under paragraph (a) of this section, this section applies to all CMS Medicare provider enrollment application submissions, including, but not limited to, the following:

(1) Form CMS–855 initial applications, change of information requests, changes of ownership, revalidations, and reactivations.

(2) Form CMS–588 (Electronic Funds Transfer (EFT) Authorization Agreement) submissions.

(3) Form CMS–20134 (Medicare Enrollment Application; Medicare Diabetes Prevention Program (MDPP) Suppliers) submissions.

(4) Any electronic or successor versions of the forms identified in paragraphs (e)(1) through (3) of this section.

[71 FR 20776, Apr. 21, 2006, as amended at 73 FR 36461, June 27, 2008; 76 FR 5964, Feb. 2, 2011; 86 FR 62419, Nov. 9, 2021]

EDITOR'S NOTE: At 86 FR 62419, Nov. 9, 2021, paragraph (a)(3) was amended by removing the phrase ''prospective provider'' and adding the word ''provider'' in its place; however, the phrase does not exist.

§ 424.526 Return of a provider's or supplier's enrollment application.

(a) *Reasons for return.* CMS may return a provider's or supplier's enrollment application for any of the following reasons:

(1) The provider or supplier sent its paper Form CMS–855, Form CMS–588, or Form CMS–20134 application to the incorrect Medicare contractor for processing.

(2) The Medicare contractor received the application more than 60 days prior

to the effective date listed on the application. (This paragraph (a)(2) does not apply to providers and suppliers submitting a Form CMS–855A application, ambulatory surgical centers, or portable x-ray suppliers.)

(3) The seller or buyer in a change of ownership submitted its Form CMS–855A or Form CMS–855B application more than 90 days prior to the anticipated date of the sale.

(4) The Medicare contractor received an initial application more than 180 days prior to the effective date listed on the application from a provider or supplier submitting a Form CMS–855A application, an ambulatory surgical center, or a portable x-ray supplier.

(5) The Medicare contractor confirms that the provider or supplier submitted an initial enrollment application prior to the expiration of the time period in which it is entitled to appeal the denial of its previously submitted application.

(6) The provider or supplier submitted an initial enrollment application prior to the expiration of their existing re-enrollment bar under § 424.535 or reapplication bar under § 424.530(f).

(7) The application is not needed for (or is inapplicable to) the transaction in question.

(8) The provider or supplier submitted a revalidation application more than 7 months prior to the provider's or supplier's revalidation due date.

(9) A Medicare Diabetes Prevention Program supplier submitted an application with a coach start date more than 30 days in the future.

(10) The provider or supplier requests that their application be withdrawn prior to or during the Medicare contractor's processing thereof.

(11) The provider or supplier submits an application that is an exact duplicate of an application that has already been processed or is currently being processed or is pending processing.

(12) The provider or supplier submits a paper Form CMS–855 or Form CMS–20134 enrollment application that is outdated or has been superseded by a revised version.

(13) The provider or supplier submits a Form CMS–855A or Form CMS–855B initial application followed by a Form CMS–855A or Form CMS–855B change of ownership application. If the Medicare contractor—

(i) Has not yet made a recommendation for approval concerning the initial application, both applications may be returned.

(ii) Has made a recommendation for approval concerning the initial application, the Medicare contractor may return the change of ownership application. If, per the Medicare contractor's written request, the provider or supplier fails to submit a new initial Form CMS–855A or Form CMS–855B application containing the new owner's information within 30 days of the date of the letter, the Medicare contractor may return the originally submitted initial Form CMS–855A or Form CMS–855B application.

(b) *Appeals*. A provider or supplier is not afforded appeal rights if their application is returned under this section.

(c) *Applicability*. Except as otherwise specified in the applicable return reason under paragraph (a) of this section, this section applies to all CMS Medicare provider enrollment application submissions including, but not limited to, the following:

(1) Form CMS–855 initial applications, change of information requests, changes of ownership, revalidations, and reactivations.

(2) Form CMS–588 submissions.

(3) Form CMS–20134 submissions.

(4) Any electronic or successor versions of the forms identified in paragraphs (c)(1) through (3) of this section.

[86 FR 62420, Nov. 9, 2021]

§ 424.527 Provisional period of enhanced oversight.

(a) *New provider or supplier*. Exclusively for purposes of both section 1866(j)(3) of the Act and this § 424.527, the term ''new provider or supplier'' is defined as any of the following:

(1) A newly enrolling Medicare provider or supplier. (This includes providers that are required to enroll as a new provider in accordance with the change in majority ownership provisions in § 424.550(b).)

(2) A certified provider or certified supplier undergoing a change of ownership consistent with the principles of 42

CFR 489.18. (This includes providers that qualify under § 424.550(b)(2) for an exception from the change in majority ownership requirements in § 424.550(b)(1) but which are undergoing a change of ownership under 42 CFR 489.18).

(3) A provider or supplier (including an HHA or hospice) undergoing a 100 percent change of ownership via a change of information request under § 424.516.

(4) A provider or supplier reactivating the provider's or supplier's Medicare enrollment and billing privileges in accordance with § 424.540(b).

(b) *Effective date.* The effective date of a provisional period of enhanced oversight that is commenced under section 1866(j)(3) of the Act is the date on which the new provider or supplier submits its first claim.

[88 FR 77877, Nov. 13, 2023, as amended at 89 FR 88485, Nov. 7, 2024]

§ 424.530 Denial of enrollment in the Medicare program.

(a) *Reasons for denial.* CMS may deny a provider's or supplier's enrollment in the Medicare program for the following reasons:

(1) *Noncompliance.* The provider or supplier is determined to not be in compliance with the enrollment requirements described in this title 42, or in the enrollment application applicable for its provider or supplier type, and has not submitted a plan of corrective action as outlined in part 488 of this chapter.

(2) *Provider or supplier conduct.* (i) The provider or supplier, or any owner, managing employee, managing organization, officer, director, authorized or delegated official, medical director, supervising physician, or other health care or administrative or management services personnel furnishing services payable by a federal health care program, of the provider or supplier is—

(A) Excluded from the Medicare, Medicaid, and any other Federal health care program, as defined in § 1001.2 of this chapter, in accordance with section 1128, 1128A, 1156, 1842, 1862, 1867 or 1892 of the Act.

(B) Debarred, suspended, or otherwise excluded from participating in any other Federal procurement or nonprocurement activity in accordance with section 2455 of the Federal Acquisition Streamlining Act (FASA).

(ii) The individuals and organizations identified in paragraph (a)(2)(i) of this section include, but are not limited to, W–2 employees and contracted individuals and organizations of the provider or supplier.

(3) *Felonies.* The provider, supplier, or any owner, managing employee, managing organization, officer, or director of the provider or supplier was, within the preceding 10 years, convicted (as that term is defined in 42 CFR 1001.2) of a Federal or State felony offense that CMS determines is detrimental to the best interests of the Medicare program and its beneficiaries.

(i) Offenses include, but are not limited in scope or severity to—

(A) Felony crimes against persons, such as murder, rape, assault, and other similar crimes for which the individual was convicted, including guilty pleas and adjudicated pretrial diversions.

(B) Financial crimes, such as extortion, embezzlement, income tax evasion, insurance fraud and other similar crimes for which the individual was convicted, including guilty pleas and adjudicated pretrial diversions.

(C) Any felony that placed the Medicare program or its beneficiaries at immediate risk, such as a malpractice suit that results in a conviction of criminal neglect or misconduct.

(D) Any felonies that would result in mandatory exclusion under section 1128(a) of the Act.

(ii) Denials based on felony convictions are for a period to be determined by the Secretary, but not less than 10 years from the date of conviction if the individual has been convicted on one previous occasion for one or more offenses.

(iii) The individuals and organizations identified in paragraph (a)(3) of this section include, but are not limited to, W–2 employees and contracted individuals and organizations of the provider or supplier.

(4) *False or misleading information.* The provider or supplier has submitted false or misleading information on the

enrollment application to gain enrollment in the Medicare program. (Offenders may be referred to the Office of Inspector General for investigation and possible criminal, civil, or administrative sanctions.)

(5) *On-site review.* Upon on-site review or other reliable evidence, CMS determines that the provider or supplier:

(i) Is not operational to furnish Medicare-covered items or services; or

(ii) Otherwise fails to satisfy any Medicare enrollment requirement.

(6) *Medicare debt.* (i) The enrolling provider, supplier, or owner thereof (as defined in § 424.502), has an existing Medicare debt.

(ii) The enrolling provider, supplier, or owner (as defined in § 424.502) thereof was previously the owner (as defined in § 424.502) of a provider or supplier that had a Medicare debt that existed when the latter's enrollment was voluntarily terminated, involuntarily terminated, or revoked, and all of the following criteria are met:

(A) The owner left the provider or supplier with the Medicare debt within 1 year before or after that provider or supplier's voluntary termination, involuntary termination or revocation.

(B) The Medicare debt has not been fully repaid.

(C) CMS determines that the uncollected debt poses an undue risk of fraud, waste, or abuse. In making this determination, CMS considers the following factors:

(*1*) The amount of the Medicare debt.

(*2*) The length and timeframe that the enrolling provider, supplier, or owner thereof was an owner of the prior entity.

(*3*) The percentage of the enrolling provider, supplier, or owner's ownership of the prior entity.

(*4*) Whether the Medicare debt is currently being appealed.

(*5*) Whether the enrolling provider, supplier, or owner thereof was an owner of the prior entity at the time the Medicare debt was incurred.

(iii) A denial of Medicare enrollment under this paragraph (a)(6) can be avoided if the enrolling provider, supplier or owner thereof does either of the following:

(A)(*1*) Satisfies the criteria set forth in § 401.607; and

(*2*) Agrees to a CMS-approved extended repayment schedule for the entire outstanding Medicare debt.

(B) Repays the debt in full.

(7) *Payment suspension.* (i) The provider or supplier, or any owning or managing employee or organization of the provider or supplier, is currently under a Medicare or Medicaid payment suspension as defined in §§ 405.370 through 405.372 or in § 455.23 of this chapter.

(ii) CMS may apply the provision in this paragraph (a)(7) to the provider or supplier under any of the provider's, supplier's, or owning or managing employee's or organization's current or former names, numerical identifiers, or business identities or to any of its existing enrollments.

(iii) In determining whether a denial is appropriate, CMS considers the following factors:

(A) The specific behavior in question.

(B) Whether the provider or supplier is the subject of other similar investigations.

(C) Any other information that CMS deems relevant to its determination.

(8) *Initial Reserve Operating Funds.* (i) CMS or its designated Medicare contractor may deny Medicare billing privileges if, within 30 days of a CMS or Medicare contractor request, a home health agency (HHA) cannot furnish supporting documentation which verifies that the HHA meets the initial reserve operating funds requirement found in § 489.28(a) of this title.

(ii) CMS may deny Medicare billing privileges upon an HHA applicant's failure to satisfy the initial reserve operating funds requirement found in 42 CFR 489.28(a).

(9) *Application fee/hardship exception.* An institutional provider's or supplier's hardship exception request is not granted, and the provider or supplier does not submit the application fee within 30 days of notification that the hardship exception request was not approved.

(10) *Temporary moratorium.* A provider or supplier submits an enrollment application for a practice location in a geographic area where CMS has imposed a temporary moratorium.

(11) *Prescribing authority.* (i) A physician or other eligible professional's

Drug Enforcement Administration (DEA) Certificate of Registration to dispense a controlled substance is currently suspended or revoked or is surrendered in response to an order to show cause;

(ii) The applicable licensing or administrative body for any State in which a physician or eligible professional practices has suspended or revoked the physician or eligible professional's ability to prescribe drugs, and such suspension or revocation is in effect on the date the physician or eligible professional submits his or her enrollment application to the Medicare contractor.

(12) *Revoked under different name, numerical identifier or business identity.* The provider or supplier is currently revoked under a different name, numerical identifier, or business identity, and the applicable reenrollment bar period has not expired. In determining whether a provider or supplier is a currently revoked provider or supplier under a different name, numerical identifier, or business identity, CMS investigates the degree of commonality by considering the following factors:

(i) Owning and managing employees and organizations (regardless of whether they have been disclosed on the Form CMS–855 application).

(ii) Geographic location.

(iii) Provider or supplier type.

(iv) Business structure.

(v) Any evidence indicating that the two parties are similar or that the provider or supplier was created to circumvent the revocation or reenrollment bar.

(13) *Affiliation that poses undue risk.* CMS determines that the provider or supplier has or has had an affiliation under § 424.519 that poses an undue risk of fraud, waste, or abuse to the Medicare program.

(14) *Other program termination or suspension.* (i) The provider or supplier is currently terminated or suspended (or otherwise barred) from participation in a State Medicaid program or any other federal health care program, or the provider's or supplier's license is currently revoked or suspended in a State other than that in which the provider or supplier is enrolling. In determining whether a denial under this paragraph (a)(14) is appropriate, CMS considers the following factors:

(A) The reason(s) for the termination, suspension, or revocation.

(B) Whether, as applicable, the provider or supplier is currently terminated or suspended (or otherwise barred) from more than one program (for example, more than one State's Medicaid program), has been subject to any other sanctions during its participation in other programs or by any other State licensing boards or has had any other final adverse actions (as that term is defined in § 424.502) imposed against it.

(C) Any other information that CMS deems relevant to its determination.

(ii) CMS may apply paragraph (a)(14)(i) of this section to the provider or supplier under any of its current or former names, numerical identifiers or business identities, and regardless of whether any appeals are pending.

(15) *Patient harm.* (i) The physician or other eligible professional (as that term is defined in 1848(k)(3)(B) of the Act) has been subject to prior action from a State oversight board, Federal or State health care program, Independent Review Organization (IRO) determination(s), or any other equivalent governmental body or program that oversees, regulates, or administers the provision of health care with underlying facts reflecting improper physician or other eligible professional conduct that led to patient harm. In determining whether a denial is appropriate, CMS considers the following factors:

(A) The nature of the patient harm.

(B) The nature of the physician's or other eligible professional's conduct.

(C) The number and type(s) of sanctions or disciplinary actions that have been imposed against the physician or other eligible professional by a State oversight board, IRO, Federal or State health care program, or any other equivalent governmental body or program that oversees, regulates, or administers the provision of health care. Such actions include, but are not limited to in scope or degree:

(*1*) License restriction(s) pertaining to certain procedures or practices.

(*2*) Required compliance appearances before State oversight board members.

(*3*) License restriction(s) regarding the ability to treat certain types of patients (for example, cannot be alone with members of a different gender after a sexual offense charge).

(*4*) Administrative/monetary penalties.

(*5*) Formal reprimand(s).

(D) If applicable, the nature of the IRO determination(s).

(E) The number of patients impacted by the physician's or other eligible professional's conduct and the degree of harm thereto or impact upon.

(ii) Paragraph (a)(15)(i) of this section does not apply to actions or orders pertaining exclusively to either of the following:

(A) Required participation in rehabilitation or mental/behavioral health programs; or

(B) Required abstinence from drugs or alcohol and random drug testing.

(16) [Reserved]

(17) *False Claims Act (FCA).* (i) The provider or supplier, or any owner, managing employee or organization, officer, or director of the provider or supplier, has had a civil judgment under the FCA (31 U.S.C. 3729 through 3733) imposed against them within the previous 10 years.

(ii) In determining whether a denial under this paragraph is appropriate, CMS considers the following factors:

(A) The number of provider or supplier actions that the judgment incorporates (for example, the number of false claims submitted).

(B) The types of provider or supplier actions involved.

(C) The monetary amount of the judgment.

(D) When the judgment occurred.

(E) Whether the provider or supplier has any history of final adverse actions (as that term is defined in § 424.502 of this chapter).

(F) Any other information that CMS deems relevant to its determination.

(18) *Supplier standard or condition violation.* (i) The independent diagnostic testing facility is non-compliant with any provision in § 410.33(g).

(ii) The DMEPOS supplier is non-compliant with any provision in § 424.57(c).

(iii) The opioid treatment program is non-compliant with any provision in § 424.67(b).

(iv) The home infusion therapy supplier is non-compliant with any provision in § 424.68(c).

(v) The Medicare diabetes prevention program is non-compliant with any provision in § 424.205(b) or (d).

(b) *Resubmission after denial.* A provider or supplier that is denied enrollment in the Medicare program cannot submit a new enrollment application until the following has occurred if the denial:

(1) Was not appealed, the provider or supplier may reapply after its appeal rights have lapsed.

(2) Was appealed, the provider or supplier may reapply after notification that the determination was upheld.

(c) *Reversal of denial.* If the denial was due to adverse activity (sanction, exclusion, debt, felony) of an owner, managing employee, managing organization, officer, director, authorized or delegated official, medical director, supervising physician, or other health care personnel of the provider or supplier furnishing Medicare reimbursable services, the denial may be reversed if the provider or supplier terminates and submits proof that it has terminated its business relationship with that individual or organization within 30 days of the denial notification.

(d) *Additional review.* When a provider or supplier is denied enrollment in Medicare, CMS automatically reviews all other related Medicare enrollment files that the denied provider or supplier has an association with (for example, as an owner or managing employee) to determine if the denial warrants an adverse action of the associated Medicare provider or supplier.

(e) *Effective date of denial.* Denial becomes effective within 30 days of the initial denial notification.

(f) *Reapplication bar.* CMS may prohibit a prospective provider or supplier from enrolling in Medicare for up to 10 years if its enrollment application is denied because the provider or supplier submitted false or misleading information on or with (or omitted information from) its application in order to gain enrollment in the Medicare program.

(1) The reapplication bar applies to the prospective provider or supplier under any of its current, former, or future names, numerical identifiers or business identities.

(2) CMS determines the bar's length by considering the following factors:

(i) The materiality of the information in question.

(ii) Whether there is evidence to suggest that the provider or supplier purposely furnished false or misleading information or deliberately withheld information.

(iii) Whether the provider or supplier has any history of final adverse actions or Medicare or Medicaid payment suspensions.

(iv) Any other information that CMS deems relevant to its determination.

(3)(i) A provider or supplier that is currently subject to a reapplication bar under paragraph (f) of this section may not order, refer, certify, or prescribe Medicare-covered services, items, or drugs.

(ii) Medicare does not pay for any otherwise covered service, item, or drug that is ordered, referred, certified, or prescribed by a provider or supplier that is currently under a reapplication bar.

[71 FR 20776, Apr. 21, 2006, as amended at 73 FR 69940, Nov. 19, 2008; 75 FR 70464, Nov. 17, 2010; 76 FR 5964, Feb. 2, 2011; 79 FR 29968, May 23, 2014; 79 FR 72531, Dec. 5, 2014; 84 FR 47853, Sept. 10, 2019; 84 FR 63203, Nov. 15, 2019; 86 FR 65682, Nov. 19, 2021; 87 FR 70231, Nov. 18, 2022; 88 FR 77878, Nov. 13, 2023; 88 FR 79541, Nov. 16, 2023]

§ 424.535 Revocation of enrollment in the Medicare program.

(a) *Reasons for revocation.* CMS may revoke a currently enrolled provider or supplier's Medicare enrollment and any corresponding provider agreement or supplier agreement for the following reasons:

(1) *Noncompliance.* The provider or supplier is determined to not be in compliance with the enrollment requirements described in this title 42, or in the enrollment application applicable for its provider or supplier type, and has not submitted a plan of corrective action as outlined in part 488 of this chapter. The provider or supplier may also be determined not to be in compliance if it has failed to pay any user fees as assessed under part 488 of this chapter.

(i) CMS may request additional documentation from the provider or supplier to determine compliance if adverse information is received or otherwise found concerning the provider or supplier.

(ii) Requested additional documentation must be submitted within 60 calendar days of request.

(2) *Provider or supplier conduct.* (i) The provider or supplier, or any owner, managing employee, managing organization, officer, director, authorized or delegated official, medical director, supervising physician, or other health care or administrative or management services personnel furnishing services payable by a Federal health care program, of the provider or supplier is—

(A) Excluded from the Medicare, Medicaid, and any other Federal health care program, as defined in § 1001.2 of this chapter, in accordance with section 1128, 1128A, 1156, 1842, 1862, 1867 or 1892 of the Act.

(B) Debarred, suspended, or otherwise excluded from participating in any other Federal procurement or nonprocurement activity in accordance with the FASA implementing regulations and the Department of Health and Human Services nonprocurement common rule at 45 CFR part 76.

(ii) The individuals and organizations identified in paragraph (a)(2)(i) of this section include, but are not limited to, W–2 employees and contracted individuals and organizations of the provider or supplier.

(3) *Felonies.*

(i) The provider, supplier, or any owner, managing employee, managing organization, officer, or director of the provider or supplier was, within the preceding 10 years, convicted (as that term is defined in 42 CFR 1001.2) of a Federal or State felony offense that CMS determines is detrimental to the best interests of the Medicare program and its beneficiaries.

(ii) Offenses include, but are not limited in scope or severity to—

(A) Felony crimes against persons, such as murder, rape, assault, and other similar crimes for which the individual was convicted, including

guilty pleas and adjudicated pretrial diversions.

(B) Financial crimes, such as extortion, embezzlement, income tax evasion, insurance fraud and other similar crimes for which the individual was convicted, including guilty pleas and adjudicated pretrial diversions.

(C) Any felony that placed the Medicare program or its beneficiaries at immediate risk, such as a malpractice suit that results in a conviction of criminal neglect or misconduct.

(D) Any felonies that would result in mandatory exclusion under section 1128(a) of the Act.

(iii) Revocations based on felony convictions are for a period to be determined by the Secretary, but not less than 10 years from the date of conviction if the individual has been convicted on one previous occasion for one or more offenses.

(iv) The individuals and organizations identified in paragraph (a)(3) of this section include, but are not limited to, W–2 employees and contracted individuals and organizations of the provider or supplier.

(4) *False or misleading information.* The provider or supplier certified as ''true'' misleading or false information on the enrollment application to be enrolled or maintain enrollment in the Medicare program. (Offenders may be subject to either fines or imprisonment, or both, in accordance with current law and regulations.)

(5) *On-site review.* Upon on-site review or other reliable evidence, CMS determines that the provider or supplier is either of the following:

(i) No longer operational to furnish Medicare-covered items or services.

(ii) Otherwise fails to satisfy any Medicare enrollment requirement.

(6) *Grounds related to provider and supplier screening requirements.* (i)(A) An institutional provider does not submit an application fee or hardship exception request that meets the requirements set forth in § 424.514 with the Medicare revalidation application; or

(B) The hardship exception is not granted and the institutional provider does not submit the applicable application form or application fee within 30 days of being notified that the hardship exception request was denied.

(ii)(A) Either of the following occurs:

(*1*) CMS is not able to deposit the full application amount into a government-owned account.

(*2*) The funds are not able to be credited to the U.S. Treasury.

(B) The provider or supplier lacks sufficient funds in the account at the banking institution whose name is imprinted on the check or other banking instrument to pay the application fee; or

(C) There is any other reason why CMS or its Medicare contractor is unable to deposit the application fee into a government-owned account.

(7) *Misuse of billing number.* The provider or supplier knowingly sells to or allows another individual or entity to use its billing number. This does not include those providers or suppliers who enter into a valid reassignment of benefits as specified in § 424.80 or a change of ownership as outlined in § 489.18 of this chapter.

(8) *Abuse of billing privileges.* Abuse of billing privileges includes either of the following:

(i) The provider or supplier submits a claim or claims for services that could not have been furnished to a specific individual on the date of service. These instances include but are not limited to the following situations:

(A) Where the beneficiary is deceased.

(B) The directing physician or beneficiary is not in the state or country when services were furnished.

(C) When the equipment necessary for testing is not present where the testing is said to have occurred.

(ii) CMS determines that the provider or supplier has a pattern or practice of submitting claims that fail to meet Medicare requirements. In making this determination, CMS considers, as appropriate or applicable, the following:

(A) The percentage of submitted claims that were denied during the period under consideration.

(B) Whether the provider or supplier has any history of final adverse actions and the nature of any such actions.

(C) The type of billing non-compliance and the specific facts surrounding said non-compliance (to the extent this can be determined).

(D) Any other information regarding the provider or supplier's specific circumstances that CMS deems relevant to its determination.

(9) *Failure to report.* The provider or supplier did not comply with the reporting requirements specified in §424.516(d) or (e), §410.33(g)(2) of this chapter, or §424.57(c)(2). In determining whether a revocation under this paragraph (a)(9) is appropriate, CMS considers the following factors:

(i) Whether the data in question was reported.

(ii) If the data was reported, how belatedly.

(iii) The materiality of the data in question.

(iv) Any other information that CMS deems relevant to its determination.

(10) *Failure to document or provide CMS access to documentation.* (i) The provider or supplier did not comply with the documentation or CMS access requirements specified in §424.516(f) of this subpart.

(ii) A provider or supplier that meets the revocation criteria specified in paragraph (a)(10)(i) of this section, is subject to revocation for a period of not more than 1 year for each act of noncompliance.

(11) *Initial reserve operating funds.* CMS or its designated Medicare contractor may revoke the Medicare billing privileges of an HHA and the corresponding provider agreement if, within 30 days of a CMS or Medicare contractor request, the HHA cannot furnish supporting documentation verifying that the HHA meets the initial reserve operating funds requirement found in 42 CFR 489.28(a).

(12) *Other program termination.* (i) The provider or supplier is terminated, revoked or otherwise barred from participation in a State Medicaid program or any other federal health care program. In determining whether a revocation under this paragraph (a)(12) is appropriate, CMS considers the following factors:

(A) The reason(s) for the termination or revocation.

(B) Whether the provider or supplier is currently terminated, revoked or otherwise barred from more than one program (for example, more than one State's Medicaid program) or has been subject to any other sanctions during its participation in other programs.

(C) Any other information that CMS deems relevant to its determination.

(ii) Medicare may not revoke unless and until a provider or supplier has exhausted all applicable appeal rights or the timeframe for filing an appeal has expired without the provider or supplier filing an appeal.

(iii) CMS may apply paragraph (a)(12)(i) of this section to the provider or supplier under any of its current or former names, numerical identifiers or business identities.

(13) *Prescribing authority.* (i) A physician or other eligible professional's Drug Enforcement Administration (DEA) Certificate of Registration to dispense a controlled substance is currently suspended or revoked or is surrendered in response to an order to show cause;

(ii) The applicable licensing or administrative body for any state in which the physician or eligible professional practices suspends or revokes the physician or eligible professional's ability to prescribe drugs.

(14) *Improper prescribing practices.* CMS determines that the physician or eligible professional has a pattern or practice of prescribing Part B or D drugs that falls into one of the following categories:

(i) The pattern or practice is abusive or represents a threat to the health and safety of Medicare beneficiaries or both. In making this determination, CMS considers the following factors:

(A) Whether there are diagnoses to support the indications for which the drugs were prescribed.

(B) Whether there are instances when the necessary evaluation of the patient for whom the drug was prescribed could not have occurred (for example, the patient was deceased or out of state at the time of the alleged office visit).

(C) Whether the physician or eligible professional has prescribed controlled substances in excessive dosages that are linked to patient overdoses.

(D) The number and type(s) of disciplinary actions taken against the physician or eligible professional by the licensing body or medical board for the State or States in which he or she

practices, and the reason(s) for the action(s).

(E) Whether the physician or eligible professional has any history of ''final adverse actions'' (as that term is defined in § 424.502).

(F) The number and type(s) of malpractice suits that have been filed against the physician or eligible professional related to prescribing that have resulted in a final judgment against the physician or eligible professional or in which the physician or eligible professional has paid a settlement to the plaintiff(s) (to the extent this can be determined).

(G) Whether any State Medicaid program or any other public or private health insurance program has restricted, suspended, revoked, or terminated the physician or eligible professional's ability to prescribe medications, and the reason(s) for any such restriction, suspension, revocation, or termination.

(H) Any other relevant information provided to CMS.

(ii) The pattern or practice of prescribing fails to meet Medicare requirements. In making this determination, CMS considers the following factors:

(A) Whether the physician or eligible professional has a pattern or practice of prescribing without valid prescribing authority.

(B) Whether the physician or eligible professional has a pattern or practice of prescribing for controlled substances outside the scope of the prescriber's DEA registration.

(C) Whether the physician or eligible professional has a pattern or practice of prescribing drugs for indications that were not medically accepted—that is, for indications neither approved by the FDA nor medically accepted under section 1860D–2(e)(4) of the Act—and whether there is evidence that the physician or eligible professional acted in reckless disregard for the health and safety of the patient.

(15) *False Claims Act (FCA).* (i) The provider or supplier, or any owner, managing employee or organization, officer, or director of the provider or supplier, has had a civil judgment under the FCA (31 U.S.C. 3729 through 3733) imposed against them within the previous 10 years.

(ii) In determining whether a revocation under this paragraph is appropriate, CMS considers the following factors:

(A) The number of provider or supplier actions that the judgment incorporates (for example, the number of false claims submitted).

(B) The types of provider or supplier actions involved.

(C) The monetary amount of the judgment.

(D) When the judgment occurred.

(E) Whether the provider or supplier has any history of final adverse actions (as that term is defined in § 424.502).

(F) Any other information that CMS deems relevant to its determination.

(16) [Reserved]

(17) *Debt referred to the United States Department of Treasury.* (i) The provider or supplier failed to repay a debt that CMS appropriately referred to the United States Department of Treasury. In determining whether a revocation under this paragraph (a)(17) is appropriate, CMS considers the following factors:

(A) The reason(s) for the failure to fully repay the debt (to the extent this can be determined).

(B) Whether the provider or supplier has attempted to repay the debt (to the extent this can be determined).

(C) Whether the provider or supplier has responded to CMS' requests for payment (to the extent this can be determined).

(D) Whether the provider or supplier has any history of final adverse actions or Medicare or Medicaid payment suspensions.

(E) The amount of the debt.

(F) Any other evidence that CMS deems relevant to its determination.

(ii) Paragraph (17)(i) of this paragraph does not apply to the following situations:

(A) The provider's or supplier's Medicare debt has been discharged by a bankruptcy court; or

(B) The administrative appeals process concerning the debt has not been exhausted or the timeframe for filing such an appeal (at the appropriate level of appeal) has not expired.

(18) *Revoked under different name, numerical identifier or business identity.* The provider or supplier is currently

revoked under a different name, numerical identifier, or business identity, and the applicable reenrollment bar period has not expired. In determining whether a provider or supplier is a currently revoked provider or supplier under a different name, numerical identifier, or business identity, CMS investigates the degree of commonality by considering the following factors:

(i) Owning and managing employees and organizations (regardless of whether they have been disclosed on the Form CMS–855 application).

(ii) Geographic location.

(iii) Provider or supplier type.

(iv) Business structure.

(v) Any evidence indicating that the two parties are similar or that the provider or supplier was created to circumvent the revocation or reenrollment bar.

(19) *Affiliation that poses an undue risk.* CMS determines that the provider or supplier has or has had an affiliation under §424.519 that poses an undue risk of fraud, waste, or abuse to the Medicare program.

(20) *Billing from non-compliant location.* CMS may revoke a provider's or supplier's Medicare enrollment or enrollments, even if all of the practice locations associated with a particular enrollment comply with Medicare enrollment requirements, if the provider or supplier billed for services performed at or items furnished from a location that it knew or should have known did not comply with Medicare enrollment requirements. In determining whether and how many of the provider's or supplier's enrollments, involving the non-compliant location or other locations, should be revoked, CMS considers the following factors:

(i) The reason(s) for and the specific facts behind the location's non-compliance.

(ii) The number of additional locations involved.

(iii) Whether the provider or supplier has any history of final adverse actions or Medicare or Medicaid payment suspensions.

(iv) The degree of risk that the location's continuance poses to the Medicare Trust Funds.

(v) The length of time that the non-compliant location was non-compliant.

(vi) The amount that was billed for services performed at or items furnished from the non-compliant location.

(vii) Any other evidence that CMS deems relevant to its determination.

(21) *Abusive ordering, certifying, referring, or prescribing of Part A or B services, items or drugs.* The physician or eligible professional has a pattern or practice of ordering, certifying, referring, or prescribing Medicare Part A or B services, items, or drugs that is abusive, represents a threat to the health and safety of Medicare beneficiaries, or otherwise fails to meet Medicare requirements. In making its determination as to whether such a pattern or practice exists, CMS considers the following factors:

(i) Whether the physician's or eligible professional's diagnoses support the orders, certifications, referrals or prescriptions in question.

(ii) Whether there are instances where the necessary evaluation of the patient for whom the service, item or drug was ordered, certified, referred, or prescribed could not have occurred (for example, the patient was deceased or out of state at the time of the alleged office visit).

(iii) The number and type(s) of disciplinary actions taken against the physician or eligible professional by the licensing body or medical board for the state or states in which he or she practices, and the reason(s) for the action(s).

(iv) Whether the physician or eligible professional has any history of final adverse actions (as that term is defined in §424.502).

(v) The length of time over which the pattern or practice has continued.

(vi) How long the physician or eligible professional has been enrolled in Medicare.

(vii) The number and type(s) of malpractice suits that have been filed against the physician or eligible professional related to ordering, certifying, referring or prescribing that have resulted in a final judgment against the physician or eligible professional or in which the physician or eligible professional has paid a settlement to the plaintiff(s) (to the extent this can be determined).

(viii) Whether any State Medicaid program or any other public or private health insurance program has restricted, suspended, revoked, or terminated the physician's or eligible professional's ability to practice medicine, and the reason(s) for any such restriction, suspension, revocation, or termination.

(ix) Any other information that CMS deems relevant to its determination.

(22) *Patient harm.* (i) The physician or other eligible professional (as that term is defined in 1848(k)(3)(B) of the Act) has been subject to prior action from a State oversight board, Federal or State health care program, Independent Review Organization (IRO) determination(s), or any other equivalent governmental body or program that oversees, regulates, or administers the provision of health care with underlying facts reflecting improper physician or other eligible professional conduct that led to patient harm. In determining whether a revocation is appropriate, CMS considers the following factors:

(A) The nature of the patient harm.

(B) The nature of the physician's or other eligible professional's conduct.

(C) The number and type(s) of sanctions or disciplinary actions that have been imposed against the physician or other eligible professional by the State oversight board, IRO, Federal or State health care program, or any other equivalent governmental body or program that oversees, regulates, or administers the provision of health care. Such actions include, but are not limited to in scope or degree:

(*1*) License restriction(s) pertaining to certain procedures or practices.

(*2*) Required compliance appearances before State medical board members.

(*3*) License restriction(s) regarding the ability to treat certain types of patients (for example, cannot be alone with members of a different gender after a sexual offense charge).

(*4*) Administrative or monetary penalties.

(*5*) Formal reprimand(s).

(D) If applicable, the nature of the IRO determination(s).

(E) The number of patients impacted by the physician's or other eligible professional's conduct and the degree of harm thereto or impact upon.

(ii) Paragraph (a)(22)(i) of this section does not apply to actions or orders pertaining exclusively to either of the following:

(A) Required participation in rehabilitation or mental/behavioral health programs; or

(B) Required abstinence from drugs or alcohol and random drug testing.

(23) *Supplier standard or condition violation.* (i) The independent diagnostic testing facility is non-compliant with any provision in 42 CFR 410.33(g).

(ii) The DMEPOS supplier is non-compliant with any provision in § 424.57(c).

(iii) The opioid treatment program is non-compliant with any provision in § 424.67(b) or (e).

(iv) The home infusion therapy supplier is non-compliant with any provision in § 424.68(c) or (e).

(v) The Medicare diabetes prevention program is non-compliant with any provision in § 424.205(b) or (d).

(b) *Effect of revocation on provider agreements.* When a provider's or supplier's billing privilege is revoked, any provider agreement in effect at the time of revocation is terminated effective with the date of revocation.

(c) *Reapplying after revocation.* (1) After a provider or supplier has had their enrollment revoked, they are barred from participating in the Medicare program from the effective date of the revocation until the end of the reenrollment bar. The reenrollment bar—

(i) Begins 30 days after CMS or its contractor mails notice of the revocation and lasts a minimum of 1 year, but not greater than 10 years (except for the situations described in paragraphs (c)(2) and (3) of this section), depending on the severity of the basis for revocation.

(ii) Does not apply in the event a revocation of Medicare enrollment is imposed under paragraph (a)(1) of this section based upon a provider's or supplier's failure to respond timely to a revalidation request or other request for information.

(2)(i) CMS may add up to 3 more years to the provider's or supplier's reenrollment bar (even if such period exceeds the 10-year period identified in

paragraph (c)(1) of this section) if it determines that the provider or supplier is attempting to circumvent its existing reenrollment bar by enrolling in Medicare under a different name, numerical identifier or business identity.

(ii) A provider's or supplier's appeal rights regarding paragraph (c)(2)(i) of this section—

(A) Are governed by part 498 of this chapter; and

(B) Do not extend to the imposition of the original reenrollment bar under paragraph (c)(1) of this section; and

(C) Are limited to any additional years imposed under paragraph (c)(2)(i) of this section.

(3) CMS may impose a reenrollment bar of up to 20 years on a provider or supplier if the provider or supplier is being revoked from Medicare for the second time. In determining the length of the reenrollment bar under this paragraph (c)(3), CMS considers the following factors:

(i) The reasons for the revocations.

(ii) The length of time between the revocations.

(iii) Whether the provider or supplier has any history of final adverse actions (other than Medicare revocations) or Medicare or Medicaid payment suspensions.

(iv) Any other information that CMS deems relevant to its determination.

(4) A reenrollment bar applies to a provider or supplier under any of its current, former or future names, numerical identifiers or business identities.

(d) *Re-enrollment after revocation.* If a provider or supplier seeks to re-establish enrollment in the Medicare program after notification that its billing privileges is revoked (either after the appeals process is exhausted or in place of the appeals process), the following conditions apply:

(1) The provider or supplier must reenroll in the Medicare program through the completion and submission of a new applicable enrollment application and applicable documentation, as a new provider or supplier, for validation by CMS.

(2) Providers must be resurveyed and recertified by the State survey agency as a new provider and must establish a new provider agreement with CMS's Regional Office.

(e) *Reversal of revocation.* If the revocation was due to adverse activity (sanction, exclusion, or felony) against the provider's or supplier's owner, managing employee, managing organization, officer, director, authorized or delegated official, medical director, supervising physician, or other health care or administrative or management services personnel furnishing services payable by a Federal health care program, the revocation may be reversed if the provider or supplier terminates and submits proof that it has terminated its business relationship with that party within 15 days of the revocation notification.

(f) *Additional review.* When a provider or supplier is revoked from the Medicare program, CMS automatically reviews all other related Medicare enrollment files that the revoked provider or supplier has an association with (for example, as an owner or managing employee) to determine if the revocation warrants an adverse action of the associated Medicare provider or supplier.

(g) *Effective date of revocation.* (1) Except as described in paragraphs (g)(2) and (g)(3) of this section, a revocation becomes effective 30 days after CMS or the CMS contractor mails notice of its determination to the provider or supplier.

(2) Except as described in paragraph (g)(3) of this section, the revocation effective dates in the situations identified in this paragraph (g)(2) are as follows:

(i) For revocations based on a Federal exclusion or debarment, the date of the exclusion or debarment.

(ii) For revocations based on a felony conviction, the date of the felony conviction.

(iii) For revocations based on a State license suspension or revocation, the date of the license suspension or revocation.

(iv) For revocations based on a CMS determination that the provider's or supplier's practice location is nonoperational, the date on which the provider's or supplier's practice location was no longer operational (per CMS' or the CMS contractor's determination).

(v) For revocations based on a State license surrender in lieu of further disciplinary action, the date of the license surrender.

(vi) For revocations based on termination from a Federal health care program other than Medicare (for example, Medicaid), the date of the termination.

(vii) For revocations based on termination of a provider agreement under part 489 of this chapter, and as applicable to the type of provider involved, the later of the following:

(A) The date of the provider agreement termination; or

(B) The date that CMS establishes under § 489.55.

(viii) For revocations based on § 424.535(a)(23), the effective dates are as follows:

(A) If the standard or condition violation involves the suspension, revocation, or termination (or surrender in lieu of further disciplinary action) of the provider's or supplier's Federal or State license, certification, accreditation, or MDPP recognition, the effective date is the date of the license, certification, accreditation, or MDPP recognition suspension, revocation, termination, or surrender.

(B) If the standard or condition violation involves a non-operational practice location, the effective date is the date the non-operational status began.

(C) If the standard violation involves a felony conviction of an individual or entity described in § 424.67(b)(6)(i), the effective date is the date of the felony conviction.

(D) For all standard violations not addressed in paragraphs (A) through (C), the effective date in paragraph (g)(1) applies if the effective date in paragraph (g)(3) does not.

(3) If the action that resulted in the revocation occurred prior to the effective date of the provider's or supplier's enrollment, the effective date of the revocation is the same as the effective date of enrollment.

(h) *Submission of claims for services furnished before revocation.* (1)(i) Except for HHAs as described in paragraph (h)(1)(ii) of this section, a revoked provider or supplier must, within 60 calendar days after the effective date of revocation, submit all claims for items and services furnished before the date of the revocation letter.

(ii) A revoked HHA must submit all claims for items and services within 60 days after the later of the following:

(A) The effective date of the revocation.

(B) The date that the HHA's last payable episode ends.

(2) Nothing in this paragraph (h) impacts the requirements of § 424.44 regarding the timely filing of claims.

(i) *Extension of revocation.* (1) If a provider's or supplier's Medicare enrollment is revoked under paragraph (a) of this section, CMS may revoke any and all of the provider's or supplier's Medicare enrollments, including those under different names, numerical identifiers or business identities and those under different types.

(2) In determining whether to revoke a provider's or supplier's other enrollments under this paragraph (i), CMS considers the following factors:

(i) The reason for the revocation and the facts of the case.

(ii) Whether any final adverse actions have been imposed against the provider or supplier regarding its other enrollments.

(iii) The number and type(s) of other enrollments.

(iv) Any other information that CMS deems relevant to its determination.

(j) *Voluntary termination.* (1) CMS may revoke a provider's or supplier's Medicare enrollment if CMS determines that the provider or supplier voluntarily terminated its Medicare enrollment in order to avoid a revocation under paragraph (a) of this section that CMS would have imposed had the provider or supplier remained enrolled in Medicare. In making its determination, CMS considers the following factors:

(i) Whether there is evidence to suggest that the provider knew or should have known that it was or would be out of compliance with Medicare requirements.

(ii) Whether there is evidence to suggest that the provider knew or should have known that its Medicare enrollment would be revoked.

(iii) Whether there is evidence to suggest that the provider voluntarily terminated its Medicare enrollment in order to circumvent such revocation.

(iv) Any other evidence or information that CMS deems relevant to its determination.

(2) A revocation under paragraph (j)(1) of this section is effective the day before the Medicare contractor receives the provider's or supplier's Form CMS–855 voluntary termination application.

[71 FR 20776, Apr. 21, 2006, as amended at 72 FR 53648, Sept. 19, 2007; 73 FR 36461, June 27, 2008; 73 FR 69940, Nov. 19, 2008; 75 FR 24449, May 5, 2010; 75 FR 70465, Nov. 17, 2010; 76 FR 5964, Feb. 2, 2011; 77 FR 25318, Apr. 27, 2012; 77 FR 29030, May 16, 2012; 79 FR 29968, May 23, 2014; 79 FR 72532, Dec. 5, 2014; 84 FR 47854, Sept. 10, 2019; 84 FR 63204, Nov. 15, 2019; 86 FR 65682, Nov. 19, 2021; 87 FR 70232, Nov. 18, 2022; 88 FR 79541, Nov. 16, 2023]

§ 424.540 Deactivation of Medicare billing privileges.

(a) *Reasons for deactivation.* CMS may deactivate the Medicare billing privileges of a provider or supplier for any of the following reasons:

(1) The provider or supplier does not submit any Medicare claims for 6 consecutive calendar months. The 6 month period will begin the 1st day of the 1st month without a claims submission through the last day of the 6th month without a submitted claim.

(2) The provider or supplier does not report a change to the information supplied on the enrollment application within the applicable time period required under this title.

(3) The provider or supplier does not furnish complete and accurate information and all supporting documentation within 90 calendar days of receipt of notification from CMS to submit an enrollment application and supporting documentation, or resubmit and certify to the accuracy of its enrollment information.

(4) The provider or supplier is not in compliance with all enrollment requirements in this title.

(5) The provider's or supplier's practice location is non-operational or otherwise invalid.

(6) The provider or supplier is deceased.

(7) The provider or supplier is voluntarily withdrawing from Medicare.

(8) The provider is the seller in an HHA change of ownership under § 424.550(b)(1).

(b) *Reactivation of billing privileges.*

(1) In order for a deactivated provider or supplier to reactivate its Medicare billing privileges, the provider or supplier must recertify that its enrollment information currently on file with Medicare is correct, furnish any missing information as appropriate, and be in compliance with all applicable enrollment requirements in this title.

(2) Notwithstanding paragraph (b)(1) of this section, CMS may, for any reason, require a deactivated provider or supplier to, as a prerequisite for reactivating its billing privileges, submit a complete Form CMS–855 application.

(3) Except as provided in paragraph (b)(3)(i) of this section, reactivation of Medicare billing privileges does not require a new certification of the provider or supplier by the State survey agency or the establishment of a new provider agreement.

(i) An HHA whose Medicare billing privileges are deactivated under the provisions found at paragraph (a) of this section must obtain an initial State survey or accreditation by an approved accreditation organization before its Medicare billing privileges can be reactivated.

(ii) [Reserved]

(c) *Effect of deactivation.* The deactivation of Medicare billing privileges does not have any effect on a provider's or supplier's participation agreement or any conditions of participation.

(d) *Effective dates.* (1)(i) Except as provided in paragraph (d)(1)(ii) of this section, the effective date of a deactivation is the date on which the deactivation is imposed under this section.

(ii) A retroactive deactivation effective date (based on the date that the provider's or supplier's action or noncompliance occurred or commenced (as applicable)) may be imposed in the following instances:

(A) For the deactivation reasons in paragraphs (a)(2) through (4) of this section, the effective date is the date on which the provider or supplier became non-compliant.

(B) For the deactivation reason in paragraph (a)(5) of this section, the effective date is the date on which the provider's or supplier's practice location became non-operational or otherwise invalid.

(C) For the deactivation reason in paragraph (a)(6) of this section, the effective date is the date of death of the provider or supplier.

(D) For the deactivation reason in paragraph (a)(7) of this section, the effective date is the date on which the provider or supplier voluntarily withdrew from Medicare.

(E) For the deactivation reason in paragraph (a)(8) of this section, the effective date is the date of the sale.

(2) The effective date of a reactivation of billing privileges under this section is the date on which the Medicare contractor received the provider's or supplier's reactivation submission that was processed to approval by the Medicare contractor.

(e) *Payment prohibition.* A provider or supplier may not receive payment for services or items furnished while deactivated under this section.

[71 FR 20776, Apr. 21, 2006, as amended at 74 FR 58134, Nov. 10, 2009; 77 FR 29030, May 16, 2012; 84 FR 47856, Sept. 10, 2019; 86 FR 62420, Nov. 9, 2021; 88 FR 77878, Nov. 13, 2023]

§ 424.541 Stay of enrollment.

(a)(1) CMS may stay an enrolled provider's or supplier's enrollment if the provider or supplier:

(i) Is non-compliant with at least one enrollment requirement in Title 42; and.

(ii) Can remedy the non-compliance via the submission of, as applicable to the situation, a Form CMS–855, Form CMS–20134, or Form CMS–588 change of information or revalidation application.

(2) During the period of any stay imposed under this section, the following apply:

(i) The provider or supplier remains enrolled in Medicare;

(ii)(A) Except as stated in paragraph (a)(2)(ii)(B) of this section, claims submitted by the provider or supplier with dates of service within the stay period will be rejected.

(B) Notwithstanding paragraph (a)(2)(ii)(A), claims submitted by the provider or supplier with dates of service within the stay period are eligible for payment (and may be resubmitted by the provider or supplier within applicable timeframes specified in Title 42) if:

(*1*) CMS or its contractor determines that the provider or supplier has resumed compliance with all Medicare enrollment requirements in Title 42; and

(*2*) The stay ends (as described in subsection (a)(5) of this section) on or before the 60th day of the stay period.

(3) A stay of enrollment lasts no longer than 60 days from the postmark date of the notification letter, which is the effective date of the stay.

(4) CMS notifies the affected provider or supplier in writing of the imposition of the stay.

(5) A stay of enrollment ends on the date on which CMS or its contractor determines that the provider or supplier has resumed compliance with all Medicare enrollment requirements in Title 42 or the day after the 60-day stay period expires, whichever occurs first.

(b)(1) If a provider or supplier receives written notice from CMS or its contractor that the provider or supplier is subject to a stay under this section, the provider or supplier has 15 calendar days from the date of the written notice to submit a rebuttal to the stay as described in paragraph (b) of this section.

(2) CMS may, at its discretion, extend the 15-day time-period referenced in paragraph (b)(1) of this section.

(3) Any rebuttal submitted pursuant to paragraph (b) of this section must:

(i) Be in writing.

(ii) Specify the facts or issues about which the provider or supplier disagrees with the stay's imposition and/or the effective date, and the reasons for disagreement.

(iii) Submit all documentation the provider or supplier wants CMS to consider in its review of the stay.

(iv) Be submitted in the form of a letter that is signed and dated by the individual supplier (if enrolled as an individual physician or nonphysician practitioner), the authorized official or delegated official (as those terms are defined in § 424.502), or a legal representative (as defined in 42 CFR 498.10). If the legal representative is an attorney, the attorney must include a statement that he or she has the authority to represent the provider or supplier; this statement is sufficient to constitute notice of such authority. If the legal

representative is not an attorney, the provider or supplier must file with CMS written notice of the appointment of a representative; this notice of appointment must be signed and dated by, as applicable, the individual supplier, the authorized official or delegated official, or a legal representative.

(4) The provider's or supplier's failure to submit a rebuttal that is both timely under paragraph (b)(1) of this section and fully compliant with all of the requirements of paragraph (b)(3) of this section constitutes a waiver of all rebuttal rights under this section.

(5) Upon receipt of a timely and compliant stay rebuttal, CMS reviews the rebuttal to determine whether the imposition of the stay and/or the effective date thereof are correct.

(6) A determination made under paragraph (b) of this section is not an initial determination under 42 CFR 498.3(b) and therefore not appealable.

(7) Nothing in paragraph (b) of this section requires CMS to delay the imposition of a stay pending the completion of the review described in paragraph (b)(5) of this section.

(8)(i) Nothing in paragraph (b) of this section requires CMS to delay the imposition of a deactivation or revocation, pending the completion of the review described in paragraph (b)(5) of this section.

(ii)(A) If CMS deactivates the provider or supplier during the stay, any rebuttal to the stay that the provider or supplier submits that meets the requirements of paragraph (b) of this section is combined and considered with the provider's or supplier's rebuttal to the deactivation under § 424.546 if CMS has not yet made a determination on the stay rebuttal pursuant to this section.

(B) In all cases other than that described in paragraph (b)(8)(ii)(A) of this section, a stay rebuttal that was submitted in compliance with the requirements of paragraph (b) of this section is considered separately and independently of any review of any other rebuttal or, for revocations, appeal under 42 CFR part 498.

[88 FR 79542, Nov. 16, 2023, as amended at 89 FR 9784, Feb. 12, 2024]

§ 424.542 Prohibition on ordering, certifying, referring, or prescribing based on felony conviction.

(a) *General prohibition.* A physician or other eligible professional (regardless of whether he or she is or was enrolled in Medicare) who has had a felony conviction within the previous 10 years that CMS determines is detrimental to the best interests of the Medicare program and its beneficiaries may not order, refer, certify, or prescribe Medicare-covered services, items, or drugs.

(b) *Payment.* Medicare does not pay for any otherwise covered service, item, or drug that is ordered, referred, certified, or prescribed by a physician or other eligible professional (as that term is defined in section 1848(k)(3)(B) of the Act) who has had a felony conviction within the previous 10 years that CMS determines is detrimental to the best interests of the Medicare program and its beneficiaries.

[88 FR 77878, Nov. 13, 2023]

§ 424.545 Provider and supplier appeal rights.

(a) *General.* A prospective provider or supplier that is denied enrollment in the Medicare program, or a provider or supplier whose Medicare enrollment has been revoked may appeal CMS' decision in accordance with part 498, subpart A of this chapter.

(1) *Appeals resulting in the termination of a provider agreement.* (i) When revocation of billing privileges also results in the termination of a corresponding provider agreement, the provider may appeal CMS' decision in accordance with part 498 of this chapter with the final decision of the appeal applying to both the billing privileges and the provider agreement.

(ii) When a provider appeals the revocation of billing privileges and the termination of its provider agreement, there will be one appeals process which will address both matters. The appeal procedures for revocation of Medicare billing privileges will apply.

(2) *Payment of unpaid claims.* Payment is not made during the appeals process. If the provider or supplier is successful in overturning a denial or revocation, unpaid claims for services furnished during the overturned period may be resubmitted.

(b) A provider or supplier whose billing privileges are deactivated may file a rebuttal in accordance with § 424.546 of this chapter.

(c) The provider or supplier must be able to demonstrate that it meets the enrollment requirements and it must be able to make available any documents and records that support the provisions of this regulation and the Medicare enrollment application if requested by CMS or its agents.

[71 FR 20776, Apr. 21, 2006, as amended at 73 FR 36461, June 27, 2008; 86 FR 65683, Nov. 19, 2021]

§ 424.546 Deactivation rebuttals.

(a) *Rebuttal submittal period.* (1) If a provider or supplier receives written notice from CMS or its contractor that the provider's or supplier's billing privileges are to be or have been deactivated under § 424.540, the provider or supplier has 15 calendar days from the date of the written notice to submit a rebuttal to CMS as permitted under § 424.545(b).

(2) CMS may, at its discretion, extend the 15-day time-period referenced in paragraph (a)(1) of this section.

(b) *Rebuttal requirements.* A rebuttal submitted pursuant to this section and § 424.545(b) must:

(1) Be in writing.

(2) Specify the facts or issues about which the provider or supplier disagrees with the deactivation's imposition and/or the effective date, and the reasons for disagreement.

(3) Submit all documentation the provider or supplier wants CMS to consider in its review of the deactivation.

(4) Be submitted in the form of a letter that is signed and dated by the individual supplier (if enrolled as an individual physician or nonphysician practitioner), the authorized official or delegated official (as those terms are defined in 42 CFR 424.502), or a legal representative (as defined in 42 CFR 498.10). If the legal representative is an attorney, the attorney must include a statement that he or she has the authority to represent the provider or supplier; this statement is sufficient to constitute notice of such authority. If the legal representative is not an attorney, the provider or supplier must file with CMS written notice of the appointment of a representative; this notice of appointment must be signed and dated by, as applicable, the individual supplier, the authorized official or delegated official, or a legal representative.

(c) *Waiver of rebuttal rights.* The provider's or supplier's failure to submit a rebuttal that is both timely under paragraph (a) of this section and fully compliant with all of the requirements of paragraph (b) of this section constitutes a waiver of all rebuttal rights under this section and § 424.545(b).

(d) *CMS review.* Upon receipt of a timely and compliant deactivation rebuttal, CMS reviews the rebuttal to determine whether the imposition of the deactivation and/or the designated effective date are correct.

(e) *Imposition.* Nothing in this section or in § 424.545(b) requires CMS to delay the imposition of a deactivation pending the completion of the review described in paragraph (d) of this section.

(f) *Initial determination.* A determination made under this section is not an initial determination under § 498.3(b) of this chapter and therefore not appealable.

[86 FR 65683, Nov. 19, 2021]

§ 424.550 Prohibitions on the sale or transfer of billing privileges.

(a) *General rule.* A provider or supplier is prohibited from selling its Medicare billing number or privileges to any individual or entity, or allowing another individual or entity to use its Medicare billing number.

(b) *Change of ownership.* In the case of a provider undergoing a change of ownership in accordance with part 489, subpart A of this chapter, the current owner and the prospective new owner must complete and submit enrollment applications before completion of the change of ownership. If the current owner fails to complete and submit an enrollment application to report the change, the current owner may be sanctioned or penalized, even after the date of ownership change, in accordance with §§ 424.520, 424.540, and 489.53 of this chapter. If the prospective new owner fails to submit a new enrollment application containing information concerning the new owner within 30 days of the change of ownership, CMS

may deactivate the Medicare billing number. If an incomplete enrollment application is submitted, CMS may also deactivate the Medicare billing number based upon material omissions on the submitted enrollment application, or based on preliminary information received or determined by CMS that makes CMS question whether the new owner is ultimately granted a final transference of the provider agreement.

(1) Unless an exception in paragraph (b)(2) of this section applies, if there is a change in majority ownership of a home health agency (HHA) or hospice by sale (including asset sales, stock transfers, mergers, and consolidations) within 36 months after the effective date of the HHA's or hospice's initial enrollment in Medicare or within 36 months after the HHA's or hospice's most recent change in majority ownership, the provider agreement and Medicare billing privileges do not convey to the new owner. The prospective provider/owner of the HHA or hospice must instead do both of the following:

(i) Enroll in the Medicare program as a new (initial) HHA or hospice under the provisions of §424.510 of this subpart.

(ii) Obtain a State survey or an accreditation from an approved accreditation organization.

(2)(i) The HHA or hospice submitted 2 consecutive years of full cost reports since initial enrollment or the last change in majority ownership, whichever is later. For purposes of the exception in this paragraph (b)(2)(i), low utilization or no utilization cost reports do not qualify as full cost reports.

(ii) An HHA's or hospice's parent company is undergoing an internal corporate restructuring, such as a merger or consolidation.

(iii) The owners of an existing HHA or hospice are changing the HHA's or hospice's existing business structure (for example, from a corporation to a partnership (general or limited); from an LLC to a corporation; from a partnership (general or limited) to an LLC) and the owners remain the same.

(iv) An individual owner of an HHA or hospice dies.

(c) *Suppliers not covered by part 489 of this chapter.* For those suppliers not covered by part 489 of this chapter, any change in the ownership or control of that supplier must be reported on the enrollment application within 30 days of the change as noted in §424.540(a)(2). Generally, a change of ownership that also changes the tax identification number requires the completion and submission of a new enrollment application from the new owner.

[71 FR 20776, Apr. 21, 2006, as amended at 74 FR 58134, Nov. 10, 2009; 75 FR 70465, Nov. 17, 2010; 75 FR 76293, Dec. 8, 2010; 86 FR 62421, Nov. 9, 2021; 88 FR 77878, Nov. 13, 2023]

§424.555 Payment liability.

(a) No payment may be made for otherwise Medicare covered items or services furnished to a Medicare beneficiary by suppliers of durable medical equipment, prosthetics, orthotics, and other supplies unless the supplier obtains (and renews, as set forth in section 1834(j) of the Act) Medicare billing privileges.

(b) No payment may be made for otherwise Medicare covered items or services furnished to a Medicare beneficiary by a provider or supplier if the billing privileges of the provider or supplier are deactivated, denied, or revoked, or if the provider or supplier is currently under a stay of enrollment (except as stated in §424.541(a)(2)(ii)(B)). The Medicare beneficiary has no financial responsibility for expenses, and the provider or supplier must refund on a timely basis to the Medicare beneficiary any amounts collected from the Medicare beneficiary for these otherwise Medicare covered items or services.

(c) If any provider or supplier furnishes an otherwise Medicare covered item or service for which payment may not be made by reason of paragraph (b) of this section, any expense incurred for such otherwise Medicare covered item or service shall be the responsibility of the provider or supplier. The provider or supplier may also be criminally liable for pursuing payments that may not be made by reason of paragraph (b) of this section, in accordance with section 1128B(a)(3) of the Act.

[71 FR 20776, Apr. 21, 2006, as amended at 88 FR 79543, Nov. 16, 2023]

§ 424.565 Overpayment.

A physician or nonphysician practitioner organization, physician or nonphysician practitioner that does not comply with the reporting requirements specified in § 424.516(d)(1)(ii) and (iii) of this subpart is assessed an overpayment back to the date of the final adverse action or change in practice location. Overpayments are processed in accordance with part 405 subpart C of this chapter.

[73 FR 69941, Nov. 19, 2008]

§ 424.570 Moratoria on newly enrolling Medicare providers and suppliers.

(a) *Temporary moratoria*—(1) *General rules.* (i) CMS may impose a moratorium on the enrollment of new Medicare providers and suppliers of a particular type or the establishment of new practice locations of a particular type in a particular geographic area.

(ii) CMS will announce the temporary enrollment moratorium in a FEDERAL REGISTER document that includes the rationale for imposition of the temporary enrollment moratorium.

(iii) The temporary moratorium does not apply to any of the following:

(A) Changes in practice location (except if the location is changing from a location outside the moratorium area to a location inside the moratorium area).

(B) Changes in provider or supplier information, such as phone numbers.

(C) Changes in ownership (except changes in ownership of home health agencies that would require an initial enrollment).

(iv) A temporary moratorium does not apply to any enrollment application that has been received by the Medicare contractor prior to the date the moratorium is imposed.

(2) *Imposition of a temporary moratoria.* CMS may impose the temporary moratorium if—

(i) CMS determines that there is a significant potential for fraud, waste or abuse with respect to a particular provider or supplier type or particular geographic area or both. CMS's determination is based on its review of existing data, and without limitation, identifies a trend that appears to be associated with a high risk of fraud, waste or abuse, such as a—

(A) Highly disproportionate number of providers or suppliers in a category relative to the number of beneficiaries; or

(B) Rapid increase in enrollment applications within a category;

(ii) A State Medicaid program has imposed a moratorium on a group of Medicaid providers or suppliers that are also eligible to enroll in the Medicare program;

(iii) A State has imposed a moratorium on enrollment in a particular geographic area or on a particular provider or supplier type or both; or

(iv) CMS, in consultation the HHS OIG or the Department of Justice or both and with the approval of the CMS Administrator identifies either or both of the following as having a significant potential for fraud, waste or abuse in the Medicare program:

(A) A particular provider or supplier type.

(B) Any particular geographic area.

(b) *Duration of moratoria.* A moratorium under this section may be imposed for a period of 6 months and, if deemed necessary by CMS, may be extended in 6-month increments. CMS will publish a document in the FEDERAL REGISTER when it extends a moratorium.

(c) *Denial of enrollment: Moratoria.* A Medicare contractor denies the enrollment application of a provider or supplier if the provider or supplier is subject to a moratorium as specified in paragraph (a) of this section.

(d) *Lifting moratoria.* CMS will publish a document in the FEDERAL REGISTER when a moratorium is lifted. CMS may lift a temporary moratorium at any time after imposition of the moratorium if one of the following occur:

(1) The President declares an area a disaster under the Robert T. Stafford Disaster Relief and Emergency Assistance Act, 42 U.S.C. 5121–5206 (Stafford Act).

(2) Circumstances warranting the imposition of a moratorium have abated or CMS has implemented program safeguards to address the program vulnerability.

(3) The Secretary has declared a public health emergency under section 319

of the Public Health Service Act in the area subject to a temporary moratorium.

(4) In the judgment of the Secretary, the moratorium is no longer needed.

[76 FR 5965, Feb. 2, 2011, as amended at 84 FR 47856, Sept. 10, 2019]

§ 424.575 Rural emergency hospitals.

(a) A rural emergency hospital (as defined in § 485.502 of this chapter) must comply with all applicable provisions in this subpart in order to enroll and maintain enrollment in Medicare.

(b) A provider that was enrolled in Medicare as of December 27, 2020, as a critical access hospital or a hospital (as defined in section 1886(d)(1)(B) of the Social Security Act) with not more than 50 beds located in a county (or equivalent unit of local government) in a rural area (as defined in section 1886(d)(2)(D) of the Social Security Act) (or treated as being located in a rural area pursuant to section 1886(d)(8)(E) of the Social Security Act) converts its existing enrollment to that of a rural emergency hospital (as defined in § 485.502 of this chapter) via a Form CMS–855A change of information application per § 424.516 rather than a Form CMS–855A initial enrollment application.

[87 FR 72293, Nov. 23, 2022]

PART 425—MEDICARE SHARED SAVINGS PROGRAM

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SOURCE: 76 FR 67973, Nov. 2, 2011, unless otherwise noted.

Subpart A—General Provisions

§ 425.10 Basis and scope.

(a) *Basis.* This part implements section 1899 of the Act by establishing a shared savings program that promotes accountability for a patient population, coordinates items and services under Medicare parts A and B, and encourages investment in infrastructure and redesigned care processes for high quality and efficient services. The regulations under this part must not be construed to affect the payment, coverage, program integrity, and other requirements that apply to providers and suppliers under FFS Medicare, except as permitted under section 1899(f) of the Act.

(b) *Scope.* This part sets forth the following:

(1) The eligibility requirements for an ACO to participate in the Medicare Shared Savings Program (Shared Savings Program).

(2) Application procedures and provisions of the participation agreement.

(3) Program requirements and beneficiary protections.

(4) The method for assigning Medicare fee-for-service beneficiaries to ACOs.

(5) Quality performance standards, reporting requirements, and data sharing.

(6) Payment criteria and methodologies (one-sided model and two-sided models).

(7) Compliance monitoring and sanctions for noncompliance.

(8) Reconsideration review process.

[76 FR 67973, Nov. 2, 2011, as amended at 80 FR 32833, June 9, 2015]

§ 425.20 Definitions.

As used in this part, unless otherwise indicated—

Accountable care organization (ACO) means a legal entity that is recognized and authorized under applicable State, Federal, or Tribal law, is identified by a Taxpayer Identification Number (TIN), and is formed by one or more ACO participants(s) that is(are) defined at § 425.102(a) and may also include any other ACO participants described at § 425.102(b).

ACO participant means an entity identified by a Medicare-enrolled billing TIN through which one or more ACO providers/suppliers bill Medicare, that alone or together with one or more other ACO participants compose an ACO, and that is included on the list of ACO participants that is required under § 425.118.

ACO participant agreement means the written agreement (as required at § 425.116) between the ACO and ACO participant in which the ACO participant agrees to participate in, and comply with, the requirements of the Shared Savings Program.

ACO professional means an individual who is Medicare-enrolled and bills for items and services furnished to Medicare fee-for-service beneficiaries under a Medicare billing number assigned to the TIN of an ACO participant in accordance with applicable Medicare regulations and who is either of the following:

(1) A physician legally authorized to practice medicine and surgery by the State in which he or she performs such function or action.

(2) A practitioner who is one of the following:

(i) A physician assistant (as defined at § 410.74(a)(2) of this chapter).

(ii) A nurse practitioner (as defined at § 410.75(b) of this chapter).

(iii) A clinical nurse specialist (as defined at § 410.76(b) of this chapter).

ACO provider/supplier means an individual or entity that meets all of the following:

(1) Is a—

(i) Provider (as defined at § 400.202 of this chapter); or

(ii) Supplier (as defined at § 400.202 of this chapter).

(2) Is enrolled in Medicare.

(3) Bills for items and services furnished to Medicare fee-for-service beneficiaries during the agreement period under a Medicare billing number assigned to the TIN of an ACO participant in accordance with applicable Medicare regulations.

(4) Is included on the list of ACO providers/suppliers that is required under § 425.118.

ACO's regional service area means all counties where one or more beneficiaries assigned to the ACO reside.

Agreement period means the term of the participation agreement.

Antitrust Agency means the Department of Justice or Federal Trade Commission.

Assignable beneficiary means a Medicare fee-for-service beneficiary who receives at least one primary care service with a date of service during a specified 12-month assignment window from a Medicare-enrolled physician who is a primary care physician or who has one of the specialty designations included in § 425.402(c). For performance year 2025 and subsequent performance years, a Medicare fee-for-service beneficiary who does not meet this requirement but who meets both of the following criteria will also be considered an assignable beneficiary—

(1) Receives at least one primary care service with a date of service during a specified 24-month expanded window for assignment from a Medicare-enrolled physician who is a primary care physician or who has one of the specialty designations included in § 425.402(c).

(2) Receives at least one primary care service with a date of service during a specified 12-month assignment window from a Medicare-enrolled practitioner who is one of the following:

(i) A physician assistant (as defined at § 410.74(a)(2) of this chapter).

(ii) A nurse practitioner (as defined at § 410.75(b) of this chapter).

(iii) A clinical nurse specialist (as defined at § 410.76(b) of this chapter).

Assignment means the operational process by which CMS determines whether a beneficiary has chosen to receive a sufficient level of the requisite primary care services from ACO professionals so that the ACO may be appropriately designated as exercising basic responsibility for that beneficiary's care during a given benchmark or performance year.

Assignment window means the 12-month period used to assign beneficiaries to an ACO, or to identify assignable beneficiaries, or both.

At-risk beneficiary means, but is not limited to, a beneficiary who—

(1) Has a high risk score on the CMS–HCC risk adjustment model;

(2) Is considered high cost due to having two or more hospitalizations or emergency room visits each year;

(3) Is dually eligible for Medicare and Medicaid;

(4) Has a high utilization pattern;

(5) Has one or more chronic conditions;

(6) Has had a recent diagnosis that is expected to result in increased cost;

(7) Is entitled to Medicare because of disability; or

(8) Is diagnosed with a mental health or substance abuse disorder.

Beneficiary eligible for Medicare CQMs means a beneficiary identified for purposes of reporting Medicare CQMs for ACOs participating in the Medicare Shared Savings Program (Medicare CQMs), who is either of the following:

(1) A Medicare fee-for-service beneficiary (as defined at § 425.20) who –

(i) Meets the criteria for a beneficiary to be assigned to an ACO described at § 425.401(a); and

(ii) Had at least one claim with a date of service during the measurement period from an ACO professional who is a primary care physician or who has one of the specialty designations included in § 425.402(c), or who is a physician assistant, nurse practitioner, or clinical nurse specialist.

(2) A Medicare fee-for-service beneficiary who is assigned to an ACO in accordance with § 425.402(e) because the beneficiary designated an ACO professional participating in an ACO as responsible for coordinating their overall care.

BY stands for benchmark year.

Certified Electronic Health Record Technology (CEHRT) has the same meaning given this term under § 414.1305 of this chapter.

Continuously assigned beneficiary means a beneficiary assigned to the ACO in the current performance year who was either assigned to or received a primary care service from any of the ACO participants during the assignment window for the most recent prior benchmark or performance year.

Covered professional services has the same meaning given these terms under section 1848(k)(3)(A) of the Act.

Critical access hospital (CAH) has the same meaning given this term under § 400.202 of this chapter.

Eligible clinician has the same meaning given this term under § 414.1305 of this chapter.

Eligible professional has the meanings given this term under section 1848(k)(3)(B) of the Act.

Expanded window for assignment means the 24-month period used to assign beneficiaries to an ACO, or to identify assignable beneficiaries, or both that includes the applicable 12-month assignment window and the preceding 12 months.

Experienced with performance-based risk Medicare ACO initiatives means an ACO that CMS determines meets the criteria in either paragraph (1) or (2) of this definition.

(1) The ACO is the same legal entity as a current or previous ACO that is participating in, or has participated in, a performance-based risk Medicare ACO initiative as defined under this section, or that deferred its entry into a second Shared Savings Program agreement period under a two-sided model under § 425.200(e).

(2) Forty percent or more of the ACO's ACO participants participated in a performance-based risk Medicare ACO initiative, or in an ACO that deferred its entry into a second Shared Savings Program agreement period under a two-sided model under § 425.200(e), in any of the 5 most recent performance years. An ACO participant is considered to have participated in a performance-based risk Medicare ACO initiative if the ACO participant TIN was or will be included in financial reconciliation for one or more performance years under such initiative during any of the 5 most recent performance years.

Federally qualified health center (FQHC) has the same meaning given to this term under § 405.2401(b) of this chapter.

High revenue ACO means an ACO whose total Medicare Parts A and B fee-for-service revenue of its ACO participants based on revenue for the most recent calendar year for which 12 months of data are available, is at least 35 percent of the total Medicare Parts A and B fee-for-service expenditures for the ACO's assigned beneficiaries based on expenditures for the most recent calendar year for which 12 months of data are available.

Hospital means a hospital as defined in section 1886(d)(1)(B) of the Act.

Inexperienced with performance-based risk Medicare ACO initiatives means an ACO that CMS determines meets all of the following:

(1) The ACO is a legal entity that has not participated in any performance-based risk Medicare ACO initiative as defined under this section, and has not deferred its entry into a second Shared Savings Program agreement period under a two-sided model under § 425.200(e).

(2) Less than 40 percent of the ACO's ACO participants participated in a performance-based risk Medicare ACO initiative, or in an ACO that deferred its entry into a second Shared Savings Program agreement period under a two-sided model under § 425.200(e), in each of the 5 most recent performance years. An ACO participant is considered to have participated in a performance-based risk Medicare ACO initiative if the ACO participant TIN was or will be included in financial reconciliation for one or more performance years under such initiative during any of the 5 most recent performance years.

Low revenue ACO means an ACO whose total Medicare Parts A and B fee-for-service revenue of its ACO participants based on revenue for the most recent calendar year for which 12 months of data are available, is less than 35 percent of the total Medicare Parts A and B fee-for-service expenditures for the ACO's assigned beneficiaries based on expenditures for the most recent calendar year for which 12 months of data are available.

Marketing materials and activities include, but are not limited to, general audience materials such as brochures, advertisements, outreach events, letters to beneficiaries, Web pages, data sharing opt out letters, mailings, social media, or other activities conducted by or on behalf of the ACO, or by ACO participants, or ACO providers/suppliers participating in the ACO, when used to

educate, solicit, notify, or contact Medicare beneficiaries or providers and suppliers regarding the Shared Savings Program. The following beneficiary communications are not marketing materials and activities: Certain informational materials customized or limited to a subset of beneficiaries; materials that do not include information about the ACO, its ACO participants, or its ACO providers/suppliers; materials that cover beneficiary-specific billing and claims issues or other specific individual health related issues; educational information on specific medical conditions (for example, flu shot reminders), written referrals for health care items and services, and materials or activities that do not constitute ''marketing'' under 45 CFR 164.501 and 164.508(a)(3)(i).

Medicare fee-for-service beneficiary means an individual who is—

(1) Enrolled in the original Medicare fee-for-service program under both parts A and B; and

(2) Not enrolled in any of the following:

(i) A MA plan under part C.

(ii) An eligible organization under section 1876 of the Act.

(iii) A PACE program under section 1894 of the Act.

Medicare Shared Savings Program (Shared Savings Program) means the program, established under section 1899 of the Act and implemented in this part.

Newly assigned beneficiary means a beneficiary that is assigned to the ACO in the current performance year who was neither assigned to nor received a primary care service from any of the ACO participants during the assignment window for the most recent prior benchmark or performance year.

One-sided model means a model under which the ACO may share savings with the Medicare program, if it meets the requirements for doing so, but is not liable for sharing any losses incurred under subpart G of this part.

Participation agreement means the written agreement required under § 425.208(a) between the ACO and CMS that, along with the regulations in this part, govern the ACO's participation in the Shared Savings Program.

Performance-based risk Medicare ACO initiative means, for purposes of this part, an initiative implemented by CMS that requires an ACO to participate under a two-sided model during its agreement period, including the following options and initiatives:

(1) Participation options within the Shared Savings Program as follows:

(i) For performance years beginning prior to January 1, 2023, BASIC track (Levels A through E).

(ii) For performance years beginning January 1, 2023 and in subsequent years, BASIC track (Levels C through E).

(iii) ENHANCED track.

(iv) Track 2.

(2) The Innovation Center ACO models under which an ACO accepts risk for shared losses as follows:

(i) Pioneer ACO Model.

(ii) Next Generation ACO Model.

(iii) Comprehensive ESRD Care Model two-sided risk tracks.

(iv) Track 1+ Model.

(3) Other initiatives involving two-sided risk as may be specified by CMS.

Performance year means the 12-month period beginning on January 1 of each year during the agreement period, unless otherwise specified in § 425.200(c) or noted in the participation agreement.

Physician means a doctor of medicine or osteopathy (as defined in section 1861(r)(1) of the Act).

Physician Quality Reporting System (PQRS) means the quality reporting system established under section 1848(k) of the Act.

Primary care physician means:

(1) For performance years 2012 through 2015, a physician included in an attestation by the ACO as provided under § 425.404 for services furnished in an FQHC or RHC, or a physician who has a primary care specialty designation of internal medicine, general practice, family practice, or geriatric medicine;

(2) For performance years 2016 through 2018, a physician included in an attestation by the ACO as provided under § 425.404 for services furnished in an FQHC or RHC, or a physician who has a primary care specialty designation of internal medicine, general practice, family practice, geriatric medicine, or pediatric medicine; and

(3) For performance year 2019 and subsequent years, a physician who has a primary care specialty designation of internal medicine, general practice, family practice, geriatric medicine, or pediatric medicine.

Primary care services means the set of services identified by the HCPCS and revenue center codes designated under § 425.400(c).

Quality measures means the measures defined by the Secretary, under section 1899 of the Act, to assess the quality of care furnished by an ACO, such as measures of clinical processes and outcomes, patient and, where practicable, caregiver experience of care and utilization.

Re-entering ACO means an ACO that does not meet the definition of a renewing ACO and meets either of the following conditions:

(1) Is the same legal entity as an ACO, as defined in this section, that previously participated in the program and is applying to participate in the program after a break in participation, because it is either—

(i) An ACO whose participation agreement expired without having been renewed; or

(ii) An ACO whose participation agreement was terminated under § 425.218 or § 425.220.

(2) Is a new legal entity that has never participated in the Shared Savings Program and is applying to participate in the program and more than 50 percent of its ACO participants were included on the ACO participant list under § 425.118, of the same ACO in any of the 5 most recent performance years prior to the agreement start date.

Renewing ACO means an ACO that continues its participation in the program for a consecutive agreement period, without a break in participation, because it is either—

(1) An ACO whose participation agreement expired and that immediately enters a new agreement period to continue its participation in the program; or

(2) An ACO that terminated its current participation agreement under § 425.220 and immediately enters a new agreement period to continue its participation in the program.

Reporting period, for purposes of subpart F of this part, means the calendar year from January 1 to December 31.

Rural health clinic (RHC) has the same meaning given to this term under § 405.2401(b) of this chapter.

Shared losses means a portion of the ACO's performance year Medicare fee-for-service Parts A and B expenditures, above the applicable benchmark, it must repay to CMS. An ACO's eligibility for shared losses will be determined for each performance year. For an ACO requesting interim payment, shared losses may result from the interim payment calculation.

Shared savings means a portion of the ACO's performance year Medicare fee-for-service Parts A and B expenditures, below the applicable benchmark, it is eligible to receive payment for from CMS. An ACO's eligibility for shared savings will be determined for each performance year. For an ACO requesting interim payment, shared savings may result from the interim payment system calculation.

Taxpayer Identification Number (TIN) means a Federal taxpayer identification number or employer identification number as defined by the IRS in 26 CFR 301.6109–1.

Two-sided model means a model under which the ACO may share savings with the Medicare program, if it meets the requirements for doing so, and is also liable for sharing any losses incurred under subpart G of this part.

[76 FR 67973, Nov. 2, 2011, as amended at 80 FR 32833, June 9, 2015; 80 FR 71385, Nov. 16, 2015; 81 FR 38013, June 10, 2016; 82 FR 53368, Nov. 15, 2017; 83 FR 60092, Nov. 23, 2018; 83 FR 68062, Dec. 31, 2018; 87 FR 70232, Nov. 18, 2022; 88 FR 79543, Nov. 16, 2023]

Subpart B—Shared Savings Program Eligibility Requirements

§ 425.100 General.

(a) Under the Shared Savings Program, ACO participants may work together to manage and coordinate care for Medicare fee-for-service beneficiaries through an ACO that meets the criteria specified in this part. The ACO must become accountable for the quality, cost, and overall care of the Medicare fee-for-service beneficiaries assigned to the ACO.

(b) An ACO is eligible to receive payments for shared savings under subpart G of this part if all of the following conditions are met:

(1) The ACO meets or exceeds the applicable minimum savings rate established under §§ 425.604, 425.605 (except as provided under § 425.605(h)), 425.606, 425.609, or 425.610.

(2) The ACO meets the minimum quality performance standards established under § 425.500 (for performance years or a performance period beginning on or before January 1, 2020), or under the quality performance standard established under § 425.512 (for performance years beginning on or after January 1, 2021).

(3) The ACO otherwise maintains its eligibility to participate in the Shared Savings Program under this part.

(c) ACOs that operate under a two-sided model and meet or exceed a minimum loss rate established under § 425.605, § 425.606, § 425.609 or § 425.610 must share losses with the Medicare program under subpart G of the part.

(d) An ACO is eligible to receive advance investment payments if it meets the criteria under § 425.630(b).

(e) An ACO is eligible to receive prepaid shared savings if it meets the criteria under § 425.640(b).

[76 FR 67973, Nov. 2, 2011, as amended at 80 FR 32834, June 9, 2015; 83 FR 60092, Nov. 23, 2018; 83 FR 68083, Dec. 31, 2018; 85 FR 85038, Dec. 28, 2020; 87 FR 70232, Nov. 18, 2022; 89 FR 98566, Dec. 9, 2024]

§ 425.102 Eligible providers and suppliers.

(a) The following ACO participants or combinations of ACO participants are eligible to form an ACO that may apply to participate in the Shared Savings Program:

(1) ACO professionals in group practice arrangements.

(2) Networks of individual practices of ACO professionals.

(3) Partnerships or joint venture arrangements between hospitals and ACO professionals.

(4) Hospitals employing ACO professionals.

(5) CAHs that bill under Method II (as described in § 413.70(b)(3) of this chapter).

(6) RHCs.

(7) FQHCs.

(8) Teaching hospitals that have elected under § 415.160 of this subchapter to receive payment on a reasonable cost basis for the direct medical and surgical services of their physicians.

(b) Other ACO participants that are not identified in paragraph (a) of this section are eligible to participate through an ACO formed by one or more of the ACO participants identified in paragraph (a) of this section.

[76 FR 67973, Nov. 2, 2011, as amended at 80 FR 71386, Nov. 16, 2015]

§ 425.104 Legal entity.

(a) An ACO must be a legal entity, formed under applicable State, Federal, or Tribal law, and authorized to conduct business in each State in which it operates for purposes of the following:

(1) Receiving and distributing shared savings.

(2) Repaying shared losses or other monies determined to be owed to CMS.

(3) Establishing, reporting, and ensuring provider compliance with health care quality criteria, including quality performance standards.

(4) Fulfilling other ACO functions identified in this part.

(b) An ACO formed by two or more ACO participants, each of which is identified by a unique TIN, must be a legal entity separate from any of its ACO participants.

(c) An ACO formed by a single ACO participant may use its existing legal entity and governing body, provided it satisfies the other requirements in §§ 425.104 and 425.106.

[76 FR 67973, Nov. 2, 2011, as amended at 80 FR 32834, June 9, 2015]

§ 425.106 Shared governance.

(a) *General rule.* (1) An ACO must maintain an identifiable governing body with ultimate authority to execute the functions of an ACO as defined under this part, including but not limited to, the processes defined under § 425.112 to promote evidence-based medicine and patient engagement, to report on quality and cost measures, and to coordinate care.

(2) The governing body of the ACO must satisfy all of the following criteria:

(i) Be the same as the governing body of the legal entity that is the ACO.

(ii) Be separate and unique to the ACO and must not be the same as the governing body of any ACO participant, except as provided in § 425.104(c).

(iii) Satisfy all other requirements of this section.

(b) *Responsibilities of the governing body and its members.* (1) The governing body must have responsibility for oversight and strategic direction of the ACO, holding ACO management accountable for the ACO's activities as described in this part.

(2) The governing body must have a transparent governing process.

(3) The governing body members must have a fiduciary duty to the ACO, including the duty of loyalty, and must act consistent with that fiduciary duty.

(c) *Composition and control of the governing body.* (1) The ACO must—

(i) Establish a mechanism for shared governance among the ACO participants or combinations of ACO participants (as identified in § 425.102(a)) that formed the ACO; and

(ii) Provide for meaningful participation in the composition and control of the ACO's governing body for ACO participants or their designated representatives.

(2) The ACO governing body must include a Medicare beneficiary who—

(i) Is served by the ACO;

(ii) Is not an ACO provider/supplier;

(iii) Does not have a conflict of interest with the ACO; and

(iv) Does not have an immediate family member who has a conflict of interest with the ACO.

(3) At least 75 percent control of the ACO's governing body must be held by ACO participants.

(4) The governing body members may serve in a similar or complementary manner for an ACO participant.

(5)(i) In cases in which the composition of the ACO's governing body does not meet the requirements of paragraph (c)(2) of this section, the ACO must describe why it seeks to differ from these requirements and how the ACO will provide meaningful representation in ACO governance by Medicare beneficiaries.

(ii) For agreement periods beginning before January 1, 2024, in cases in which the composition of the ACO's governing body does not meet the requirements of paragraph (c)(3) of this section, the ACO must describe why it seeks to differ from these requirements and how the ACO will involve ACO participants in innovative ways in ACO governance.

(d) *Conflict of interest.* The ACO governing body must have a conflict of interest policy that applies to members of the governing body. The conflict of interest policy must—

(1) Require each member of the governing body to disclose relevant financial interests; and

(2) Provide a procedure to determine whether a conflict of interest exists and set forth a process to address any conflicts that arise.

(3) The conflict of interest policy must address remedial action for members of the governing body that fail to comply with the policy.

[76 FR 67973, Nov. 2, 2011, as amended at 80 FR 32835, June 9, 2015; 88 FR 79544, Nov. 16, 2023]

§ 425.108 Leadership and management.

(a) An ACO must have a leadership and management structure that includes clinical and administrative systems that align with and support the goals of the Shared Savings Program and the aims of better care for individuals, better health for populations, and lower growth in expenditures.

(b) The ACO's operations must be managed by an executive, officer, manager, general partner, or similar party whose appointment and removal are under the control of the ACO's governing body and whose leadership team has demonstrated the ability to influence or direct clinical practice to improve efficiency processes and outcomes.

(c) Clinical management and oversight must be managed by a senior-level medical director. The medical director must be all of the following:

(1) A board-certified physician.

(2) Licensed in a State in which the ACO operates.

(3) Physically present on a regular basis at any clinic, office or other location of the ACO, an ACO participant, or an ACO provider/supplier.

(d) Each ACO participant and each ACO provider/supplier must demonstrate a meaningful commitment to the mission of the ACO to ensure the ACO's likely success.

(1) Meaningful commitment may include, for example, a sufficient financial or human investment (for example, time and effort) in the ongoing operations of the ACO such that the potential loss or recoupment of the investment is likely to motivate the ACO participant and ACO provider/supplier to achieve the ACO's mission under the Shared Savings Program.

(2) A meaningful commitment can be shown when an ACO participant or ACO provider/supplier agrees to comply with and implement the ACO's processes required by § 425.112 and is held accountable for meeting the ACO's performance standards for each required process.

[76 FR 67973, Nov. 2, 2011, as amended at 80 FR 32835, June 9, 2015]

§ 425.110 Number of ACO professionals and beneficiaries.

(a)(1) The ACO must include primary care ACO professionals that are sufficient for the number of Medicare fee-for-service beneficiaries assigned to the ACO under subpart E of this part. The ACO must have at least 5,000 assigned beneficiaries.

(2) CMS deems an ACO to have initially satisfied the requirement to have at least 5,000 assigned beneficiaries as specified in paragraph (a)(1) of this section if 5,000 or more beneficiaries are historically assigned to the ACO participants in each of the 3 benchmark years, as calculated using the assignment methodology set forth in subpart E of this part. In the case of the third benchmark year, CMS uses the most recent data available to estimate the number of assigned beneficiaries.

(b) If at any time during the performance year, an ACO's assigned population falls below 5,000, the ACO may be subject to the actions described in §§ 425.216 and 425.218.

(1) While under a CAP, the ACO remains eligible for shared savings and liable for shared losses.

(2) For performance years starting before January 1, 2025, if the ACO's assigned population is not at least 5,000 by the end of the performance year specified by CMS in its request for a corrective action plan (CAP), CMS terminates the participation agreement and the ACO is not eligible to share in savings for that performance year.

(3) In determining financial performance for an ACO with fewer than 5,000 assigned beneficiaries, the MSR/MLR is calculated as follows:

(i) For ACOs with a variable MSR and MLR (if applicable), the MSR and MLR (if applicable) are set at a level consistent with the number of assigned beneficiaries.

(ii) For performance years starting before July 1, 2019, for ACOs with a fixed MSR/MLR, the MSR/MLR remains fixed at the level consistent with the choice of MSR and MLR that the ACO made at the start of the agreement period.

(iii) For performance years starting on July 1, 2019 and in subsequent years, for ACOs that selected a fixed MSR/MLR at the start of the agreement period or prior to entering a two-sided model during their agreement period, the MSR/MLR is calculated as follows:

(A) The MSR/MLR is set at a level based on the number of beneficiaries assigned to the ACO.

(*1*) The MSR is the same as the MSR that would apply in a one-sided model under § 425.604(b) (for Track 2 ACOs) or § 425.605(b)(1) (for BASIC track and ENHANCED track ACOs) and is based on the number of assigned beneficiaries.

(*2*) The MLR is equal to the negative MSR.

(B) The MSR and MLR revert to the fixed level previously selected by the ACO for any subsequent performance year in the agreement period in which the ACO's assigned beneficiary population is 5,000 or more.

[76 FR 67973, Nov. 2, 2011, as amended at 80 FR 32835, June 9, 2015; 81 FR 80559, Nov. 15, 2016; 83 FR 68063, Dec. 31, 2018; 89 FR 98566, Dec. 9, 2024]

§ 425.112 Required processes and patient-centeredness criteria.

(a) *General.* (1) An ACO must—

(i) Promote evidence-based medicine and beneficiary engagement, internally report on quality and cost metrics, and coordinate care;

(ii) Adopt a focus on patient centeredness that is promoted by the governing body and integrated into practice by leadership and management working with the organization's health care teams; and

(iii) Have defined processes to fulfill these requirements.

(2) An ACO must have a qualified healthcare professional responsible for the ACO's quality assurance and improvement program, which must include the defined processes included in paragraphs (b)(1) through (4) of this section.

(3) For each process specified in paragraphs (b)(1) through (4) of this section, the ACO must—

(i) Require ACO participants and ACO providers/suppliers to comply with and implement each process (and subelement thereof), including the remedial processes and penalties (including the potential for expulsion) applicable to ACO participants and ACO providers/suppliers for failure to comply with and implement the required process; and

(ii) Employ its internal assessments of cost and quality of care to improve continuously the ACO's care practices.

(b) *Required processes.* The ACO must define, establish, implement, evaluate, and periodically update processes to accomplish the following:

(1) Promote evidence-based medicine. These processes must cover diagnoses with significant potential for the ACO to achieve quality improvements taking into account the circumstances of individual beneficiaries.

(2) Promote patient engagement. These processes must address the following areas:

(i) Compliance with patient experience of care survey requirements in § 425.500 or § 425.510, as applicable.

(ii) Compliance with beneficiary representative requirements in § 425.106.

(iii) A process for evaluating the health needs of the ACO's population, including consideration of diversity in its patient populations, and a plan to address the needs of its population.

(A) In its plan to address the needs of its population, the ACO must describe how it intends to partner with community stakeholders to improve the health of its population.

(B) An ACO that has a stakeholder organization serving on its governing body will be deemed to have satisfied the requirement to partner with community stakeholders.

(iv) Communication of clinical knowledge/evidence-based medicine to beneficiaries in a way that is understandable to them.

(v) Beneficiary engagement and shared decision-making that takes into account the beneficiaries' unique needs, preferences, values, and priorities;

(vi) Written standards in place for beneficiary access and communication, and a process in place for beneficiaries to access their medical record.

(3) Develop an infrastructure for its ACO participants and ACO providers/suppliers to internally report on quality and cost metrics that enables the ACO to monitor, provide feedback, and evaluate its ACO participants and ACO provider(s)/supplier(s) performance and to use these results to improve care over time.

(4) Coordinate care across and among primary care physicians, specialists, and acute and post-acute providers and suppliers. The ACO must—

(i) Define its methods and processes established to coordinate care throughout an episode of care and during its transitions, such as discharge from a hospital or transfer of care from a primary care physician to a specialist (both inside and outside the ACO); and

(ii) Have a written plan to:

(A) Implement an individualized care program that promotes improved outcomes for, at a minimum, the ACO's high-risk and multiple chronic condition patients.

(B) Identify additional target populations that would benefit from individualized care plans. Individualized care plans must take into account the community resources available to the individual.

(C) Encourage and promote use of enabling technologies for improving care

coordination for beneficiaries. Enabling technologies may include one or more of the following:

(*1*) Electronic health records and other health IT tools.

(*2*) Telehealth services, including remote patient monitoring.

(*3*) Electronic exchange of health information.

(*4*) Other electronic tools to engage beneficiaries in their care.

(D) Partner with long-term and post-acute care providers, both inside and outside the ACO, to improve care coordination for its assigned beneficiaries.

[76 FR 67973, Nov. 2, 2011, as amended at 80 FR 32835, June 9, 2015; 82 FR 53368, Nov. 15, 2017; 85 FR 85038, Dec. 28, 2020]

§ 425.114 Participation in other shared savings initiatives.

(a) ACOs may not participate in the Shared Savings Program if they include an ACO participant that participates in the independence at home medical practice pilot program under section 1866E of the Act, a model tested or expanded under section 1115A of the Act that involves shared savings, or any other Medicare initiative that involves shared savings.

(b) CMS will review and deny an ACO's application if any ACO participants are participating in another Medicare initiative that involves shared savings payments.

(c) CMS will determine an appropriate method to ensure no duplication in payments for beneficiaries assigned to other shared savings programs or initiatives, including initiatives involving dually eligible beneficiaries, when such other shared savings programs have an assignment methodology that is different from the Shared Savings Program.

§ 425.116 Agreements with ACO participants and ACO providers/suppliers.

(a) *ACO participant agreements.* For performance year 2017 and subsequent performance years, the ACO must have an ACO participant agreement with each ACO participant that complies with the following criteria:

(1) The only parties to the agreement are the ACO and the ACO participant.

(2) The agreement must be signed on behalf of the ACO and the ACO participant by individuals who are authorized to bind the ACO and the ACO participant, respectively.

(3) The agreement must expressly require the ACO participant to agree, and to ensure that each ACO provider/supplier billing through the TIN of the ACO participant agrees, to participate in the Shared Savings Program and to comply with the requirements of the Shared Savings Program and all other applicable laws and regulations (including, but not limited to, those specified at § 425.208(b)).

(4) The agreement must set forth the ACO participant's rights and obligations in, and representation by, the ACO, including without limitation, the quality reporting requirements set forth in subpart F of this part, the beneficiary notification requirements set forth at § 425.312, and how participation in the Shared Savings Program affects the ability of the ACO participant and its ACO providers/suppliers to participate in other Medicare demonstration projects or programs that involve shared savings.

(5) The agreement must describe how the opportunity to receive shared savings or other financial arrangements will encourage the ACO participant to adhere to the quality assurance and improvement program and evidence-based medicine guidelines established by the ACO.

(6) The agreement must require the ACO participant to update its enrollment information, including the addition and deletion of ACO professionals and ACO providers/suppliers billing through the TIN of the ACO participant, on a timely basis in accordance with Medicare program requirements and to notify the ACO of any such changes within 30 days after the change.

(7) The agreement must permit the ACO to take remedial action against the ACO participant, and must require the ACO participant to take remedial action against its ACO providers/suppliers, including imposition of a corrective action plan, denial of incentive payments, and termination of the ACO participant agreement, to address noncompliance with the requirements of

the Shared Savings Program and other program integrity issues, including those identified by CMS.

(8) The agreement must be for a term of at least 1 performance year and must articulate potential consequences for early termination from the ACO.

(9) The agreement must require completion of a close-out process upon termination or expiration of the agreement that requires the ACO participant to furnish all data necessary to complete the annual assessment of the ACO's quality of care and addresses other relevant matters.

(b) *Agreements with ACO providers/suppliers.* ACOs have the option of contracting directly with its ACO providers/suppliers regarding items and services furnished to beneficiaries aligned to the ACO. For performance year 2017 and subsequent performance years, an ACO's agreement with an ACO provider/supplier regarding such items and services must satisfy the following criteria:

(1) The only parties to the agreement are the ACO and the ACO provider/supplier.

(2) The agreement must be signed by the ACO provider/supplier and by an individual who is authorized to bind the ACO.

(3) The agreement must expressly require the ACO provider/supplier to agree to participate in the Shared Savings Program and to comply with the requirements of the Shared Savings Program and all other applicable laws and regulations (including, but not limited to, those specified at § 425.208(b)).

(4) The agreement must set forth the ACO provider's/supplier's rights and obligations in, and representation by, the ACO, including without limitation, the quality reporting requirements set forth in subpart F of this part, the beneficiary notification requirements set forth at § 425.312, and how participation in the Shared Savings Program affects the ability of the ACO provider/supplier to participate in other Medicare demonstration projects or programs that involve shared savings.

(5) The agreement must describe how the opportunity to receive shared savings or other financial arrangements will encourage the ACO provider/supplier to adhere to the quality assurance and improvement program and evidence-based medicine guidelines established by the ACO.

(6) The agreement must require the ACO provider/supplier to—

(i) Update its enrollment information on a timely basis in accordance with Medicare program requirements; and

(ii) Notify the ACO of any such changes within 30 days after the change.

(7) The agreement must permit the ACO to take remedial action including the following against the ACO provider/supplier to address noncompliance with the requirements of the Shared Savings Program and other program integrity issues, including those identified by CMS:

(i) Imposition of a corrective action plan.

(ii) Denial of incentive payments.

(iii) Termination of the ACO participant agreement.

(c) *Submission of agreements.* The ACO must submit an executed ACO participant agreement for each ACO participant that it requests to add to its list of ACO participants in accordance with § 425.118. The agreements may be submitted in the form and manner set forth in § 425.204(c)(6) or as otherwise specified by CMS.

[80 FR 32835, June 9, 2015; as amended at 86 FR 65683, Nov. 19, 2021]

§ 425.118 Required reporting of ACO participants and ACO providers/suppliers.

(a) *List requirements.* (1) The ACO must maintain, update, and submit to CMS an accurate and complete list identifying each ACO participant (including its Medicare-enrolled TIN) and each ACO provider/supplier (including its NPI or other identifier) in accordance with this section.

(2) Before the start of an agreement period, before each performance year thereafter, and at such other times as specified by CMS, the ACO must submit to CMS an ACO participant list and an ACO provider/supplier list. The ACO may request consideration of claims billed under merged and acquired Medicare-enrolled TINs in accordance with the process set forth at § 425.204(g).

(3) The ACO must certify the submitted lists in accordance with § 425.302(a)(2).

(4) All Medicare enrolled individuals and entities that have reassigned their right to receive Medicare payment to the TIN of the ACO participant must be included on the ACO provider/supplier list and must agree to participate in the ACO and comply with the requirements of the Shared Savings Program before the ACO submits the ACO participant list and the ACO provider/supplier list.

(b) *Changes to the ACO participant list*—(1) *Additions.* (i) An ACO must submit to CMS a request to add an entity and its Medicare enrolled TIN to its ACO participant list. This request must be submitted at such time and in the form and manner specified by CMS.

(ii) If CMS approves the request, the entity and its Medicare enrolled TIN is added to the ACO participant list effective January 1 of the following performance year.

(iii) CMS may deny the request on the basis that the entity is not eligible to be an ACO participant or on the basis of the results of the screening performed under § 425.305(a).

(2) *Deletions.* (i) An ACO must notify CMS no later than 30 days after the termination of an ACO participant agreement. Such notice must be submitted in the form and manner specified by CMS and must include the termination date of the ACO participant agreement.

(ii) The entity is deleted from the ACO participant list as of the termination date of the ACO participant agreement.

(3) *Adjustments.* (i) CMS annually adjusts an ACO's assignment, historical benchmark, the quality reporting sample, and the obligation of the ACO to report on behalf of eligible professionals that bill under the TIN of an ACO participant for certain CMS quality initiatives to reflect the addition or deletion of entities from the list of ACO participants that is submitted to CMS before the start of a performance year in accordance with paragraph (a) of this section.

(ii) Absent unusual circumstances, CMS does not make adjustments during the performance year to the ACO's assignment, historical benchmark, performance year financial calculations, the quality reporting sample, or the obligation of the ACO to report on behalf of eligible professionals that bill under the TIN of an ACO participant for certain CMS quality initiatives to reflect the addition or deletion of entities from the ACO participant list that become effective during the performance year. CMS has sole discretion to determine whether unusual circumstances exist that would warrant such adjustments.

(c) *Changes to the ACO provider/supplier list*—(1) *Additions.* (i) An ACO must notify CMS within 30 days after an individual or entity becomes a Medicare-enrolled provider or supplier that bills for items and services it furnishes to Medicare fee-for-service beneficiaries under a billing number assigned to the TIN of an ACO participant. The notice must be submitted in the form and manner specified by CMS.

(ii) If the ACO timely submits notice to CMS, the addition of an individual or entity to the ACO provider/supplier list is effective on the date specified in the notice furnished to CMS, but no earlier than 30 days before the date of the notice. If the ACO fails to submit timely notice to CMS, the addition of an individual or entity to the ACO provider/supplier list is effective on the date of the notice.

(2) *Deletions.* (i) An ACO must notify CMS no later than 30 days after an individual or entity ceases to be a Medicare-enrolled provider or supplier that bills for items and services it furnishes to Medicare fee-for-service beneficiaries under a billing number assigned to the TIN of an ACO participant. The notice must be submitted in the form and manner specified by CMS.

(ii) The deletion of an ACO provider/supplier from the ACO provider/supplier list is effective on the date the individual or entity ceased to be a Medicare-enrolled provider or supplier that bills for items and services it furnishes to Medicare fee-for-service beneficiaries under a billing number assigned to the TIN of an ACO participant.

(d) *Update of Medicare enrollment information.* The ACO must ensure that all changes to enrollment information

for ACO participants and ACO providers/suppliers, including changes to reassignment of the right to receive Medicare payment, are reported to CMS consistent with § 424.516.

[80 FR 32836, June 9, 2015, as amended at 83 FR 68063, Dec. 31, 2018]

Subpart C—Application Procedures and Participation Agreement

§ 425.200 Participation agreement with CMS.

(a) *General.* In order to participate in the Shared Savings Program, an ACO must enter into a participation agreement with CMS for a period of not less than the number of years specified in this section.

(b) *Agreement period.* (1) *For 2012.* For applications that are approved to participate in the Shared Savings Program for 2012, the start date for the participation agreement will be one of the following:

(i) April 1, 2012 (term of the participation agreement is 3 years and 9 months).

(ii) July 1, 2012 (term of the participation agreement is 3 years and 6 months).

(2) *For 2013 and through 2016.*

(i) The start date is January 1 of that year; and

(ii) The term of the participation agreement is 3 years unless all of the following conditions are met to extend the participation agreement by 6 months:

(A) The ACO entered an agreement period starting on January 1, 2016.

(B) The ACO elects to extend its agreement period until June 30, 2019.

(*1*) The ACO's election to extend its agreement period is made in the form and manner and according to the timeframe established by CMS; and

(*2*) An ACO executive who has the authority to legally bind the ACO must certify the election described in paragraph (b)(2)(ii)(B) of this section.

(3) *For 2017 and 2018.*

(i) The start date is January 1 of that year; and

(ii) The term of the participation agreement is 3 years, except as follows:

(A) For an ACO whose first agreement period in Track 1 began in 2014 or 2015, in which case the term of the ACO's initial agreement period under Track 1 (as described under § 425.604) may be extended, at the ACO's option, for an additional year for a total of 4 performance years if the conditions specified in paragraph (e) of this section are met.

(B) For an ACO whose agreement period started on January 1, 2018, the term of the participation agreement is extended by 12 months if both of the following conditions are met:

(*1*) The ACO elects to extend the participation agreement for a fourth performance year until December 31, 2021.

(*2*) The ACO's election to extend its agreement period is made in the form and manner and by a deadline established by CMS.

(4) *For 2019.* (i) The start date is January 1, 2019, and the term of the participation agreement is 3 years for ACOs whose first agreement period began in 2015 and who deferred renewal of their participation agreement under paragraph (e) of this section; or

(ii) The start date is July 1, 2019, and the term of the participation agreement is 5 years and 6 months.

(5) *For 2020 and subsequent years.* (i) The start date is January 1 of that year; and

(ii) The term of the participation agreement is 5 years.

(c) *Performance year.* The ACO's performance year under the participation agreement is the 12 month period beginning on January 1 of each year during the term of the participation agreement unless otherwise noted in its participation agreement, and except as follows:

(1) For an ACO with a start date of April 1, 2012, or July 1, 2012, the ACO's first performance year is defined as 21 months or 18 months, respectively.

(2) For an ACO that entered a first or second agreement period with a start date of January 1, 2016, and that elects to extend its agreement period by a 6-month period under paragraph (b)(2)(ii)(B) of this section, the ACO's fourth performance year is the 6-month period between January 1, 2019, and June 30, 2019.

(3) For an ACO that entered an agreement period with a start date of July 1, 2019, the ACO's first performance year

of the agreement period is defined as the 6-month period between July 1, 2019, and December 31, 2019.

(d) *Submission of measures.* For each performance year of the agreement period, ACOs must submit measures in the form and manner required by CMS according to § 425.500(c) or § 425.510, as applicable, and as applicable according to §§ 425.608 and 425.609.

(e) *Optional fourth year.* (1) To qualify for a fourth performance year as described in paragraph (b)(3)(ii) of this section, the ACO must meet all of the following conditions:

(i) The ACO's first agreement period in the Shared Savings Program under Track 1 began in 2014 or 2015.

(ii) Is currently participating in its first agreement period under Track 1.

(iii) Has requested renewal of its participation agreement in accordance with § 425.224.

(iv) Has selected a two-sided model (as described under § 425.606 or § 425.610 of this part) in its renewal request.

(v) Has requested an extension of its current agreement period and a 1-year deferral of the start of its second agreement period in a form and manner specified by CMS.

(vi) CMS approves the ACO's renewal, extension, and deferral requests.

(2) An ACO that is approved for renewal, extension, and deferral that terminates its participation agreement before the start of the first performance year of the second agreement period is—

(i) Considered to have terminated its participation agreement for the second agreement period under § 425.220; and

(ii) Not eligible to participate in the Shared Savings Program again until after the date on which the term of that second agreement period would have expired if the ACO had not terminated its participation, consistent with § 425.222.

[76 FR 67973, Nov. 2, 2011, as amended at 80 FR 32837, June 9, 2015; 81 FR 38013, June 10, 2016; 83 FR 60092, Nov. 23, 2018; 83 FR 68063, Dec. 31, 2018; 85 FR 27625, May 8, 2020; 85 FR 85038, Dec. 28, 2020]

§ 425.202 Application procedures.

(a) *General rules.* (1) In order to obtain a determination regarding whether it meets the requirements to participate in the Shared Savings Program, a prospective ACO must submit a complete application in the form and manner required by CMS by the deadline established by CMS.

(2) An ACO executive who has the authority to legally bind the ACO must certify to the best of his or her knowledge, information, and belief that the information contained in the application is accurate, complete, and truthful.

(3) An ACO that seeks to participate in the Shared Savings Program must agree that CMS can share a copy of their application with the Antitrust Agencies.

(b) *Condensed application form.* For determining eligibility for agreement periods beginning before July 1, 2019:(1) PGP demonstration sites applying to participate in the Shared Savings Program will have an opportunity to complete a condensed application form.

(2) A Pioneer ACO may use a condensed application form to apply for participation in the Shared Savings Program if it satisfies all of the following criteria:

(i) The applicant is the same legal entity as the Pioneer ACO.

(ii) The applicant's ACO participant list does not contain any ACO participant TINs that did not appear on the ''Confirmed Annual TIN/NPI List'' (as defined in the Pioneer ACO Model Innovation Agreement with CMS) for the applicant ACO's last full performance year in the Pioneer ACO Model.

(iii) The applicant is not applying to participate in the one-sided model.

(c) *Application review.* CMS reviews applications in accordance with § 425.206.

[76 FR 67973, Nov. 2, 2011, as amended at 80 FR 32837, June 9, 2015; 83 FR 68063, Dec. 31, 2018; 89 FR 98566, Dec. 9, 2024]

§ 425.204 Content of the application.

(a) *Accountability for beneficiaries.* As part of its application and participation agreement, the ACO must certify that the ACO, its ACO participants, and its ACO providers/suppliers have agreed to become accountable for the quality, cost, and overall care of the Medicare fee-for-service beneficiaries assigned to the ACO.

(b) *Prior participation.* Upon request by CMS during the application cycle, the ACO must submit information regarding prior participation in the Medicare Shared Savings Program by the ACO, its ACO participants, or its ACO providers/suppliers, including such information as may be necessary for CMS to determine whether to approve an ACO's application in accordance with § 425.224(b).

(2) The ACO must specify whether the related participation agreement is currently active or has been terminated. If it has been terminated, the ACO must specify whether the termination was voluntary or involuntary.

(3) If the ACO, ACO participant, or ACO provider/supplier was previously terminated from the Shared Savings Program, the ACO must identify the cause of termination and what safeguards are now in place to enable the ACO, ACO participant, or ACO provider/supplier to participate in the program for the full term of the participation agreement.

(c) *Eligibility.* (1) As part of its application, an ACO must certify that the ACO satisfies the requirements set forth in this part. Upon request, the ACO must submit the following supporting materials to demonstrate that it satisfies the requirements set forth in this part:

(i) Documents (for example, ACO participant agreements, agreements with ACO providers/suppliers, employment contracts, and operating policies) sufficient to describe the ACO participants' and ACO providers'/suppliers' rights and obligations in and representation by the ACO, and how the opportunity to receive shared savings or other financial arrangements will encourage ACO participants and ACO providers/suppliers to adhere to the quality assurance and improvement program and evidence-based clinical guidelines.

(ii) A description, or documents sufficient to describe, how the ACO will implement the required processes and patient-centeredness criteria under § 425.112, including descriptions of the remedial processes and penalties (including the potential for expulsion) that will apply if an ACO participant or an ACO provider/supplier fails to comply with and implement these processes.

(iii) Materials documenting the ACO's organization and management structure, including an organizational chart, a list of committees (including names of committee members) and their structures, and job descriptions for senior administrative and clinical leaders specifically noted in § 425.108 and § 425.112(a)(2).

(iv) Evidence that the governing body—

(A) Is an identifiable body;

(B) Represents a mechanism for shared governance for ACO participants;

(C) Is composed of representatives of its ACO participants; and

(D) Is at least 75 percent controlled by its ACO participants.

(v) Evidence that the governing body includes a Medicare beneficiary representative(s) served by the ACO who does not have a conflict of interest with the ACO, and who has no immediate family member with conflict of interest with the ACO.

(vi) A copy of the ACO's compliance plan or documentation describing the plan that will be put in place at the time the participation agreement with CMS becomes effective.

(2) Upon request, the ACO must provide copies of all documents effectuating the ACO's formation and operation, including, without limitation the following:

(i) Charters.

(ii) By-laws.

(iii) Articles of incorporation.

(iv) Partnership agreement.

(v) Joint venture agreement.

(vi) Management or asset purchase agreements.

(vii) Financial statements and records.

(viii) Resumes and other documentation required for leaders of the ACO.

(3) If an ACO requests an exception to the governing body requirement in § 425.106(c)(2) or (c)(3), the ACO must describe—

(i) Why it seeks to differ from the requirement; and

(ii) If seeking an exception to § 425.106(c)(2), how the ACO will provide meaningful representation in ACO governance by Medicare beneficiaries.

(iii) If seeking an exception to the requirement at § 425.106(c)(3), for agreement periods beginning before January 1, 2024, why the ACO is unable to meet the requirement and how it will involve ACO participants in innovative ways in ACO governance.

(4)(i) An ACO must certify that it is recognized as a legal entity in the State, Federal or Tribal area in which it was established and that it is authorized to conduct business in each State or Tribal area in which it operates.

(ii) An ACO formed among two or more ACO participants must provide evidence in its application that it is a legal entity separate from any of the ACO participants.

(5) The ACO must provide CMS with such information regarding its ACO participants and its ACO providers/suppliers participating in the program as is necessary to implement the program.

(i) The ACO must submit a list of all ACO participants and ACO providers/suppliers in accordance with § 425.118.

(ii) ACOs must also submit any other specific identifying information as required by CMS in the application process.

(iii) The ACO must certify the accuracy of this information.

(6) Upon request by CMS during the application cycle or at any point during an agreement period, the ACO must submit documents demonstrating that its ACO participants, ACO providers/suppliers, and other individuals or entities performing functions or services related to ACO activities are required to comply with the requirements of the Shared Savings Program. Upon such a request, the evidence to be submitted must include, without limitation, sample or form agreements and, in the case of ACO participant agreements, the first and signature page(s) of each executed ACO participant agreement. CMS may request all pages of an executed ACO participant agreement to confirm that it conforms to the sample form agreement submitted by the ACO. The ACO must certify that all of its ACO participant agreements comply with the requirements of this part.

(d) *Distribution of savings.* As part of its application to participate in the Shared Savings Program, an ACO must certify it has a mechanism and plan to receive and use payments for shared savings, including criteria for distributing shared savings among its ACO participants and ACO providers/suppliers.

(e) *Selection of track and option for interim payment calculation.* (1) As part of its application, an ACO must specify the Track for which it is applying (as described in § 425.600).

(2)(i) An ACO applying to participate in the program with a start date of April 1, 2012 or July 1, 2012, has the option of requesting an interim payment calculation based on the financial performance for its first 12 months of program participation and quality performance for CY 2012.

(ii) An ACO must request interim payment calculation as part of its application to participate in the Shared Savings Program.

(f) *Assurance of ability to repay.* (1) An ACO must have the ability to repay all shared losses for which it may be liable under a two-sided model and any prepaid shared savings determined to be owed.

(2) An ACO that will participate in a two-sided model must establish one or more of the following repayment mechanisms in an amount and by a deadline specified by CMS in accordance with this section:

(i) An escrow account with an insured institution.

(ii) A surety bond from a company included on the U.S. Department of Treasury's List of Certified Companies.

(iii) A line of credit at an insured institution (as evidenced by a letter of credit that the Medicare program can draw upon).

(3) An ACO that will participate under a two-sided model of the Shared Savings Program must submit for CMS approval documentation that it is capable of repaying shared losses that it may incur during its agreement period, including details supporting the adequacy of the repayment mechanism. If the ACO will receive prepaid shared savings, the repayment mechanism must also support repayment of prepaid shared savings in accordance with § 425.640.

(i) An ACO participating in Track 2 must demonstrate the adequacy of its repayment mechanism prior to any change in the terms and type of the repayment mechanism, and at such other times as requested by CMS.

(ii) An ACO entering an agreement period in Levels C, D, or E of the BASIC track or the ENHANCED track must demonstrate the adequacy of its repayment mechanism prior to the start of its agreement period, prior to any change in the terms and type of the repayment mechanism, and at such other times as requested by CMS.

(iii) An ACO entering an agreement period in Level A or Level B of the BASIC track must demonstrate the adequacy of its repayment mechanism prior to the start of any performance year in which it either elects to participate in, or is automatically transitioned to, a two-sided model, Level C, Level D, or Level E of the BASIC track, prior to any change in the terms and type of the repayment mechanism, and at such other times as requested by CMS.

(iv) An ACO that has submitted a request to renew its participation agreement must submit as part of the renewal request documentation demonstrating the adequacy of the repayment mechanism that could be used to repay any shared losses incurred and prepaid shared savings determined to be owed for performance years in the next agreement period. The repayment mechanism applicable to the new agreement period may be the same repayment mechanism currently used by the ACO, provided that the ACO submits documentation establishing that the duration of the existing repayment mechanism has been revised to comply with paragraph (f)(6)(ii) of this section, and the amount of the repayment mechanism complies with paragraph (f)(4) of this section.

(v) As part of its application, a re-entering ACO must submit documentation demonstrating the adequacy of the repayment mechanism that could be used to repay any shared losses incurred for performance years in the next agreement period. The repayment mechanism applicable to the new agreement period may be the same repayment mechanism currently used by the re-entering ACO, provided that the ACO is the same legal entity as an ACO that previously participated in the program, and the ACO submits documentation establishing that the duration of the existing repayment mechanism has been revised to comply with paragraph (f)(6)(ii) of this section and the amount of the repayment mechanism complies with paragraph (f)(4) of this section.

(4) CMS calculates the amount of the repayment mechanism as follows:

(i) For a Track 2 ACO, the repayment mechanism amount must be equal to at least 1 percent of the total per capita Medicare Parts A and B fee-for-service expenditures for the ACO's assigned beneficiaries, based on expenditures used to calculate the benchmark for the applicable agreement period, as estimated by CMS at the time of application.

(ii) For a BASIC track or ENHANCED track ACO, the repayment mechanism amount must be equal to the lesser of the following:

(A) One-half percent of the total per capita Medicare Parts A and B fee-for-service expenditures for the ACO's assigned beneficiaries, based on expenditures and the number of assigned beneficiaries for the most recent calendar year for which 12 months of data are available.

(B) One percent of the total Medicare Parts A and B fee-for-service revenue of its ACO participants, based on revenue for the most recent calendar year for which 12 months of data are available, and based on the ACO's number of assigned beneficiaries for the most recent calendar year for which 12 months of data are available.

(iii) CMS recalculates the ACO's repayment mechanism amount for the second and each subsequent performance year in the agreement period in accordance with paragraph (f)(4)(ii) of this section based on the certified ACO participant list for the relevant performance year, except that the number of assigned beneficiaries used in the calculations is the number of beneficiaries assigned to the ACO at the beginning of the relevant performance year under § 425.400(a)(2)(i) (for ACOs under preliminary prospective assignment with retrospective reconciliation)

or § 425.400(a)(3)(i) (for ACOs under prospective assignment).

(A) If the recalculated repayment mechanism amount exceeds the existing repayment mechanism amount by at least $1,000,000, CMS notifies the ACO in writing that the amount of its repayment mechanism must be increased to the recalculated repayment mechanism amount.

(B) Within 90 days after receipt of such written notice from CMS, the ACO must submit for CMS approval documentation that the amount of its repayment mechanism has been increased to the amount specified by CMS.

(iv)(A) In the case of an ACO that has submitted a request to enter a new participation agreement for an agreement period starting on or after January 1, 2022 and is a renewing ACO or a re-entering ACO that is the same legal entity as an ACO that previously participated in the program: If the ACO wishes to use its existing repayment mechanism to establish its ability to repay any shared losses incurred and prepaid shared savings determined to be owed for performance years in the new agreement period, the amount of the repayment mechanism must be equal to at least the amount calculated by CMS in accordance with paragraph (f)(4)(ii) of this section.

(B) Under the following circumstances, an ACO that renewed its participation agreement for an agreement period beginning on July 1, 2019, or January 1, 2020, may elect to decrease the amount of its repayment mechanism.

(*1*) The ACO elected to continue to use its existing repayment mechanism for the agreement period beginning on July 1, 2019, or January 1, 2020, and the amount of that repayment mechanism was greater than the repayment mechanism amount estimated at the time of renewal application according to paragraph (f)(4)(ii) of this section.

(*2*) The repayment mechanism amount for performance year 2021, as recalculated pursuant to paragraph (f)(4)(iii) of this section, is less than the existing repayment mechanism amount.

(*3*) CMS will notify the ACO in writing if the ACO may elect to decrease the amount of its repayment mechanism pursuant to this paragraph (f)(4)(iv)(B). The ACO must submit such election, together with revised repayment mechanism documentation, in a form and manner and by a deadline specified by CMS. CMS will review the revised repayment mechanism documentation and may reject the election if the repayment mechanism documentation does not comply with the requirements of this paragraph (f).

(v)(A) An ACO that established a repayment mechanism to support its participation in a two-sided model beginning on July 1, 2019, January 1, 2020, or January 1, 2021, may elect to decrease the amount of its repayment mechanism if the repayment mechanism amount for performance year 2022, as recalculated pursuant to paragraph (f)(4)(iii) of this section, is less than the existing repayment mechanism amount.

(B) CMS will notify the ACO in writing if the ACO may elect to decrease the amount of its repayment mechanism pursuant to this paragraph (f)(4)(v). The ACO must submit such election, and revised repayment mechanism documentation, in a form and manner and by a deadline specified by CMS. CMS will review the revised repayment mechanism documentation and may reject the election if the repayment mechanism documentation does not comply with the requirements of this paragraph (f).

(5) After the repayment mechanism has been used to repay any portion of shared losses owed or prepaid shared savings determined to be owed to CMS, the ACO must replenish the amount of funds available through the repayment mechanism within 90 days. The resulting amount available through the repayment mechanism must be at least the amount specified by CMS in accordance with paragraph (f)(4) of this section.

(6) The repayment mechanism must be in effect for the duration of the ACO's participation under a two-sided model plus 12 months following the conclusion of the agreement period, except as otherwise specified in this section.

(i) For an ACO that is establishing a new repayment mechanism to meet

this requirement, the repayment mechanism must satisfy one of the following criteria:

(A) The repayment mechanism covers the entire duration of the ACO's participation under a two-sided risk model plus 12 months following the conclusion of the agreement period.

(B) The repayment mechanism covers a term of at least the first two performance years in which the ACO is participating under a two-sided model and provides for automatic, annual 12-month extensions of the repayment mechanism such that the repayment mechanism will eventually remain in effect for the duration of the agreement period plus 12 months following the conclusion of the agreement period.

(ii) For a renewing ACO, or a re-entering ACO that is the same legal entity as an ACO that previously participated in the program, that wishes to use its existing repayment mechanism to establish its ability to repay any shared losses incurred and prepaid shared savings determined to be owed for performance years in the new agreement period, the existing repayment mechanism must be amended to meet one of the following criteria.

(A) The duration of the existing repayment mechanism is extended by an amount of time that covers the duration of the new agreement period plus 12 months following the conclusion of the new agreement period.

(B) The duration of the existing repayment mechanism is extended, if necessary, to cover a term of at least the first two performance years of the new agreement period and provides for automatic, annual 12-month extensions of the repayment mechanism such that the repayment mechanism will eventually remain in effect for the duration of the new agreement period plus 12 months following the conclusion of the new agreement period.

(iii) CMS may require the ACO to extend the duration of the repayment mechanism if necessary to ensure that the ACO fully repays CMS any shared losses or prepaid shared savings determined to be owed for each of the performance years of the agreement period.

(iv) The repayment mechanism may be terminated at the earliest of the following conditions:

(A) The ACO has fully repaid CMS any shared losses owed or prepaid shared savings determined to be owed for each of the performance years of the agreement period under a two-sided model.

(B) CMS has exhausted the amount reserved by the ACO's repayment mechanism and the arrangement does not need to be maintained to support the ACO's participation under the Shared Savings Program.

(C) CMS determines that the ACO does not owe any shared losses or prepaid shared savings under the Shared Savings Program for any of the performance years of the agreement period.

(g) *Consideration of claims billed under merged and acquired entities' TINs.* An ACO may request that CMS consider, for purposes of beneficiary assignment and establishing the ACO's benchmark under §§ 425.601, 425.602, 425.603, or 425.652, claims billed under the TINs of entities that have been acquired through sale or merger by an ACO participant.

(1) The ACO may include an acquired entity's TIN on its ACO participant list under the following circumstances:

(i) The ACO participant has subsumed the acquired entity's TIN in its entirety, including all of the providers and suppliers that reassigned their right to receive Medicare payment to the acquired entity's TIN.

(ii) Each provider or supplier that previously reassigned his or her right to receive Medicare payment to the acquired entity's TIN has reassigned his or her right to receive Medicare payment to the TIN of the acquiring ACO participant and has been added to the ACO provider/supplier list under paragraph (c)(5) of the section.

(iii) The acquired entity's TIN is no longer used to bill Medicare.

(2) The ACO must submit the following supporting documentation in the form and manner specified by CMS.

(i) An attestation that—

(A) Identifies by TIN both the acquired entity and the ACO participant that acquired it;

(B) Specifies that all the providers and suppliers that previously reassigned their right to receive Medicare payment to the acquired entity's TIN have reassigned such right to the TIN of the identified ACO participant and have been added to the ACO provider/supplier list under paragraph (c)(5) of this section; and

(C) Specifies that the acquired entity's TIN is no longer used to bill Medicare.

(ii) Documentation sufficient to demonstrate that the acquired entity's TIN was merged with or purchased by the ACO participant.

[76 FR 67973, Nov. 2, 2011, as amended at 80 FR 32837, June 9, 2015; 81 FR 80559, Nov. 15, 2016; 82 FR 53369, Nov. 15, 2017; 83 FR 68063, Dec. 31, 2018; 85 FR 85038, Dec. 28, 2020; 86 FR 65683, Nov. 19, 2021; 87 FR 70232, Nov. 18, 2022; 88 FR 79544, Nov. 16, 2023; 89 FR 98566, Dec. 9, 2024]

§ 425.206 Evaluation procedures for applications.

(a) *Basis for evaluation and determination.* (1) CMS evaluates an ACO's application to determine whether an applicant satisfies the requirements of this part and is qualified to participate in the Shared Savings Program, and approves or denies applications accordingly. Applications are approved or denied on the basis of the following:

(i) Information contained in and submitted with the application by an application deadline specified by CMS.

(ii) Supplemental information that was submitted in response to a CMS request and by a deadline specified by CMS.

(iii) Other information available to CMS.

(2) CMS notifies an ACO applicant when supplemental information is required for CMS to make a determination on the ACO's application and provides an opportunity for the ACO to submit the information.

(3) CMS may deny an application if an ACO applicant fails to submit requested information by the deadlines established by CMS.

(b) *Notice of determination.* (1) CMS notifies in writing each applicant ACO of its determination to approve or deny the ACO's application to participate in the Shared Savings Program.

(2) If CMS denies the application, the notice will indicate that the ACO is not qualified to participate in the Shared Savings Program, specify the reasons why the ACO is not so qualified, and inform the ACO of its right to request reconsideration review in accordance with the procedures specified in subpart I of this part.

[76 FR 67973, Nov. 2, 2011, as amended at 80 FR 32838, June 9, 2015]

§ 425.208 Provisions of participation agreement.

(a) *General rules.* (1) Upon being notified by CMS of its approval to participate in the Shared Savings Program, an executive of that ACO who has the ability to legally bind the ACO must sign and submit to CMS a participation agreement.

(2) Under the participation agreement the ACO must agree to comply with the provisions of this part in order to participate in the Shared Savings Program.

(b) *Compliance with laws.* The ACO must agree, and must require its ACO participants, ACO providers/suppliers, and other individuals or entities performing functions or services related to the ACO's activities to agree, or to comply with all applicable laws including, but not limited to, the following:

(1) Federal criminal law.

(2) The False Claims Act (31 U.S.C. 3729 *et seq.*).

(3) The anti-kickback statute (42 U.S.C. 1320a–7b(b)).

(4) The civil monetary penalties law (42 U.S.C. 1320a–7a).

(5) The physician self-referral law (42 U.S.C. 1395nn).

(6) The information blocking provision of the 21st Century Cures Act (42 U.S.C. 300jj–52).

(c) *Certifications.* (1) The ACO must agree, as a condition of participating in the program and receiving any shared savings payment, that an individual with the authority to legally bind the ACO will certify the accuracy, completeness, and truthfulness of any data or information requested by or submitted to CMS, including, but not limited to, the application form, participation agreement, and any quality data or other information on which CMS

bases its calculation of shared savings payments and shared losses.

(2) Certifications must meet the requirements at §425.302.

[76 FR 67973, Nov. 2, 2011, as amended at 89 FR 54717, July 1, 2024]

§425.210 Application of agreement to ACO participants, ACO providers/suppliers, and others.

(a) The ACO must provide a copy of its participation agreement with CMS to all ACO participants, ACO providers/suppliers, and other individuals and entities involved in ACO governance.

(b) All contracts or arrangements between or among the ACO, ACO participants, ACO providers/suppliers, and other individuals or entities performing functions or services related to ACO activities must require compliance with the requirements and conditions of this part, including, but not limited to, those specified in the participation agreement with CMS.

§425.212 Changes to program requirements during the agreement period.

(a) An ACO is subject to all regulatory changes that become effective during the agreement period, with the exception of the following program areas, unless otherwise required by statute:

(1) Eligibility requirements concerning the structure and governance of ACOs.

(2) Calculation of sharing rate.

(b) In those instances where there are changes in law or regulations, the ACO will be required to submit to CMS for review and approval, as a supplement to its original application, an explanation detailing how it will modify its processes to address these changes in law or regulations.

(c) If an ACO does not modify its processes to address a change in law or regulations, it will be placed on a CAP. If the ACO fails to effectuate the necessary modifications while under the CAP, the ACO will be terminated from the Shared Savings Program using the procedures in §425.218.

(d) An ACO will be permitted to terminate its agreement, in those instances where Shared Savings Program statutory and regulatory standards are established during the agreement period which the ACO believes will impact its ability to continue to participate in the Shared Savings Program.

[76 FR 67973, Nov. 2, 2011, as amended at 80 FR 32838, June 9, 2015]

§425.214 Managing changes to the ACO during the agreement period.

(a)(1) An ACO must notify CMS within 30 days of any significant change.

(2) An ACO's failure to notify CMS of a significant change does not preclude CMS from determining that the ACO has experienced a significant change.

(3) A ''significant change'' occurs when an ACO is no longer able to meet the eligibility or program requirements of this part.

(b) Upon becoming aware of a significant change or receiving an ACO's notice of a significant change described in paragraph (b) of this section, CMS reevaluates the ACO's eligibility to continue to participate in the Shared Savings Program and may request additional documentation. CMS may make a determination that includes one of the following:

(1) The ACO may continue to operate under the new structure.

(2) The ACO structure is so different from the initially approved ACO that it must terminate its participation agreement and submit a new application for participation.

(3) The ACO no longer meets the eligibility criteria for the program and its participation agreement must be terminated.

(4) CMS and the ACO may mutually decide to terminate the participation agreement.

[76 FR 67973, Nov. 2, 2011, as amended at 80 FR 32838, June 9, 2015]

§425.216 Actions prior to termination.

(a) *Pre-termination actions.* (1) If CMS concludes that termination of an ACO from the Shared Savings Program is warranted, CMS may take one or more of the following actions prior to termination of the ACO from the Shared Savings Program.

(i) Provide a warning notice to the ACO regarding noncompliance with one or more program requirements.

(ii) Request a CAP from the ACO.

(iii) Place the ACO on a special monitoring plan.

(2) Nothing in this part, including the actions set forth in paragraph (a)(1) of this section, negates, diminishes, or otherwise alters the applicability of other laws, rules, or regulations, including, but not limited to, the Sherman Act (15 U.S.C. 1 *et seq.*), the Clayton Act (15 U.S.C. 12), and the Federal Trade Commission Act (15 U.S.C. 45 *et seq.*).

(b) *Corrective action plans.* (1) The ACO must submit a CAP for CMS approval by the deadline indicated on the notice of violation.

(i) The CAP must address what actions the ACO will take to ensure that the ACO, ACO participants, ACO providers/suppliers or other individuals or entities performing functions or services related to the ACO's activities or both correct any deficiencies and comply with all applicable Shared Savings Program requirements.

(ii) The ACO's performance will be monitored and evaluated during and after the CAP process.

(2) CMS may terminate the participation agreement if the ACO fails to submit, obtain approval for, or implement a CAP, or fails to demonstrate improved performance upon completion of the CAP.

[76 FR 67973, Nov. 2, 2011, as amended at 80 FR 32839, June 9, 2015]

§ 425.218 Termination of the participation agreement by CMS.

(a) *General.* CMS may terminate the participation agreement with an ACO when an ACO, the ACO participants, ACO providers/suppliers or other individuals or entities performing functions or services related to ACO activities fail to comply with any of the requirements of the Shared Savings Program under this part.

(b) *Grounds for termination by CMS.* CMS may terminate the participation agreement for reasons including, but not limited to the following:

(1) Non-compliance with eligibility and other requirements described in this part.

(2) The imposition of sanctions or other actions taken against the ACO by an accrediting organization, State, Federal or local government agency leading to inability of the ACO to comply with the requirements under this part.

(3) Violations of any applicable laws, rules, or regulations that are relevant to ACO operations, including, but not limited to, the laws specified at § 425.208(b).

(4) Failure to comply with CMS requests for documentation or other information by the deadline specified by CMS.

(5) Submitting false or fraudulent data or information.

(c) CMS may immediately terminate a participation agreement without taking any of the pre-termination actions set forth in § 425.216.

(d) *Notice of termination by CMS.* CMS notifies an ACO in writing of its decision to terminate the participation agreement.

[76 FR 67973, Nov. 2, 2011, as amended at 80 FR 32839, June 9, 2015; 89 FR 54717, July 1, 2024]

§ 425.220 Termination of the participation agreement by the ACO.

(a) *Notice of termination.* An ACO must provide at least 30 days advance written notice to CMS and its ACO participants of its decision to terminate the participation agreement and the effective date of its termination.

(b) [Reserved]

[76 FR 67973, Nov. 2, 2011, as amended at 80 FR 32839, June 9, 2015; 83 FR 68064, Dec. 31, 2018]

§ 425.221 Close-out procedures and payment consequences of early termination.

(a) *Close-out procedures.* (1) An ACO whose participation agreement has expired or is terminated by CMS under § 425.218 or by the ACO under § 425.220 must implement close-out procedures including but not limited to the following issues in a form and manner and by a deadline specified by CMS:

(i) Notice to ACO participants of termination.

(ii) Record retention.

(iii) Data sharing.

(iv) Quality reporting.

(v) Beneficiary continuity of care.

(2) ACOs that fail to complete close-out procedures in the form and manner and by the deadline specified by CMS will not be eligible to share in savings.

(b) *Payment consequences of early termination.* (1) *Receipt of shared savings.* (i) Except as set forth in paragraph (b)(3)(i) of this section, an ACO that terminates its participation agreement under § 425.220 is eligible to receive shared savings for the performance year during which the termination becomes effective only if all of the following conditions are met:

(A) CMS designates or approves an effective date of termination of the last calendar day of the performance year.

(B) The ACO has completed all closeout procedures by the deadline specified by CMS.

(C) The ACO has satisfied the criteria for sharing in savings for the performance year.

(ii) If the participation agreement is terminated at any time by CMS under § 425.218, the ACO is not eligible to receive shared savings for the performance year during which the termination becomes effective.

(2) *Payment of shared losses.* (i) Except as set forth in paragraph (b)(3)(i) of this section, for performance years beginning before July 1, 2019, an ACO under a two-sided model is not liable for any shared losses if its participation agreement is terminated effective before the last calendar day of a performance year.

(ii) Except as set forth in paragraph (b)(3)(ii) of this section, for performance years beginning on July 1, 2019 and subsequent performance years, an ACO under a two-sided model is liable for a pro-rated share of any shared losses, as calculated in paragraph (b)(2)(iii) of this section, if its participation agreement is terminated effective before the last calendar day of a performance year.

(A) An ACO under a two-sided model that terminates its participation agreement under § 425.220 with an effective date of termination after June 30th of a 12-month performance year is liable for a pro-rated share of any shared losses determined for the performance year during which the termination becomes effective.

(B) An ACO under a two-sided model whose participation agreement is terminated by CMS under § 425.218 is liable for a pro-rated share of any shared losses determined for the performance year during which the termination becomes effective.

(iii) The pro-rated share of losses described in paragraph (b)(2)(ii) of this section is calculated as follows:

(A) In the case of a 12-month performance year, the shared losses incurred during the 12 months of the performance year are multiplied by the quotient equal to the number of months of participation in the program during the performance year, including the month in which the termination was effective, divided by 12.

(B) In the case of a 6-month performance year beginning July 1, 2019, the shared losses incurred during CY 2019 are multiplied by the quotient equal to the number of months of participation in the program during the performance year, including the month in which the termination was effective, divided by 12.

(3) *Exceptions.* (i) An ACO starting a 12-month performance year on January 1, 2019, that terminates its participation agreement with an effective date of termination of June 30, 2019, and that enters a new agreement period beginning on July 1, 2019, is eligible for pro-rated shared savings or liable for pro-rated shared losses for the 6-month period from January 1, 2019, through June 30, 2019, as determined in accordance with § 425.609.

(ii) An ACO under a two-sided model that terminates its participation agreement under § 425.220 during the 6-month performance year beginning July 1, 2019, with an effective date of termination prior to the last calendar day of the performance year is not liable for shared losses incurred during the performance year.

[80 FR 32839, June 9, 2015, as amended at 83 FR 60092, Nov. 23, 2018; 83 FR 68064, Dec. 31, 2018]

§ 425.222 Eligibility to re-enter the program for agreement periods beginning before July 1, 2019.

(a) For purposes of determining the eligibility of a re-entering ACO to enter an agreement period beginning before July 1, 2019, the ACO may participate in the Shared Savings Program again only after the date on

which the term of its original participation agreement would have expired if the ACO had not been terminated.

(b) For purposes of determining the eligibility of a re-entering ACO to enter an agreement period beginning before July 1, 2019, an ACO whose participation agreement was previously terminated must demonstrate in its application that it has corrected the deficiencies that caused it to be terminated from the Shared Savings Program and has processes in place to ensure that it remains in compliance with the terms of the new participation agreement.

(c) For purposes of determining the eligibility of a re-entering ACO to enter an agreement period beginning before July 1, 2019, an ACO whose participation agreement was previously terminated or expired without having been renewed may re-enter the program for a subsequent agreement period.

(1) If the termination occurred less than half way through the agreement period, an ACO that was previously under a one-sided model may reenter the program under the one-sided model or a two-sided model. If the ACO reenters the program under the one-sided model, the ACO will be considered to be in the same agreement period under the one-sided model as it was at the time of termination.

(2) If the termination occurred more than half way through the agreement period, an ACO that was previously in its first agreement period under the one-sided model may reenter the program under the one-sided model or a two-sided model. If the ACO reenters the program under the one-sided model, the ACO will be considered to be in its second agreement period under the one-sided model. An ACO that was previously in its second agreement period under the one-sided model must reenter the program under a two-sided model.

(3) Regardless of the date of termination, an ACO that was previously under a two-sided model may only reapply for participation in a two-sided model.

[76 FR 67973, Nov. 2, 2011, as amended at 80 FR 32839, June 9, 2015; 83 FR 68065, Dec. 31, 2018]

§ 425.224 Application procedures for renewing ACOs and re-entering ACOs.

(a) *General rules.* A renewing ACO or a re-entering ACO may apply to enter a new participation agreement with CMS for participation in the Shared Savings Program.

(1) In order to obtain a determination regarding whether it meets the requirements to participate in the Shared Savings Program, the ACO must submit a complete application in the form and manner and by the deadline specified by CMS.

(2) An ACO executive who has the authority to legally bind the ACO must certify to the best of his or her knowledge, information, and belief that the information contained in the application is accurate, complete, and truthful.

(3) An ACO that seeks to enter a new participation agreement under the Shared Savings Program must agree that CMS can share a copy of its application with the Antitrust Agencies.

(4) The ACO must select a participation option in accordance with the requirements specified in § 425.600. Regardless of the date of termination or expiration of the participation agreement, a renewing ACO or re-entering ACO that was previously under a two-sided model may only reapply for participation in a two-sided model.

(b) *Review of application.* (1) CMS determines whether to approve a renewing ACO's or re-entering ACO's application based on an evaluation of all of the following factors:

(i) Whether the ACO satisfies the criteria for operating under the selected risk track.

(ii) The ACO's history of noncompliance with the requirements of the Shared Savings Program, including, but not limited to, the following factors:

(A) Whether the ACO demonstrated a pattern of failure to meet the quality performance standards or met any of the criteria for termination under § 425.316(c)(1)(ii) or (c)(2)(ii).

(B) For 2 performance years of the ACO's previous agreement period, regardless of whether the years are in consecutive order, whether the average per capita Medicare Parts A and B fee-

for-service expenditures for the ACO's assigned beneficiary population exceeded its updated benchmark by an amount equal to or exceeding either of the following:

(*1*) The ACO's negative MSR, under a one-sided model.

(*2*) The ACO's MLR, under a two-sided model.

(C) Whether the ACO failed to repay shared losses in full within 90 days as required under subpart G of this part for any performance year of the ACO's previous agreement period in a two-sided model.

(D) For an ACO that has participated in a two-sided model authorized under section 1115A of the Act, whether the ACO failed to repay shared losses for any performance year as required under the terms of the ACO's participation agreement for such model.

(iii) Whether the ACO has demonstrated in its application that it has corrected the deficiencies that caused any noncompliance identified in paragraph (b)(1)(ii) of this section to occur, and any other factors that may have caused the ACO to be terminated from the Shared Savings Program, and has processes in place to ensure that it remains in compliance with the terms of the new participation agreement.

(iv) Whether the ACO has established that it is in compliance with the eligibility and other requirements of the Shared Savings Program to enter a new participation agreement, including the ability to repay losses by establishing an adequate repayment mechanism under § 425.204(f), if applicable.

(v) The results of a program integrity screening of the ACO, its ACO participants, and its ACO providers/suppliers (conducted in accordance with § 425.305(a)).

(2) Applications are approved or denied on the basis of the following information:

(i) Information contained in and submitted with the application by a deadline specified by CMS.

(ii) Supplemental information that was submitted by a deadline specified by CMS in response to a CMS request for information.

(iii) Other information available to CMS.

(3) CMS notifies the ACO when supplemental information is required for CMS to make such a determination and provides an opportunity for the ACO to submit the information.

(c) *Notice of determination.* (1) CMS notifies the ACO in writing of its determination to approve or deny the ACO's application.

(2) If CMS denies the application, the notice of determination—

(i) Specifies the reasons for the denial; and

(ii) Informs the ACO of its right to request reconsideration review in accordance with the procedures specified in subpart I of this part.

[80 FR 32839, June 9, 2015, as amended at 83 FR 68065, Dec. 31, 2018; 85 FR 85039, Dec. 28, 2020; 87 FR 70232, Nov. 18, 2022; 89 FR 98566, Dec. 9, 2024]

§ 425.226 Annual participation elections.

(a) *General.* This section applies to ACOs in agreement periods beginning on July 1, 2019, and in subsequent years. Before the start of a performance year, an ACO may make elections related to its participation in the Shared Savings Program, as specified in this section, effective at the start of the applicable performance year and for the remaining years of the agreement period, unless superseded by a later election in accordance with this section.

(1) *Selection of beneficiary assignment methodology.* An ACO may select the assignment methodology that CMS employs for assignment of beneficiaries under subpart E of this part. An ACO may select either of the following:

(i) Preliminary prospective assignment with retrospective reconciliation, as described in § 425.400(a)(2).

(ii) Prospective assignment, as described in § 425.400(a)(3).

(2) *Selection of BASIC track level.* An ACO participating under the BASIC track in the glide path may select a higher level of risk and potential reward, as provided in this section.

(i) An ACO participating under the BASIC track's glide path may elect to transition to a higher level of risk and potential reward within the glide path

than the level of risk and potential reward that the ACO would be automatically transitioned to in the applicable year as specified in § 425.605(d)(1). The automatic transition to higher levels of risk and potential reward within the BASIC track's glide path continues to apply to all subsequent years of the agreement period in the BASIC track.

(ii) An ACO transitioning to a higher level of risk and potential reward under paragraph (a)(2)(i) of this section must meet all requirements to participate under the selected level of performance-based risk, including both of the following:

(A) Establishing an adequate repayment mechanism as specified under § 425.204(f).

(B) Selecting a MSR/MLR from the options specified under § 425.605(b).

(b) *Election procedures.* (1) All annual elections must be made in a form and manner and according to the timeframe established by CMS.

(2) ACO executive who has the authority to legally bind the ACO must certify the elections described in this section.

[83 FR 68066, Dec. 31, 2018]

Subpart D—Program Requirements and Beneficiary Protections

§ 425.300 Compliance plan.

(a) The ACO must have a compliance plan that includes at least the following elements:

(1) A designated compliance official or individual who is not legal counsel to the ACO and reports directly to the ACO's governing body.

(2) Mechanisms for identifying and addressing compliance problems related to the ACO's operations and performance.

(3) A method for employees or contractors of the ACO, ACO participants, ACO providers/suppliers, and other individuals or entities performing functions or services related to ACO activities to anonymously report suspected problems related to the ACO to the compliance officer.

(4) Compliance training for the ACO, the ACO participants, and the ACO providers/suppliers.

(5) A requirement for the ACO to report probable violations of law to an appropriate law enforcement agency.

(b)(1) ACOs that are existing entities may use the current compliance officer if the compliance officer meets the requirements set forth in paragraph (a)(1) of this section.

(2) An ACO's compliance plan must be in compliance with and be updated periodically to reflect changes in law and regulations.

§ 425.302 Program requirements for data submission and certifications.

(a) *Requirements for data submission and certification.* (1) The ACO, its ACO participants, its ACO providers/suppliers or individuals or other entities performing functions or services related to ACO activities must submit all data and information, including data on measures designated by CMS under § 425.500 or § 425.510, as applicable, in a form and manner specified by CMS.

(2) *Certification of data upon submission.* With respect to data and information that are generated or submitted by the ACO, ACO participants, ACO providers/suppliers, or other individuals or entities performing functions or services related to ACO activities, an individual with the authority to legally bind the individual or entity submitting such data or information must certify the accuracy, completeness, and truthfulness of the data and information to the best of his or her knowledge information and belief.

(3) *Annual certification.* At the end of each performance year, an individual with the legal authority to bind the ACO must certify to the best of his or her knowledge, information, and belief—

(i) That the ACO, its ACO participants, its ACO providers/suppliers, and other individuals or entities performing functions or services related to ACO activities are in compliance with program requirements;

(ii) The accuracy, completeness, and truthfulness of all data and information that are generated or submitted by the ACO, ACO participants, ACO providers/suppliers, or other individuals or entities performing functions or

services related to ACO activities, including any quality data or other information or data relied upon by CMS in determining the ACO's eligibility for, and the amount of a shared savings payment or the amount of shared losses or other monies owed to CMS; and

(iii) For performance years starting on January 1, 2019 through 2024, the percentage of eligible clinicians participating in the ACO that use CEHRT to document and communicate clinical care to their patients or other health care providers meets or exceeds the applicable percentage specified by CMS at § 425.506(f).

(iv) That the ACO has moved all advance investment payments received during that performance year into a designated advance investment payments account established under § 425.630(e) and the advance investment payments have been dispersed only for allowable uses.

(b) [Reserved]

[76 FR 67973, Nov. 2, 2011, as amended at 83 FR 60092, Nov. 23, 2018; 85 FR 85039, Dec. 28, 2020; 87 FR 70232, Nov. 18, 2022; 88 FR 79544, Nov. 16, 2023]

§ 425.304 Beneficiary incentives.

(a) *General.* (1) Except as set forth in this section, or as otherwise permitted by law, ACOs, ACO participants, ACO providers/suppliers, and other individuals or entities performing functions or services related to ACO activities are prohibited from providing gifts or other remuneration to beneficiaries as inducements for receiving items or services from or remaining in, an ACO or with ACO providers/suppliers in a particular ACO or receiving items or services from ACO participants or ACO providers/suppliers.

(2) Nothing in this section shall be construed as prohibiting an ACO from using shared savings received under this part to cover the cost of an in-kind item or service or incentive payment provided to a beneficiary under paragraph (b) or (c) of this section.

(b) *In-kind incentives.* ACOs, ACO participants, ACO providers/suppliers, and other individuals or entities performing functions or services related to ACO activities may provide in-kind items or services to Medicare fee-for-service beneficiaries if all of the following conditions are satisfied:

(1) There is a reasonable connection between the items and services and the medical care of the beneficiary.

(2) The items or services are preventive care items or services or advance a clinical goal for the beneficiary, including adherence to a treatment regime, adherence to a drug regime, adherence to a follow-up care plan, or management of a chronic disease or condition.

(3) The in-kind item or service is not a Medicare-covered item or service for the beneficiary on the date the in-kind item or service is furnished to the beneficiary.

(c) *Monetary incentives*—(1) *General.* For performance years beginning on July 1, 2019 and for subsequent performance years, an ACO that is participating under Track 2, Levels C, D, or E of the BASIC track, or the ENHANCED track may, in accordance with this section, establish a beneficiary incentive program to provide monetary incentive payments to Medicare fee-for-service beneficiaries who receive a qualifying service.

(2) *Application procedures.* (i) To establish or reestablish a beneficiary incentive program, an ACO must submit a complete application in the form and manner and by a deadline specified by CMS.

(ii) CMS evaluates an ACO's application to determine whether the ACO satisfies the requirements of this section, and approves or denies the application.

(iii) If an ACO wishes to make a material change to its CMS-approved beneficiary incentive program, the ACO must submit a description of the material change to CMS in a form and manner and by a deadline specified by CMS. CMS will promptly evaluate the proposed material change and approve or reject it.

(3) *Beneficiary incentive program requirements.* An ACO must begin to operate its approved beneficiary incentive program beginning on July 1, 2019 or January 1 of the relevant performance year.

(i) *Duration.* (A) Subject to the termination provision at paragraph (c)(7) of this section, an ACO must operate its

approved beneficiary incentive program for an initial period of 18 months in the case of an ACO approved to operate a beneficiary incentive program beginning on July 1, 2019, or 12 months in the case of an ACO approved to operate a beneficiary incentive program beginning on January 1 of a performance year.

(B) For each consecutive year that an ACO wishes to operate its beneficiary incentive program after the CMS-approved initial period, it must certify all of the following by a deadline specified by CMS:

(*1*) Its intent to continue to operate the beneficiary incentive program for the entirety of the relevant performance year.

(*2*) That the beneficiary incentive program meets all applicable requirements.

(ii) *Beneficiary eligibility.* A fee-for-service beneficiary is eligible to receive an incentive payment under a beneficiary incentive program if the beneficiary is assigned to the ACO through either of the following:

(A) Preliminary prospective assignment, as described in § 425.400(a)(2).

(B) Prospective assignment, as described in § 425.400(a)(3).

(iii) *Qualifying service.* For purposes of this section, a qualifying service is a primary care service (as defined in § 425.20) with respect to which coinsurance applies under Part B, if the service is furnished through an ACO by one of the following:

(A) An ACO professional who has a primary care specialty designation included in the definition of primary care physician under § 425.20.

(B) An ACO professional who is a physician assistant, nurse practitioner, or certified nurse specialist.

(C) A FQHC or RHC.

(iv) *Incentive payments.* (A) An ACO that establishes a beneficiary incentive program must furnish an incentive payment for each qualifying service furnished to a beneficiary described in paragraph (c)(3)(ii) of this section in accordance with this section.

(B) Each incentive payment made by an ACO under a beneficiary incentive program must satisfy all of the following conditions:

(*1*) The incentive payment is in the form of a check, debit card, or a traceable cash equivalent.

(*2*) The value of the incentive payment does not exceed $20, as adjusted annually by the percentage increase in the consumer price index for all urban consumers (United States city average) for the 12-month period ending with June of the previous year, rounded to the nearest whole dollar amount.

(*3*) The incentive payment is provided by the ACO to the beneficiary no later than 30 days after a qualifying service is furnished.

(C) An ACO must furnish incentive payments in the same amount to each eligible Medicare fee-for-service beneficiary without regard to enrollment of such beneficiary in a Medicare supplemental policy (described in section 1882(g)(1) of the Act), in a State Medicaid plan under title XIX or a waiver of such a plan, or in any other health insurance policy or health benefit plan.

(4) *Program integrity requirements*—(i) *Record retention.* An ACO that establishes a beneficiary incentive program must maintain records related to the beneficiary incentive program that include the following:

(A) Identification of each beneficiary that received an incentive payment, including beneficiary name and HICN or Medicare beneficiary identifier.

(B) The type and amount of each incentive payment made to each beneficiary.

(C) The date each beneficiary received a qualifying service, the corresponding HCPCS code for the qualifying service, and identification of the ACO provider/supplier that furnished the qualifying service.

(D) The date the ACO provided each incentive payment to each beneficiary.

(ii) *Source of funding.* (A) An ACO must not use funds from any entity or organization outside of the ACO to establish or operate a beneficiary incentive program.

(B) An ACO must not directly, through insurance, or otherwise, bill or otherwise shift the cost of establishing or operating a beneficiary incentive program to a Federal health care program.

(iii) *Beneficiary notifications.* An ACO or its ACO participants shall notify assigned beneficiaries of the availability of the beneficiary incentive program in accordance with § 425.312(b).

(iv) *Marketing prohibition.* Except for the beneficiary notifications required under this section, the beneficiary incentive program is not the subject of marketing materials and activities, including but not limited to, an advertisement or solicitation to a beneficiary or any potential patient whose care is paid for in whole or in part by a Federal health care program (as defined at 42 U.S.C. 1320a–7b(f)).

(5) *Effect on program calculations.* CMS disregards incentive payments made by an ACO under paragraph (c) of this section in calculating an ACO's benchmarks, estimated average per capita Medicare expenditures, and shared savings and losses.

(6) *Income exemptions.* Incentive payments made under a beneficiary incentive program are not considered income or resources or otherwise taken into account for purposes of either of the following:

(i) Determining eligibility for benefits or assistance (or the amount or extent of benefits or assistance) under any Federal program or under any State or local program financed in whole or in part with Federal funds.

(ii) Any Federal or State laws relating to taxation.

(7) *Termination.* CMS may require an ACO to terminate its beneficiary incentive program at any time for either of the following:

(i) Failure to comply with the requirements of this section.

(ii) Any of the grounds for ACO termination set forth in § 425.218(b).

(d) *Application of the CMS-sponsored model patient incentives safe harbor.* CMS has determined that the Federal anti-kickback statute safe harbor for CMS-sponsored model patient incentives (§ 1001.952(ii)(2) of this title) is available to protect remuneration furnished in the prepaid shared savings option of the Shared Savings Program in the form of direct beneficiary services that meets all safe harbor requirements set forth in § 1001.952(ii) of this title.

[83 FR 68066, Dec. 31, 2018, as amended at 89 FR 98566, Dec. 9, 2024]

§ 425.305 Other program safeguards.

(a) *Screening of ACO applicants.* (1) ACOs, ACO participants, and ACO providers/suppliers are reviewed during the Shared Savings Program application process and periodically thereafter with regard to their program integrity history, including any history of Medicare program exclusions or other sanctions and affiliations with individuals or entities that have a history of program integrity issues. Program integrity history issues include, but are not limited to, a history of Medicare program exclusions or other sanctions, noncompliance with the requirements of the Shared Savings Program, or violations of laws specified at § 425.208(b).

(2) ACOs, ACO participants, or ACO providers/suppliers whose screening reveals a history of program integrity issues or affiliations with individuals or entities that have a history of program integrity issues may be subject to denial of their Shared Savings Program applications or the imposition of additional safeguards or assurances against program integrity risks.

(b) *Prohibition on certain required referrals and cost shifting.* ACOs, ACO participants, and ACO providers/suppliers are prohibited from doing the following:

(1) Conditioning the participation of ACO participants, ACO providers/suppliers, other individuals or entities performing functions or services related to ACO activities in the ACO on referrals of Federal health care program business that the ACO, its ACO participants, or ACO providers/suppliers or other individuals or entities performing functions or services related to ACO activities know or should know is being (or would be) provided to beneficiaries who are not assigned to the ACO.

(2) Requiring that beneficiaries be referred only to ACO participants or ACO providers/suppliers within the ACO or to any other provider or supplier, except that the prohibition does not apply to referrals made by employees or contractors who are operating within the scope of their employment or contractual arrangement to the employer or contracting entity, provided

that the employees and contractors remain free to make referrals without restriction or limitation if the beneficiary expresses a preference for a different provider, practitioner, or supplier; the beneficiary's insurer determines the provider, practitioner, or supplier; or the referral is not in the beneficiary's best medical interests in the judgment of the referring party.

[83 FR 68067, Dec. 31, 2018, as amended at 89 FR 54717, July 1, 2024]

§ 425.306 Participant agreement and exclusivity of ACO participants.

(a) Each ACO participant must commit to the term of the participation agreement and sign an ACO participant agreement that complies with the requirements of this part.

(b)(1) Except as specified in paragraph (b)(2) of this section, ACO participants are not required to be exclusive to one Shared Savings Program ACO.

(2) Each ACO participant that submits claims for services used to determine the ACO's assigned population under subpart E of this part must be exclusive to one Shared Savings Program ACO. If, during a benchmark or performance year (including the 3-month claims runout for such benchmark or performance year), an ACO participant that participates in more than one ACO submits claims for services used in assignment under subpart E of this part, then:

(i) CMS will not consider any services billed through the TIN of the ACO participant when performing assignment under subpart E of this part for the benchmark or performance year.

(ii) The ACO may be subject to the pre-termination actions set forth in § 425.216, termination under § 425.218, or both.

[80 FR 32840, June 9, 2015, as amended at 82 FR 53369, Nov. 15, 2017]

§ 425.308 Public reporting and transparency.

(a) *ACO public reporting Web page.* Each ACO must create and maintain a dedicated Web page on which it publicly reports the information set forth in paragraph (b) of this section. The ACO must report the address of such Web page to CMS in a form and manner specified by CMS and must notify CMS of changes to the web address in the form and manner specified by CMS.

(b) *Information to be reported.* The ACO must publicly report the following information in a standardized format specified by CMS:

(1) Name and location.

(2) Primary contact.

(3) Organizational information, including all of the following:

(i) Identification of ACO participants.

(ii) Identification of participants in joint ventures between ACO professionals and hospitals.

(iii) Identification of the members of its governing body.

(iv) Identification of key clinical and administrative leadership.

(v) Identification of associated committees and committee leadership.

(vi) Identification of the types of ACO participants or combinations of ACO participants (as listed in § 425.102(a)) that formed the ACO.

(4) Shared savings and losses information, including the following:

(i) Amount of any payment of shared savings received by the ACO or shared losses owed to CMS.

(ii) Total proportion of shared savings invested in infrastructure, redesigned care processes and other resources required to support the three-part aim goals of better health for populations, better care for individuals and lower growth in expenditures, including the proportion distributed among ACO participants.

(5) The ACO's performance on all quality measures.

(6) Use of payment rule waivers under § 425.612, if applicable, or telehealth services under § 425.613, if applicable, or both.

(7) Information about a beneficiary incentive program established under § 425.304(c), if applicable, including the following, for each performance year:

(i) Total number of beneficiaries who received an incentive payment.

(ii) Total number of incentive payments furnished.

(iii) HCPCS codes associated with any qualifying service for which an incentive payment was furnished.

(iv) Total value of all incentive payments furnished.

(v) Total of each type of incentive payment (for example, check or debit card) furnished.

(8) Information, updated annually about the ACO's use of advance investment payments under §425.630, for each performance year, including the following:

(i) The ACO's spend plan.

(ii) The total amount of any advance investment payments received from CMS.

(iii) An itemization of how advance investment payments were spent during the year, including expenditure categories, the dollar amounts spent on the various categories, any changes to the spend plan submitted under §425.630(d), and such other information as may be specified by CMS.

(9) For performance year 2025 and subsequent performance years, the total number of ACO participants, ACO providers/suppliers, and ACO professionals that are MIPS eligible clinicians, Qualifying APM Participants (QPs), or Partial Qualifying APM Participants (Partial QPs) (each as defined at §414.1305 of this chapter) that earn a MIPS performance category score for the MIPS Promoting Interoperability performance category as set forth in §425.507 that is comprised of the following—

(i) The number of ACO participants, ACO providers/suppliers, and ACO professionals that meet the requirements of §425.507(a) and are not excluded under §425.507(b) for the applicable performance year; and

(ii) The number of ACO participants, ACO providers/suppliers, and ACO professionals that are excluded under §425.507(b) that voluntarily reported and received a MIPS Promoting Interoperability performance category score for the applicable performance year.

(10) Information updated annually about the ACO's use of prepaid shared savings under §425.640, for each performance year, including the following:

(i) Total amount of any prepaid shared savings received from CMS.

(ii) The ACO's spend plan.

(iii) An itemization of how prepaid shared savings were spent during the year, including expenditure categories, the dollar amounts spent on the various categories, information about which groups of beneficiaries received direct beneficiary services that were purchased with prepaid shared savings and investments that were made in the ACO with prepaid shared savings, how these direct beneficiary services were provided to beneficiaries and how the direct beneficiary services and investments supported the care of beneficiaries, any changes to the spend plan as submitted under §425.640(d)(2) (if applicable), and such other information as may be specified by CMS.

(c) *Approval of public reporting information.* Information reported on an ACO's public reporting Web page in compliance with the requirements of the standardized format specified by CMS is not subject to marketing review and approval under §425.310.

(d) *Public reporting by CMS.* CMS may publicly report ACO-specific information, including but not limited to the ACO public reporting Web page address and the information required to be publicly reported under paragraph (b) of this section.

[80 FR 32840, June 9, 2015, as amended at 83 FR 68068, Dec. 31, 2018; 87 FR 70232, Nov. 18, 2022; 88 FR 79544, Nov. 16, 2023; 89 FR 98566, Dec. 9, 2024]

§425.310 Marketing requirements.

(a) *Requirements.* Marketing materials and activities must:

(1) Use template language developed by CMS, if available.

(2) Not be used in a discriminatory manner or for discriminatory purposes.

(3) Comply with §425.304 regarding beneficiary incentives.

(4) Not be materially inaccurate or misleading.

(b) *Monitoring.* (1) CMS may request the submission of marketing materials and activities at any time. If CMS determines that the marketing materials and activities do not comply with the requirements of paragraph (a) of this section, CMS will issue written notice of disapproval to the ACO.

(2) The ACO shall discontinue, and require its ACO participants, ACO providers/suppliers, and other individuals or entities performing functions or services related to ACO activities to discontinue, use of any marketing materials or activities disapproved by CMS.

(c) *Sanctions.* Failure to comply with this section will subject the ACO to the penalties set forth in § 425.216, termination under § 425.218, or both.

[87 FR 70233, Nov. 18, 2022]

§ 425.312 Beneficiary notifications.

(a) *Notifications to fee-for-service beneficiaries.* (1) An ACO shall ensure that Medicare fee-for-service beneficiaries are notified about all of the following in the manner set forth in paragraph (a)(2) of this section:

(i) That each ACO participant and its ACO providers/suppliers are participating in the Shared Savings Program.

(ii) The beneficiary's opportunity to decline claims data sharing under § 425.708.

(iii) Beginning July 1, 2019, the beneficiary's ability to, and the process by which, he or she may identify or change identification of the individual he or she designated for purposes of voluntary alignment (as described in § 425.402(e)).

(2) Notification of the information specified in paragraph (a)(1) of this section must be carried out through the following methods:

(i) By an ACO participant posting signs in all of its facilities.

(ii) By an ACO participant making standardized written notices available upon request in all settings in which beneficiaries receive primary care services.

(iii) In the case of an ACO that has selected preliminary prospective assignment with retrospective reconciliation, by the ACO or ACO participant providing each beneficiary who received at least one primary care service during the assignment window or applicable expanded window for assignment (as defined in § 425.20) from a physician who is an ACO professional in the ACO and who is a primary care physician as defined under § 425.20 or who has one of the primary specialty designations included in § 425.402(c), a FQHC or RHC that is part of the ACO, or an ACO professional in the ACO whom the beneficiary designated as responsible for coordinating their overall care under § 425.402(e) with a standardized written notice at least once during an agreement period in the form and manner specified by CMS. The standardized written notice must be furnished to all of these beneficiaries prior to or at the first primary care service visit during the first performance year in which the beneficiary receives a primary care service from an ACO participant.

(iv) In the case of an ACO that has selected prospective assignment, by the ACO or ACO participant providing each prospectively assigned beneficiary with a standardized written notice at least once during an agreement period in the form and manner specified by CMS. The standardized written notice must be furnished during the performance year for which the beneficiary is prospectively assigned to the ACO.

(v) Following the provision of the standardized written notice to a beneficiary, as specified in paragraphs (a)(2)(iii) and (iv) of this section, the ACO or ACO participant must provide a verbal or written follow-up communication to the beneficiary.

(A) The follow-up communication must occur no later than 180 days from the date the standardized written notice was provided.

(B) The ACO must retain a record of all beneficiaries receiving the follow-up communication, and the form and manner in which the communication was made available to the beneficiary. The ACO must make these records available to CMS upon request.

(b) *Beneficiary incentive program notifications.* (1) Beginning July 1, 2019, an ACO that operates a beneficiary incentive program under § 425.304(c) shall ensure that the ACO or its ACO participants notify assigned beneficiaries of the availability of the beneficiary incentive program, including a description of the qualifying services for which an assigned beneficiary is eligible to receive an incentive payment (as described in § 425.304(c)).

(2) Notification of the information specified in paragraph (b)(1) of this section must be carried out by an ACO or ACO participant during each relevant performance year by providing each assigned beneficiary with a standardized written notice prior to or at the first primary care visit of the performance year in the form and manner specified by CMS.

(c) The beneficiary notifications under this section meet the definition of marketing materials and activities under §425.20 and therefore must meet all applicable marketing requirements described in §425.310.

[76 FR 67973, Nov. 2, 2011, as amended at 80 FR 32840, June 9, 2015; 83 FR 68068, Dec. 31, 2018; 86 FR 65684, Nov. 19, 2021; 87 FR 70233, Nov. 18, 2022; 89 FR 98566, Dec. 9, 2024]

§425.314 Audits and record retention.

(a) *Right to audit.* The ACO must agree, and must require its ACO participants, ACO providers/suppliers, and other individuals or entities performing functions or services related to ACO activities to agree, that the CMS, DHHS, the Comptroller General, the Federal Government or their designees have the right to audit, inspect, investigate, and evaluate any books, contracts, records, documents and other evidence of the ACO, ACO participants, and ACO providers/suppliers, and other individuals or entities performing functions or services related to ACO activities that pertain to all of the following:

(1) The ACO's compliance with Shared Savings Program.

(2) The quality of services performed and determination of amount due to or from CMS under the participation agreement.

(3) The ability of the ACO to bear the risk of potential losses and to repay any losses to CMS.

(4) The ACO's operation of a beneficiary incentive program.

(b) *Maintenance of records.* An ACO must agree, and must require its ACO participants, ACO providers/suppliers, and other individuals or entities performing functions or services related to ACO activities to agree to the following:

(1) To maintain and give CMS, DHHS, the Comptroller General, the Federal Government or their designees access to all books, contracts, records, documents, and other evidence (including data related to Medicare utilization and costs, quality performance measures, shared savings distributions, information related to operation of a beneficiary incentive program, and other financial arrangements related to ACO activities) sufficient to enable the audit, evaluation, investigation, and inspection of the ACO's compliance with program requirements, quality of services performed, right to any shared savings payment, or obligation to repay losses, ability to bear the risk of potential losses, and ability to repay any losses to CMS.

(2) To maintain such books, contracts, records, documents, and other evidence for a period of 10 years from the final date of the agreement period or from the date of completion of any audit, evaluation, or inspection, whichever is later, unless—

(i) CMS determines there is a special need to retain a particular record or group of records for a longer period and notifies the ACO at least 30 days before the normal disposition date; or

(ii) There has been a termination, dispute, or allegation of fraud or similar fault against the ACO, its ACO participants, its ACO providers/suppliers, or other individuals or entities performing functions or services related to ACO activities, in which case ACOs must retain records for an additional 6 years from the date of any resulting final resolution of the termination, dispute, or allegation of fraud or similar fault.

(c) *Responsibility of the ACO.* Notwithstanding any arrangements between or among an ACO, ACO participants, ACO providers/suppliers, and other individuals or entities performing functions or services related to ACO activities, the ACO must have ultimate responsibility for adhering to and otherwise fully complying with all terms and conditions of its participation agreement with CMS, including the requirements set forth in this section.

(d) *OIG authority.* None of the provisions of this part limit or restrict OIG's authority to audit, evaluate, investigate, or inspect the ACO, its ACO participants, its ACO providers/suppliers and other individuals or entities performing functions or services related to ACO activities.

[76 FR 67973, Nov. 2, 2011, as amended at 80 FR 32840, June 9, 2015; 81 FR 38013, June 10, 2016; 83 FR 68068, Dec. 31, 2018]

§ 425.315 Reopening determinations of ACO shared savings or shared losses to correct financial reconciliation calculations.

(a) *Reopenings.* (1) If CMS determines that the amount of shared savings due to the ACO or the amount of shared losses owed by the ACO has been calculated in error, CMS may reopen the initial determination or a final agency determination under subpart I of this part and issue a revised initial determination:

(i) At any time in the case of fraud or similar fault as defined in § 405.902; or

(ii) Not later than 4 years after the date of the notification to the ACO of the initial determination of savings or losses for the relevant performance year under § 425.604(f), § 425.605(e), § 425.606(h), § 425.609(e) or § 425.610(h), for good cause.

(2) Good cause may be established when—

(i) There is new and material evidence that was not available or known at the time of the payment determination and may result in a different conclusion; or

(ii) The evidence that was considered in making the payment determination clearly shows on its face that an obvious error was made at the time of the payment determination.

(3) A change of legal interpretation or policy by CMS in a regulation, CMS ruling or CMS general instruction, whether made in response to judicial precedent or otherwise, is not a basis for reopening a payment determination under this section.

(4) CMS has the sole discretion to determine whether to reopen a payment determination under this section.

(b) *Reopening requests.* An ACO may request a reopening in a form and manner specified by CMS and consistent with the timeframes for a reopening specified in paragraphs (a)(1)(i) and (ii) of this section.

[81 FR 38013, June 10, 2016, as amended at 83 FR 60092, Nov. 23, 2018; 83 FR 68068, Dec. 31, 2018; 89 FR 98567, Dec. 9, 2024]

§ 425.316 Monitoring of ACOs.

(a) *General rule.* (1) In order to ensure that the ACO continues to satisfy the eligibility and program requirements under this part, CMS monitors and assesses the performance of ACOs, their ACO participants, and ACO providers/suppliers.

(2) CMS employs a range of methods to monitor and assess the performance of ACOs, ACO participants, and ACO providers/suppliers, including but not limited to any of the following, as appropriate:

(i) Analysis of specific financial and quality measurement data reported by the ACO as well as aggregate annual and quarterly reports.

(ii) Analysis of beneficiary and provider complaints.

(iii) Audits (including, for example, analysis of claims, chart review (medical record), beneficiary survey reviews, coding audits, on-site compliance reviews).

(b) *Monitoring ACO avoidance of at-risk beneficiaries.* (1) CMS may use one or more of the methods described in paragraph (a)(2) of this section (as appropriate) to identify trends and patterns suggesting that an ACO has avoided at-risk beneficiaries. The results of these analyses may subsequently require further investigation and follow-up with beneficiaries or the ACO and its ACO participants, ACO providers/suppliers, or other individuals or entities performing functions or services related to the ACO's activities, in order to substantiate cases of beneficiary avoidance.

(2)(i) CMS, at its sole discretion, may take any of the pre-termination actions set forth in § 425.216(a)(1) or immediately terminate, if it determines that an ACO, its ACO participants, any ACO providers/suppliers, or other individuals or entities performing functions or services related to the ACO's activities avoids at-risk beneficiaries.

(ii) If CMS requires the ACO to submit a CAP, the ACO will—

(A) Submit a CAP that addresses actions the ACO will take to ensure that the ACO, ACO participants, ACO providers/suppliers, or other individuals or entities performing functions or services related to the ACO's activities cease avoidance of at-risk beneficiaries.

(B) Not receive any shared savings payments during the time it is under the CAP.

(C) Not be eligible to receive shared savings for the performance year attributable to the time that necessitated the CAP (the time period during which the ACO avoided at risk beneficiaries).

(iii) CMS will re-evaluate the ACO during and after the CAP implementation period to determine if the ACO has continued to avoid at-risk beneficiaries. The ACO will be terminated if CMS determines that the ACO has continued to avoid at-risk beneficiaries during or after the CAP implementation period.

(c) *Monitoring ACO compliance with quality performance standards.* To identify ACOs that are not meeting the quality performance standards, CMS will review an ACO's submission of quality measurement data under §425.500 or §425.512. CMS may request additional documentation from an ACO, ACO participants, or ACO providers/suppliers, as appropriate. If an ACO does not meet quality performance standards or fails to report on one or more quality measures, CMS will take the following actions:

(1) *For performance years (or a performance period) beginning on or before January 1, 2020.* (i) The ACO may be given a warning for the first time it fails to meet the minimum attainment level on at least 70 percent of the measures, as determined under §425.502, in one or more domains and may be subject to a CAP. CMS may forgo the issuance of the warning letter depending on the nature and severity of the noncompliance and instead subject the ACO to actions set forth at §425.216 or immediately terminate the ACO's participation agreement under §425.218.

(ii) The ACO's compliance with the quality performance standards will be re-evaluated the following year. If the ACO continues to fail to meet the quality performance standard in the following year, the agreement will be terminated.

(iii) An ACO will not qualify to share in savings in any year it fails to report accurately, completely, and timely on the quality performance measures.

(2) *For performance years beginning on or after January 1, 2021.* (i) If the ACO fails to meet the quality performance standard, CMS may take one or more of the actions prior to termination specified in §425.216. Depending on the nature and severity of the noncompliance, CMS may forgo pre-termination actions and may immediately terminate the ACO's participation agreement under §425.218.

(ii) CMS will terminate an ACO's participation agreement under any of the following circumstances:

(A) The ACO fails to meet the quality performance standard for 2 consecutive performance years within an agreement period.

(B) The ACO fails to meet the quality performance standard for any 3 performance years within an agreement period, regardless of whether the years are in consecutive order.

(C) A renewing ACO or re-entering ACO fails to meet the quality performance standard for the last performance year of the ACO's previous agreement period and this occurrence was either the second consecutive performance year of failed quality performance or the third nonconsecutive performance year of failed quality performance during the previous agreement period.

(D) A renewing ACO or re-entering ACO fails to meet the quality performance standard for 2 consecutive performance years across 2 agreement periods, specifically the last performance year of the ACO's previous agreement period and the first performance year of the ACO's new agreement period.

(d) *Monitoring ACO financial performance.* (1) For performance years beginning on July 1, 2019 and subsequent performance years, CMS determines whether the Medicare Parts A and B fee-for-service expenditures for the ACO's assigned beneficiaries for the performance year exceed the ACO's updated benchmark by an amount equal to or exceeding either the ACO's negative MSR under a one-sided model, or the ACO's MLR under a two-sided model.

(2) If the Medicare Parts A and B fee-for-service expenditures for the ACO's assigned beneficiaries for the performance year exceed the ACO's updated benchmark as specified in paragraph (d)(1) of this section, CMS may take any of the pre-termination actions set forth in §425.216.

(3) If the Medicare Parts A and B fee-for-service expenditures for the ACO's assigned beneficiaries for the performance year exceed the ACO's updated benchmark as specified in paragraph (d)(1) of this section for another performance year of the agreement period, CMS may immediately or with advance notice terminate the ACO's participation agreement under § 425.218.

(e) *Monitoring ACO eligibility for advance investment payments.* (1) CMS monitors an ACO that receives advance investment payments pursuant to § 425.630 for changes in its ACO participants that may cause the ACO to no longer meet the standards specified in § 425.630(b)(3) and (4).

(2) If CMS determines that an ACO participating in advance investment payments became experienced with performance-based risk Medicare ACO initiatives during its first or second performance year of its agreement period or that the ACO became a high revenue ACO during any performance year of its agreement period, CMS—

(i) Will cease payment of advance investment payments no later than the quarter after the ACO became experienced with performance-based risk Medicare ACO initiatives or became a high revenue ACO.

(ii) May take compliance action as specified in §§ 425.216 and 425.218.

(3) If an ACO remains an ACO experienced with performance-based risk Medicare ACO initiatives or a high revenue ACO after a deadline specified by CMS pursuant to compliance action under this section, the ACO must repay all advance investment payments it received. CMS will provide written notification to the ACO of the amount due and the ACO must pay such amount no later than 90 days after the receipt of such notification.

(f) *Monitoring ACO eligibility for and use of prepaid shared savings.* (1) CMS monitors an ACO that receives prepaid shared savings pursuant to § 425.640 to ensure ACO compliance with § 425.640(e) and to determine whether it would be appropriate to withhold or terminate an ACO's prepaid shared savings under § 425.640(h).

(2) If CMS determines that an ACO receiving prepaid shared savings is using the funds for a prohibited use under § 425.640(e)(2), fails to spend the funding in accordance with § 425.640(e)(1)(i) and (ii), or spends more than 50 percent of the estimated annual payment amount on staffing and healthcare infrastructure CMS:

(i) Will require the ACO to reallocate the funding as permitted by § 425.640(e) and submit an updated spend plan demonstrating the reallocation by a deadline specified by CMS.

(ii) May take compliance action as specified in §§ 425.216, 425.218, and 425.640(h)(1).

(3) If an ACO fails to reallocate prepaid shared savings it received as described in paragraph (f)(2)(i) of this section by a deadline specified by CMS, the ACO must repay all prepaid shared savings it received and may be subject to compliance action as specified in §§ 425.216 and 425.218. CMS will provide written notification to the ACO of the amount due and the ACO must pay such amount no later than 90 days after the receipt of such notification.

[76 FR 67973, Nov. 2, 2011, as amended at 80 FR 32840, June 9, 2015; 81 FR 80559, Nov. 15, 2016; 83 FR 68069, Dec. 31, 2018; 85 FR 85039, Dec. 28, 2020; 87 FR 70233, Nov. 18, 2022; 88 FR 79544, Nov. 16, 2023; 89 FR 98567, Dec. 9, 2024]

Subpart E—Assignment of Beneficiaries

§ 425.400 General.

(a)(1) *General.* CMS employs the assignment methodology described in § 425.402 and § 425.404 for purposes of benchmarking, preliminary prospective assignment (including quarterly updates), retrospective reconciliation, and prospective assignment.

(i) A Medicare fee-for-service beneficiary is assigned to an ACO if the—

(A) Beneficiary meets the eligibility criteria under § 425.401(a); and

(B) Beneficiary's utilization of primary care services meets the criteria established under the assignment methodology described in § 425.402 and § 425.404.

(ii) CMS applies a step-wise process based on the beneficiary's utilization of primary care services provided under Title XVIII by a physician who is an ACO professional during each performance year for which shared savings are to be determined and, with respect to

ACOs participating in a 6-month performance year during CY 2019, during the entirety of CY 2019 as specified in § 425.609.

(2) *Preliminary prospective assignment with retrospective reconciliation.* (i) Medicare assigns beneficiaries in a preliminary manner at the beginning of a performance year based on most recent data available.

(ii) Assignment will be updated quarterly based on the most recent 12 or 24 months of data, as applicable, under the methodology described in §§ 425.402 and 425.404.

(iii) In determining final assignment for a benchmark or performance year, CMS will exclude any services furnished during the benchmark or performance year that are billed through the TIN of an ACO participant that is an ACO participant in more than one ACO.

(3) *Prospective assignment.* (i) Medicare fee-for-service beneficiaries are prospectively assigned to an ACO at the beginning of each benchmark or performance year based on the beneficiary's use of primary care services in the most recent 12 or 24 months, as applicable, for which data are available, using the assignment methodology described in §§ 425.402 and 425.404.

(ii) Beneficiaries that are prospectively assigned to an ACO under paragraph (a)(3)(i) of this section will remain assigned to the ACO at the end of the benchmark or performance year unless they meet any of the exclusion criteria under § 425.401(b).

(4) *Assignment methodology applied to ACO.* (i) For agreement periods beginning before July 1, 2019, the applicable assignment methodology is determined based on track as specified in § 425.600(a).

(A) Preliminary prospective assignment with retrospective reconciliation as described in paragraph (a)(2) of this section applies to Track 1 and Track 2 ACOs.

(B) Prospective assignment as described in paragraph (a)(3) of this section applies to Track 3 ACOs.

(ii) For agreement periods beginning on July 1, 2019 and in subsequent years, an ACO may select the assignment methodology that CMS employs for assignment of beneficiaries under this subpart.

(A) An ACO may select either of the following:

(*1*) Preliminary prospective assignment with retrospective reconciliation, as described in paragraph (a)(2) of this section.

(*2*) Prospective assignment, as described in paragraph (a)(3) of this section.

(B) This selection is made prior to the start of each agreement period, and may be modified prior to the start of each performance year as specified in § 425.226.

(b) Beneficiary assignment to an ACO is for purposes of determining the population of Medicare fee-for-service beneficiaries for whose care the ACO is accountable under subpart F of this part, and for determining whether an ACO has achieved savings under subpart G of this part, and in no way diminishes or restricts the rights of beneficiaries assigned to an ACO to exercise free choice in determining where to receive health care services.

(c) Primary care services for purposes of assigning beneficiaries are identified by selected HCPCS/CPT codes, or revenue center codes.

(1) Primary care service codes are as follows:

(i) For performance years 2012 through 2015:

(A) CPT codes:

(*1*) 99201 through 99215.

(*2*) 99304 through 99340.

(*3*) 99341 through 99350.

(B) HCPCS codes G0402 (the code for the Welcome to Medicare visit) and G0438 and G0439 (codes for the annual wellness visits).

(C) Revenue center codes 0521, 0522, 0524, and 0525 submitted by FQHCs (for services furnished prior to January 1, 2011), or by RHCs.

(ii) For performance year 2016 as follows:

(A) CPT codes:

(*1*) 99201 through 99215.

(*2*) 99304 through 99340.

(*3*) 99341 through 99350.

(*4*) 99495, 99496, and 99490.

(B) HCPCS codes:

(*1*) G0402 (the code for the Welcome to Medicare visit) and

(*2*) G0438 and G0439 (codes for the annual wellness visits).

(*3*) G0463 for services furnished in ETA hospitals.

(C) Revenue center codes 0521, 0522, 0524, and 0525 submitted by FQHCs (for services furnished prior to January 1, 2011), or by RHCs.

(iii) For performance years 2017 and 2018 as follows:

(A) CPT codes:

(*1*) 99201 through 99215.

(*2*) 99304 through 99318 (excluding claims including the POS 31 modifier).

(*3*) 99319 through 99340.

(*4*) 99341 through 99350.

(*5*) 99495, 99496, and 99490.

(B) HCPCS Codes:

(*1*) G0402 (the code for the Welcome to Medicare visit) and

(*2*) G0438 and G0439 (codes for the annual wellness visits).

(*3*) G0463 for services furnished in ETA hospitals.

(C) Revenue center codes 0521, 0522, 0524, and 0525 submitted by FQHCs (for services furnished prior to January 1, 2011), or by RHCs.

(iv) For performance years (or a performance period) during 2019, and performance year 2020 as follows:

(A) CPT codes:

(*1*) 99201 through 99215 (codes for office or other outpatient visit for the evaluation and management of a patient).

(*2*) 99304 through 99318 (codes for professional services furnished in a nursing facility; services identified by these codes furnished in a SNF are excluded).

(*3*) 99319 through 99340 (codes for patient domiciliary, rest home, or custodial care visit).

(*4*) 99341 through 99350 (codes for evaluation and management services furnished in a patients' home for claims identified by place of service modifier 12).

(*5*) 99487, 99489 and 99490 (codes for chronic care management).

(*6*) 99495 and 99496 (codes for transitional care management services).

(*7*) 99497 and 99498 (codes for advance care planning).

(*8*) 96160 and 96161 (codes for administration of health risk assessment).

(*9*) 99354 and 99355 (add-on codes, for prolonged evaluation and management or psychotherapy services beyond the typical service time of the primary procedure; when the base code is also a primary care service code under this paragraph (c)(1)).

(*10*) 99484, 99492, 99493 and 99494 (codes for behavioral health integration services).

(B) HCPCS codes:

(*1*) G0402 (the code for the Welcome to Medicare visit) and

(*2*) G0438 and G0439 (codes for the annual wellness visits).

(*3*) G0463 for services furnished in ETA hospitals.

(*4*) G0506 (code for chronic care management).

(*5*) G0444 (codes for annual depression screening service).

(*6*) G0442 (code for alcohol misuse screening service).

(*7*) G0443 (code for alcohol misuse counseling service).

(v) For the performance year starting on January 1, 2021:

(A) CPT codes:

(*1*) 96160 and 96161 (codes for administration of health risk assessment).

(*2*) 99201 through 99215 (codes for office or other outpatient visit for the evaluation and management of a patient).

(*3*) 99304 through 99318 (codes for professional services furnished in a nursing facility; professional services or services reported on an FQHC or RHC claim identified by these codes are excluded when furnished in a SNF).

(*4*) 99319 through 99340 (codes for patient domiciliary, rest home, or custodial care visit).

(*5*) 99341 through 99350 (codes for evaluation and management services furnished in a patient's home for claims identified by place of service modifier 12).

(*6*) 99354 and 99355 (add-on codes, for prolonged evaluation and management or psychotherapy services beyond the typical service time of the primary procedure; when the base code is also a primary care service code under this paragraph (c)(1)(v)).

(*7*) 99421, 99422, and 99423 (codes for online digital evaluation and management).

(*8*) 99439 (code for non-complex chronic care management).

(*9*) 99483 (code for assessment of and care planning for patients with cognitive impairment).

(*10*) 99484, 99492, 99493 and 99494 (codes for behavioral health integration services).

(*11*) 99487, 99489, 99490 and 99491 (codes for chronic care management).

(*12*) 99495 and 99496 (codes for transitional care management services).

(*13*) 99497 and 99498 (codes for advance care planning; services identified by these codes furnished in an inpatient setting are excluded).

(B) HCPCS codes:

(*1*) G0402 (code for the Welcome to Medicare visit).

(*2*) G0438 and G0439 (codes for the annual wellness visits).

(*3*) G0442 (code for alcohol misuse screening service).

(*4*) G0443 (code for alcohol misuse counseling service).

(*5*) G0444 (code for annual depression screening service).

(*6*) G0463 (code for services furnished in ETA hospitals).

(*7*) G0506 (code for chronic care management).

(*8*) G2010 (code for the remote evaluation of patient video/images).

(*9*) G2012 (code for virtual check-in).

(*10*) G2058 (code for non-complex chronic care management).

(*11*) G2064 and G2065 (codes for principal care management services).

(*12*) G2214 (code for psychiatric collaborative care model).

(vi) For the performance year starting on January 1, 2022 as follows:

(A) CPT codes:

(*1*) 96160 and 96161 (codes for administration of health risk assessment).

(*2*) 99201 through 99215 (codes for office or other outpatient visit for the evaluation and management of a patient).

(*3*) 99304 through 99318 (codes for professional services furnished in a nursing facility; professional services or services reported on an FQHC or RHC claim identified by these codes are excluded when furnished in a SNF).

(*4*) 99319 through 99340 (codes for patient domiciliary, rest home, or custodial care visit).

(*5*) 99341 through 99350 (codes for evaluation and management services furnished in a patient's home for claims identified by place of service modifier 12).

(*6*) 99354 and 99355 (add-on codes, for prolonged evaluation and management or psychotherapy services beyond the typical service time of the primary procedure; when the base code is also a primary care service code under this paragraph (c)(1)(vi)).

(*7*) 99421, 99422, and 99423 (codes for online digital evaluation and management).

(*8*) 99424, 99425, 99426, and 99427 (codes for principal care management services).

(*9*) 99437, 99487, 99489, 99490 and 99491 (codes for chronic care management).

(*10*) 99439 (code for non-complex chronic care management).

(*11*) 99483 (code for assessment of and care planning for patients with cognitive impairment).

(*12*) 99484, 99492, 99493 and 99494 (codes for behavioral health integration services).

(*13*) 99495 and 99496 (codes for transitional care management services).

(*14*) 99497 and 99498 (codes for advance care planning; services identified by these codes furnished in an inpatient setting are excluded).

(B) HCPCS codes:

(*1*) G0402 (code for the Welcome to Medicare visit).

(*2*) G0438 and G0439 (codes for the annual wellness visits).

(*3*) G0442 (code for alcohol misuse screening service).

(*4*) G0443 (code for alcohol misuse counseling service).

(*5*) G0444 (code for annual depression screening service).

(*6*) G0463 (code for services furnished in ETA hospitals).

(*7*) G0506 (code for chronic care management).

(*8*) G2010 (code for the remote evaluation of patient video/images).

(*9*) G2012 and G2252 (codes for virtual check-in).

(*10*) G2058 (code for non-complex chronic care management).

(*11*) G2064 and G2065 (codes for principal care management services).

(*12*) G2212 (code for prolonged office or other outpatient visit for the evaluation and management of a patient).

(*13*) G2214 (code for psychiatric collaborative care model).

(C) Primary care service codes include any CPT code identified by CMS that directly replaces a CPT code specified in paragraph (c)(1)(vi)(A) of this section or a HCPCS code specified in paragraph (c)(1)(vi)(B) of this section, when the assignment window (as defined in § 425.20) for a benchmark or performance year includes any day on or after the effective date of the replacement code for payment purposes under FFS Medicare.

(vii) For the performance year starting on January 1, 2023 as follows:

(A) CPT codes:

(*1*) 96160 and 96161 (codes for administration of health risk assessment).

(*2*) 99201 through 99215 (codes for office or other outpatient visit for the evaluation and management of a patient).

(*3*) 99304 through 99318 (codes for professional services furnished in a nursing facility; professional services or services reported on an FQHC or RHC claim identified by these codes are excluded when furnished in a SNF).

(*4*) 99319 through 99340 (codes for patient domiciliary, rest home, or custodial care visit).

(*5*) 99341 through 99350 (codes for evaluation and management services furnished in a patient's home).

(*6*) 99354 and 99355 (add-on codes, for prolonged evaluation and management or psychotherapy services beyond the typical service time of the primary procedure; when the base code is also a primary care service code under this paragraph (c)(1)(vii)).

(*7*) 99421, 99422, and 99423 (codes for online digital evaluation and management).

(*8*) 99424, 99425, 99426, and 99427 (codes for principal care management services).

(*9*) 99437, 99487, 99489, 99490 and 99491 (codes for chronic care management).

(*10*) 99439 (code for non-complex chronic care management).

(*11*) 99483 (code for assessment of and care planning for patients with cognitive impairment).

(*12*) 99484, 99492, 99493 and 99494 (codes for behavioral health integration services).

(*13*) 99495 and 99496 (codes for transitional care management services).

(*14*) 99497 and 99498 (codes for advance care planning; services identified by these codes furnished in an inpatient setting are excluded).

(B) HCPCS codes:

(*1*) G0402 (code for the Welcome to Medicare visit).

(*2*) G0438 and G0439 (codes for the annual wellness visits).

(*3*) G0442 (code for alcohol misuse screening service).

(*4*) G0443 (code for alcohol misuse counseling service).

(*5*) G0444 (code for annual depression screening service).

(*6*) G0463 (code for services furnished in ETA hospitals).

(*7*) G0506 (code for chronic care management).

(*8*) G2010 (code for the remote evaluation of patient video/images).

(*9*) G2012 and G2252 (codes for virtual check-in).

(*10*) G2058 (code for non-complex chronic care management).

(*11*) G2064 and G2065 (codes for principal care management services).

(*12*) G0317, G0318, and G2212 (codes for prolonged office or other outpatient visit for the evaluation and management of a patient).

(*13*) G2214 (code for psychiatric collaborative care model).

(*14*) G3002 and G3003 (codes for chronic pain management).

(C) Primary care service codes include any CPT code identified by CMS that directly replaces a CPT code specified in paragraph (c)(1)(vii)(A) of this section or a HCPCS code specified in paragraph (c)(1)(vii)(B) of this section, when the assignment window (as defined in § 425.20) for a benchmark or performance year includes any day on or after the effective date of the replacement code for payment purposes under FFS Medicare.

(viii) For the performance year starting on January 1, 2024, as follows:

(A) CPT codes:

(*1*) 96160 and 96161 (codes for administration of health risk assessment).

(*2*) 96202 and 96203 (codes for caregiver behavior management training).

(*3*) 97550, 97551, and 97552 (codes for caregiver training services).

(*4*) 99201 through 99215 (codes for office or other outpatient visit for the

evaluation and management of a patient).

(*5*) 99304 through 99318 (codes for professional services furnished in a nursing facility; professional services or services reported on an FQHC or RHC claim identified by these codes are excluded when furnished in a SNF).

(*6*) 99319 through 99340 (codes for patient domiciliary, rest home, or custodial care visit).

(*7*) 99341 through 99350 (codes for evaluation and management services furnished in a patient's home).

(*8*) 99354 and 99355 (add-on codes, for prolonged evaluation and management or psychotherapy services beyond the typical service time of the primary procedure; when the base code is also a primary care service code under this paragraph (c)(1)(viii)).

(*9*) 99406 and 99407 (codes for smoking and tobacco-use cessation counseling services).

(*10*) 99421, 99422, and 99423 (codes for online digital evaluation and management).

(*11*) 99424, 99425, 99426, and 99427 (codes for principal care management services).

(*12*) 99437, 99487, 99489, 99490 and 99491 (codes for chronic care management).

(*13*) 99439 (code for non-complex chronic care management).

(*14*) 99483 (code for assessment of and care planning for patients with cognitive impairment).

(*15*) 99484, 99492, 99493 and 99494 (codes for behavioral health integration services).

(*16*) 99495 and 99496 (codes for transitional care management services).

(*17*) 99497 and 99498 (codes for advance care planning; services identified by these codes furnished in an inpatient setting are excluded).

(B) HCPCS codes:

(*1*) G0019 and G0022 (codes for community health integration services).

(*2*) G0023 and G0024 (codes for principal illness navigation services).

(*3*) G0101 (code for cervical or vaginal cancer screening).

(*4*) G0136 (code for social determinants of health risk assessment services).

(*5*) G0317, G0318, and G2212 (codes for prolonged office or other outpatient visit for the evaluation and management of a patient).

(*6*) G0402 (code for the Welcome to Medicare visit).

(*7*) G0438 and G0439 (codes for the annual wellness visits).

(*8*) G0442 (code for alcohol misuse screening service).

(*9*) G0443 (code for alcohol misuse counseling service).

(*10*) G0444 (code for annual depression screening service).

(*11*) G0463 (code for services furnished in ETA hospitals).

(*12*) G0506 (code for chronic care management).

(*13*) G2010 (code for the remote evaluation of patient video/images).

(*14*) G2012 and G2252 (codes for virtual check-in).

(*15*) G2058 (code for non-complex chronic care management).

(*16*) G2064 and G2065 (codes for principal care management services).

(*17*) G2086, G2087, and G2088 (codes for office-based opioid use disorder services).

(*18*) G2211 (code for visit complexity inherent to evaluation and management services add-on).

(*19*) G2214 (code for psychiatric collaborative care model).

(*20*) G3002 and G3003 (codes for chronic pain management).

(C) Primary care service codes include any CPT code identified by CMS that directly replaces a CPT code specified in paragraph (c)(1)(viii)(A) of this section or a HCPCS code specified in paragraph (c)(1)(viii)(B) of this section, when the assignment window (as defined in § 425.20) for a benchmark or performance year includes any day on or after the effective date of the replacement code for payment purposes under FFS Medicare.

(ix) For the performance year starting on January 1, 2025, and subsequent performance years as follows:

(A) CPT codes:

(*1*) 96160 and 96161 (codes for administration of health risk assessment).

(*2*) 96202 and 96203 (codes for caregiver behavior management training).

(*3*) 97550, 97551, and 97552 (codes for caregiver training services).

(*4*) 98016 (code for virtual check-in).

(*5*) 99201 through 99215 (codes for office or other outpatient visit for the

evaluation and management of a patient).

(*6*) 99304 through 99318 (codes for professional services furnished in a nursing facility; professional services or services reported on an FQHC or RHC claim identified by these codes are excluded when furnished in a skilled nursing facility (SNF)).

(*7*) 99319 through 99340 (codes for patient domiciliary, rest home, or custodial care visit).

(*8*) 99341 through 99350 (codes for evaluation and management services furnished in a patient's home).

(*9*) 99354 and 99355 (add-on codes, for prolonged evaluation and management or psychotherapy services beyond the typical service time of the primary procedure; when the base code is also a primary care service code under this paragraph (c)(1)(ix)).

(*10*) 99406 and 99407 (codes for smoking and tobacco-use cessation counseling services).

(*11*) 99421, 99422, and 99423 (codes for online digital evaluation and management).

(*12*) 99424, 99425, 99426, and 99427 (codes for principal care management services).

(*13*) 99437, 99487, 99489, 99490 and 99491 (codes for chronic care management).

(*14*) 99439 (code for non-complex chronic care management).

(*15*) 99452 (code for interprofessional consultation service).

(*16*) 99483 (code for assessment of and care planning for patients with cognitive impairment).

(*17*) 99484, 99492, 99493 and 99494 (codes for behavioral health integration services).

(*18*) 99495 and 99496 (codes for transitional care management services).

(*19*) 99497 and 99498 (codes for advance care planning; services identified by these codes furnished in an inpatient setting are excluded).

(B) HCPCS codes:

(*1*) G0019 and G0022 (codes for community health integration services).

(*2*) G0023 and G0024 (codes for principal illness navigation services).

(*3*) G0101 (code for cervical or vaginal cancer screening).

(*4*) G0136 (code for social determinants of health risk assessment services).

(*5*) G0317, G0318, and G2212 (codes for prolonged office or other outpatient visit for the evaluation and management of a patient).

(*6*) G0402 (code for the Welcome to Medicare visit).

(*7*) G0438 and G0439 (codes for the annual wellness visits).

(*8*) G0442 (code for alcohol misuse screening service).

(*9*) G0443 (code for alcohol misuse counseling service).

(*10*) G0444 (code for annual depression screening service).

(*11*) G0463 (code for services furnished in electing teaching amendment (ETA) hospitals).

(*12*) G0506 (code for chronic care management).

(*13*) G0537 and G0538 (codes for cardiovascular risk assessment and risk management services).

(*14*) G0539 and G0540 (codes for individual behavior management/modification caregiver training services).

(*15*) G0541, G0542, and G0543 (codes for direct care caregiver training services).

(*16*) G0544 (code for post-discharge telephonic follow-up contacts intervention).

(*17*) G0556, G0557, and G0558 (codes for advanced primary care management services).

(*18*) G0560 (code for safety planning interventions).

(*19*) G2010 (code for the remote evaluation of patient video/images).

(*20*) G2012 and G2252 (codes for virtual check-in).

(*21*) G2058 (code for non-complex chronic care management).

(*22*) G2064 and G2065 (codes for principal care management services).

(*23*) G2086, G2087, and G2088 (codes for office-based opioid use disorder services).

(*24*) G2211 (code for visit complexity inherent to evaluation and management services add-on).

(*25*) G2214 (code for psychiatric collaborative care model).

(*26*) G3002 and G3003 (codes for chronic pain management).

(C) Primary care service codes include any CPT code identified by CMS that directly replaces a CPT code specified in paragraph (c)(1)(ix)(A) of this section or a HCPCS code specified in paragraph (c)(1)(ix)(B) of this section,

when the assignment window or expanded window for assignment (as defined in § 425.20) for a benchmark or performance year includes any day on or after the effective date of the replacement code for payment purposes under FFS Medicare.

(2)(i) Except as otherwise specified in paragraph (c)(2)(i)(A)(*2*) of this section, when the assignment window or applicable expanded window for assignment (as defined in § 425.20) for a benchmark or performance year includes any month(s) during the COVID–19 Public Health Emergency defined in § 400.200 of this chapter, in determining beneficiary assignment, we use the primary care service codes identified in paragraph (c)(1) of this section, and additional primary care service codes as follows:

(A) CPT codes:

(*1*) 99421, 99422, and 99423 (codes for online digital evaluation and management services).

(*2*) 99441, 99442, and 99443 (codes for telephone evaluation and management services). These codes are used in determining beneficiary assignment as specified in paragraphs (c)(2)(i) and (ii) of this section and until they are no longer payable under Medicare fee-for-service payment policies as specified under section 1834(m) of the Act and §§ 410.78 and 414.65 of this subchapter.

(B) HCPCS codes:

(*1*) G2010 (code for the remote evaluation of patient video/images).

(*2*) G2012 (code for virtual check-in).

(ii) Except as otherwise specified in paragraph (c)(2)(i)(A)(*2*) of this section, the additional primary care service codes specified in paragraph (c)(2)(i) of this section are applicable to all months of the assignment window or applicable expanded window for assignment (as defined in § 425.20), when the assignment window or applicable expanded window for assignment includes any month(s) during the COVID–19 Public Health Emergency defined in § 400.200 of this chapter.

[76 FR 67973, Nov. 2, 2011, as amended at 80 FR 32840, June 9, 2015; 82 FR 53369, Nov. 15, 2017; 83 FR 60092, Nov. 23, 2018; 83 FR 68069, Dec. 31, 2018; 85 FR 27625, May 8, 2020; 85 FR 85040, Dec. 28, 2020; 86 FR 65684, Nov. 19, 2021; 87 FR 70233, Nov. 18, 2022; 88 FR 79544, Nov. 16, 2023; 89 FR 98567, Dec. 9, 2024]

§ 425.401 Criteria for a beneficiary to be assigned to an ACO.

(a) A beneficiary may be assigned to an ACO under the assignment methodology in §§ 425.402 and 425.404, for a performance or benchmark year, if the beneficiary meets all of the following criteria during the assignment window:

(1)(i) Has at least 1 month of Part A and Part B enrollment; and

(ii) Does not have any months of Part A only or Part B only enrollment.

(2) Does not have any months of Medicare group (private) health plan enrollment.

(3) Is not assigned to any other Medicare shared savings initiative.

(4) Lives in the United States or U.S. territories and possessions, based on the most recent available data in our beneficiary records regarding the beneficiary's residence at the end of the assignment window.

(b) A beneficiary is excluded from the prospective assignment list of an ACO that is participating under prospective assignment under § 425.400(a)(3) at the end of a performance or benchmark year and quarterly during each performance year consistent with § 425.400(a)(3)(ii), or at the end of CY 2019 as specified in § 425.609(b)(1)(ii) and (c)(1)(ii) if the beneficiary meets any of the following criteria during the performance or benchmark year:

(1)(i) Does not have at least 1 month of Part A and Part B enrollment; and

(ii) Has any months of Part A only or Part B only enrollment.

(2) Has any months of Medicare group (private) health plan enrollment.

(3) Did not live in the United States or U.S. territories and possessions, based on the most recent available data in our beneficiary records regarding the beneficiary's residency at the end of the year.

[80 FR 32840, June 9, 2015, as amended at 83 FR 60093, Nov. 23, 2018; 83 FR 68069, Dec. 31, 2018]

§ 425.402 Basic assignment methodology.

(a) For performance years 2012 through 2015, CMS employs the following step-wise methodology to assign Medicare beneficiaries to an ACO after identifying all patients that had at least one primary care service with a

physician who is an ACO professional of that ACO:

(1)(i) Identify all primary care services rendered by primary care physicians during one of the following:

(A) The most recent 12 months (for purposes of preliminary prospective assignment and quarterly updates to the preliminary prospective assignment).

(B) The performance year (for purposes of final assignment).

(ii) The beneficiary is assigned to an ACO if the allowed charges for primary care services furnished to the beneficiary by all the primary care physicians who are ACO professionals in the ACO are greater than the allowed charges for primary care services furnished by primary care physicians who are—

(A) ACO professionals in any other ACO; and

(B) Not affiliated with any ACO and identified by a Medicare-enrolled TIN.

(2) The second step considers the remainder of the beneficiaries who have received at least one primary care service from an ACO physician, but who have not had a primary care service rendered by any primary care physician, either inside or outside the ACO. The beneficiary will be assigned to an ACO if the allowed charges for primary care services furnished to the beneficiary by all ACO professionals in the ACO are greater than the allowed charges for primary care services furnished by—

(i) All ACO professionals in any other ACO; and

(ii) Other physicians, nurse practitioners, physician assistants, clinical nurse specialists who are unaffiliated with an ACO and are identified by a Medicare-enrolled TIN.

(b) For performance year 2016 and subsequent performance years, CMS employs the following step-wise methodology to assign Medicare fee-for-service beneficiaries to an ACO based on available claims information:

(1) Identify all beneficiaries that had at least one primary care service during the applicable assignment window with a physician who is an ACO professional in the ACO and who is a primary care physician as defined under § 425.20 or who has one of the primary specialty designations included in paragraph (c) of this section.

(2) Identify all primary care services furnished to beneficiaries identified in paragraph (b)(1) of this section by ACO professionals of that ACO who are primary care physicians as defined under § 425.20, non-physician ACO professionals, and physicians with specialty designations included in paragraph (c) of this section during the applicable assignment window.

(3) Under the first step, a beneficiary identified in paragraph (b)(1) of this section is assigned to an ACO if the allowed charges for primary care services furnished to the beneficiary by primary care physicians who are ACO professionals and non-physician ACO professionals in the ACO are greater than the allowed charges for primary care services furnished by primary care physicians, nurse practitioners, physician assistants, and clinical nurse specialists who are—

(i) ACO professionals in any other ACO; or

(ii) Not affiliated with any ACO and identified by a Medicare-enrolled billing TIN.

(4) The second step considers the remainder of the beneficiaries identified in paragraph (b)(1) of this section who have not had a primary care service rendered by any primary care physician, nurse practitioner, physician assistant, or clinical nurse specialist, either inside the ACO or outside the ACO. The beneficiary will be assigned to an ACO if the allowed charges for primary care services furnished to the beneficiary by physicians who are ACO professionals with specialty designations as specified in paragraph (c) of this section are greater than the allowed charges for primary care services furnished by physicians with specialty designations as specified in paragraph (c) of this section—

(i) Who are ACO professionals in any other ACO; or

(ii) Who are unaffiliated with an ACO and are identified by a Medicare-enrolled billing TIN.

(5) For performance year 2025 and subsequent performance years, CMS employs the following third step to assign Medicare fee-for-service beneficiaries who were not identified by the

criterion specified in paragraph (b)(1) of this section:

(i) Identify all beneficiaries who had at least one primary care service with a non-physician ACO professional in the ACO during the applicable assignment window.

(ii) For the beneficiaries identified in paragraph (b)(5)(i) of this section, identify those beneficiaries that had at least one primary care service with a physician who is an ACO professional in the ACO and who is a primary care physician as defined under § 425.20 or who has one of the primary specialty designations included in paragraph (c) of this section during the applicable expanded window for assignment.

(iii) Identify all primary care services furnished to beneficiaries identified in paragraph (b)(5)(ii) of this section by ACO professionals in the ACO who are primary care physicians as defined under § 425.20, non-physician ACO professionals, and physicians with specialty designations included in paragraph (c) of this section during the applicable expanded window for assignment.

(iv) A beneficiary identified in paragraph (b)(5)(ii) of this section is assigned to the ACO if the allowed charges for primary care services furnished to the beneficiary by ACO professionals in the ACO who are primary care physicians, physicians with specialty designations included in paragraph (c) of this section, or non-physician ACO professionals during the applicable expanded window for assignment are greater than the allowed charges for primary care services furnished by primary care physicians, physicians with specialty designations as specified in paragraph (c) of this section, nurse practitioners, physician assistants, and clinical nurse specialists who are—

(A) ACO professionals in any other ACO; or

(B) Not affiliated with any ACO and identified by a Medicare-enrolled billing TIN.

(c) ACO professionals considered in the second and third step of the assignment methodology in paragraphs (b)(4) and (5) of this section include physicians who have one of the following primary specialty designations:

(1) Cardiology.

(2) Osteopathic manipulative medicine.

(3) Neurology.

(4) Obstetrics/gynecology.

(5) Sports medicine.

(6) Physical medicine and rehabilitation.

(7) Psychiatry.

(8) Geriatric psychiatry.

(9) Pulmonary disease.

(10) Nephrology.

(11) Endocrinology.

(12) Multispecialty clinic or group practice.

(13) Addiction medicine.

(14) Hematology.

(15) Hematology/oncology.

(16) Preventive medicine.

(17) Neuropsychiatry.

(18) Medical oncology.

(19) Gynecology/oncology.

(d) When considering services furnished by ACO professionals in teaching hospitals that have elected under § 415.160 of this subchapter to receive payment on a reasonable cost basis for the direct medical and surgical services of their physicians in the assignment methodology under paragraph (b) of this section, CMS uses an estimated amount based on the amounts payable under the physician fee schedule for similar services in the geographic location of the teaching hospital as a proxy for the amount of the allowed charges for the service.

(e) For performance year 2018 and subsequent performance years, if a system is available to allow a beneficiary to designate a provider or supplier as responsible for coordinating their overall care and for CMS to process the designation electronically, CMS will supplement the claims-based assignment methodology described in this section with information provided by beneficiaries regarding the provider or supplier they consider responsible for coordinating their overall care. Such designations must be made in the form and manner and by a deadline determined by CMS.

(1) Notwithstanding the assignment methodology under paragraph (b) of

this section, beneficiaries who designate an ACO professional participating in an ACO as responsible for coordinating their overall care are prospectively assigned to that ACO, regardless of track, annually at the beginning of each benchmark and performance year based on available data at the time assignment lists are determined for the benchmark and performance year.

(2) Beneficiaries are added to the ACO's list of assigned beneficiaries if all of the following conditions are satisfied:

(i) For performance year 2018:

(A) The beneficiary must have had at least one primary care service during the assignment window as defined under § 425.20 with a physician who is an ACO professional in the ACO who is a primary care physician as defined under § 425.20 or who has one of the primary specialty designations included in paragraph (c) of this section.

(B) The beneficiary meets the eligibility criteria established at § 425.401(a) and must not be excluded by the criteria at § 425.401(b). The exclusion criteria at § 425.401(b) apply for purposes of determining beneficiary eligibility for alignment to ACOs under all tracks based on the beneficiary's designation of an ACO professional as responsible for coordinating their overall care under paragraph (e) of this section.

(C) The beneficiary must have designated an ACO professional who is a primary care physician as defined at § 425.20, a physician with a specialty designation included at paragraph (c) of this section, or a nurse practitioner, physician assistant, or clinical nurse specialist as responsible for coordinating their overall care.

(D) If a beneficiary has designated a provider or supplier outside the ACO who is a primary care physician as defined at § 425.20, a physician with a specialty designation included at paragraph (c) of this section, or a nurse practitioner, physician assistant, or clinical nurse specialist, as responsible for coordinating their overall care, the beneficiary is not added to the ACO's list of assigned beneficiaries under the assignment methodology in paragraph (b) of this section.

(ii) For performance years starting on January 1, 2019, through 2024:

(A) The beneficiary meets the eligibility criteria established at § 425.401(a) and must not be excluded by the criteria at § 425.401(b). The exclusion criteria at § 425.401(b) apply for purposes of determining beneficiary eligibility for alignment to an ACO based on the beneficiary's designation of an ACO professional as responsible for coordinating their overall care under paragraph (e) of this section, regardless of the ACO's assignment methodology selection under § 425.226(a)(1).

(B) The beneficiary must have designated an ACO professional as responsible for coordinating their overall care.

(C) If a beneficiary has designated a provider or supplier outside the ACO as responsible for coordinating their overall care, the beneficiary is not added under the assignment methodology in paragraph (b) of this section to the ACO's list of assigned beneficiaries for a 12-month performance year or the ACO's list of assigned beneficiaries for a 6-month performance year, which is based on the entire CY 2019 as provided in § 425.609.

(D) The beneficiary is not assigned to an entity participating in a model tested or expanded under section 1115A of the Act under which claims-based assignment is based solely on claims for services other than primary care services and for which there has been a determination by the Secretary that waiver of the requirement in section 1899(c)(2)(B) of the Act is necessary solely for purposes of testing the model.

(iii) For performance year 2025 and subsequent performance years:

(A) The beneficiary meets the eligibility criteria established at § 425.401(a) and must not be excluded by the criteria at § 425.401(b). The exclusion criteria at § 425.401(b) apply for purposes of determining beneficiary eligibility for alignment to an ACO based on the beneficiary's designation of an ACO professional as responsible for coordinating their overall care under paragraph (e) of this section, regardless of the ACO's assignment methodology selection under § 425.226(a)(1).

(B) The beneficiary must have designated an ACO professional as responsible for coordinating their overall care.

(C) If a beneficiary has designated a provider or supplier outside the ACO as responsible for coordinating their overall care, the beneficiary is not added under the assignment methodology in paragraph (b) of this section to the ACO's list of assigned beneficiaries for a 12-month performance year.

(D) The beneficiary is not assigned to an entity participating in a model tested or expanded under section 1115A of the Act that meets the following conditions—

(*1*) Claims-based assignment for the model is based solely on either—

(*i*) Claims for primary care and/or other services related to treatment of one or more specific diseases or conditions targeted by the model; or

(*ii*) Claims for services other than primary care services; and

(*2*) There has been a determination by the Secretary that waiver of the requirement in section 1899(c)(2)(B) of the Act is necessary solely for purposes of testing the model.

(3) The ACO, ACO participants, ACO providers/suppliers, ACO professionals, and other individuals or entities performing functions and services related to ACO activities are prohibited from providing or offering gifts or other remuneration to Medicare beneficiaries as inducements for influencing a Medicare beneficiary's decision to designate or not to designate an ACO professional under paragraph (e) of this section. The ACO, ACO participants, ACO providers/suppliers, ACO professionals, and other individuals or entities performing functions and services related to ACO activities must not, directly or indirectly, commit any act or omission, nor adopt any policy that coerces or otherwise influences a Medicare beneficiary's decision to designate or not to designate an ACO professional as responsible for coordinating their overall care under paragraph (e) of this section, including but not limited to the following:

(i) Offering anything of value to the Medicare beneficiary as an inducement to influence the Medicare beneficiary's decision to designate or not to designate an ACO professional as responsible for coordinating their overall care under paragraph (e) of this section. Any items or services provided in violation of paragraph (e)(3) of this section are not considered to have a reasonable connection to the medical care of the beneficiary, as required under § 425.304(b)(1).

(ii) Withholding or threatening to withhold medical services or limiting or threatening to limit access to care.

(f) For performance year 2023 and subsequent performance years, CMS employs the following process to identify services furnished by FQHCs, RHCs, Method II CAHs, and ETA hospitals for purposes of the beneficiary assignment methodology under this section.

(1) Prior to the start of the performance year and periodically during the performance year, CMS will determine the CCNs for all FQHCs, RHCs, Method II CAHs, and ETA hospitals enrolled under the TIN of an ACO participant, including all CCNs with an active enrollment in Medicare and all CCNs with a deactivated enrollment status.

(2) CMS uses the CCNs identified in paragraph (f)(1) of this section in determining assignment for the performance year.

(3) CMS accounts for changes in CCN enrollment status during the performance year as follows:

(i) If a CCN with no prior Medicare claims experience enrolls under the TIN of an ACO participant after the ACO certifies its ACO participant list for a performance year as required under § 425.118(a)(3), CMS will consider services furnished by that CCN in determining beneficiary assignment to the ACO for the applicable performance year for ACOs under preliminary prospective assignment with retrospective reconciliation.

(ii) Services furnished by a CCN with a deactivated enrollment status that is enrolled under an ACO participant at the start of a performance year will be considered in determining beneficiary assignment to the ACO for the applicable performance year or benchmark year.

(iii) If a CCN enrolled under the TIN of an ACO participant at the start of the performance year enrolls under a

different TIN during a performance year, CMS will continue to treat services billed by the CCN as services furnished by the ACO participant it was enrolled under at the start of the performance year for purposes of determining beneficiary assignment to the ACO for the applicable performance year.

[76 FR 67973, Nov. 2, 2011, as amended at 80 FR 32841, June 9, 2015; 80 FR 71386, Nov. 16, 2015; 81 FR 80559, Nov. 15, 2016; 83 FR 60093, Nov. 23, 2018; 83 FR 68069, Dec. 31, 2018; 87 FR 70234, Nov. 18, 2022; 88 FR 79545, Nov. 16, 2023; 89 FR 98568, Dec. 9, 2024]

§ 425.404 Special assignment conditions for ACOs including FQHCs and RHCs.

CMS assigns beneficiaries to ACOs based on services furnished in FQHCs or RHCs or both consistent with the general assignment methodology in § 425.402, with special conditions:

(a) For performance years 2012 through 2018—

(1) Such ACOs are required to identify, through an attestation, physicians who directly provide primary care services in each FQHC or RHC that is an ACO participant and/or ACO provider/supplier in the ACO.

(2) Under the assignment methodology in § 425.402, CMS treats a service reported on an FQHC/RHC claim as a primary care service—

(i) If the claim includes a HCPCS or revenue center code that meets the definition of primary care services under § 425.20;

(ii) Performed by a primary care physician if the NPI of a physician identified in the attestation provided under paragraph (a)(1) of this section is reported on the claim for a primary care service (as described in paragraph (a)(2)(i) of this section) as the attending provider; and

(iii) Performed by a non-physician ACO professional if the NPI reported on the claim for a primary care service (as described in paragraph (a)(2)(i) of this section) as the attending provider is an ACO professional but is not identified in the attestation provided under paragraph (a)(1) of this section.

(b) For performance years starting on January 1, 2019, and subsequent performance years, under the assignment methodology in § 425.402, CMS treats a service reported on an FQHC/RHC claim as a primary care service performed by a primary care physician.

[76 FR 67973, Nov. 2, 2011, as amended at 80 FR 32841, June 9, 2015; 82 FR 53369, Nov. 15, 2017; 83 FR 60093, Nov. 23, 2018]

Subpart F—Quality Performance Standards and Reporting

§ 425.500 Measures to assess the quality of care furnished by an ACO for performance years (or a performance period) beginning on or before January 1, 2020.

(a) *General.* CMS establishes quality performance measures to assess the quality of care furnished by the ACO. If the ACO demonstrates to CMS that it has satisfied the quality performance requirements in this subpart, and the ACO meets all other applicable requirements, the ACO is eligible for shared savings.

(b) *Selecting measures.* (1) CMS selects the measures designated to determine an ACO's success in promoting the aims of better care for individuals, better health for populations, and lower growth in expenditures.

(2) CMS designates the measures for use in the calculation of the quality performance standard.

(3) CMS seeks to improve the quality of care furnished by ACOs over time by specifying higher standards, new measures, or both.

(c) ACOs must submit data on the measures determined under paragraph (b) of this section according to the method of submission established by CMS.

(d) *Patient experience of care survey.* (1) For performance years (or a performance period) beginning in 2014 through 2019, ACOs must select a CMS-certified vendor to administer the survey and report the results accordingly.

(2) For performance year 2020, CMS waives the CAHPS for ACOs reporting requirement and will assign all ACOs automatic credit for the CAHPS for ACOs survey measures.

(e) *Audit and validation of data.* CMS retains the right to audit and validate quality data reported by an ACO.

(1) In an audit, the ACO will provide beneficiary medical records data if requested by CMS.

(2) If, at the conclusion of the audit process the overall audit match rate between the quality data reported and the medical records provided under paragraph (e)(1) of this section is less than 80 percent, absent unusual circumstances, CMS will adjust the ACO's overall quality score proportional to the ACO's audit performance.

(3) If, at the conclusion of the audit process CMS determines there is an audit match rate of less than 90 percent, the ACO may be required to submit a CAP under § 425.216 for CMS approval.

(f) Failure to report quality measure data accurately, completely, and timely (or to timely correct such data) may subject the ACO to termination or other sanctions, as described in §§ 425.216 and 425.218.

[76 FR 67973, Nov. 2, 2011, as amended at 81 FR 80559, Nov. 15, 2016; 82 FR 53370, Nov. 15, 2017; 85 FR 85040, Dec. 28, 2020]

EDITORIAL NOTE: At 82 FR 53370, Nov. 15, 2017, § 425.500 was amended; however, a portion of the amendment could not be incorporated due to inaccurate amendatory instruction.

§ 425.502 Calculating the ACO quality performance score for performance years (or a performance period) beginning on or before January 1, 2020.

(a) *Establishing a quality performance standard.* CMS designates the quality performance standard in each performance year. The quality performance standard is the overall standard the ACO must meet in order to be eligible for shared savings.

(1) For the first performance year of an ACO's first agreement period, CMS defines the quality performance standard at the level of complete and accurate reporting for all quality measures.

(2) During subsequent performance years of the ACO's first agreement period, the quality performance standard will be phased in such that the ACO must continue to report all measures but the ACO will be assessed on performance based on the quality performance benchmark and minimum attainment level of all measures.

(3) Under the quality performance standard for each performance year of an ACO's subsequent agreement period, the ACO must continue to report on all measures but the ACO will be assessed on performance based on the quality performance benchmark and minimum attainment level of all measures.

(4) A newly introduced measure is set at the level of complete and accurate reporting for the first two reporting periods, the measure is required. For subsequent reporting periods, the quality performance standard for the measure will be assessed according to the phase-in schedule for the measure.

(5) CMS reserves the right to redesignate a measure as pay for reporting when the measure owner determines the measure no longer aligns with clinical practice or causes patient harm, or when there is a determination under the Quality Payment Program that the measure has undergone a substantive change.

(b) *Establishing a performance benchmark and minimum attainment level for measures.* (1) CMS designates a performance benchmark and minimum attainment level for each measure, and establishes a point scale for the measures.

(2)(i) CMS will define the quality benchmarks using fee-for-service Medicare data.

(ii) CMS will set benchmarks using flat percentages when the 60th percentile is equal to or greater than 80.00 percent, or when the 90th percentile is equal to or greater than 95 percent.

(iii) CMS reserves the right to use flat percentages for other measures when CMS determines that fee-for-service Medicare data are unavailable, inadequate, or unreliable to set the quality benchmarks.

(3) The minimum attainment level for pay for performance measures is set at 30 percent or the 30th percentile of the performance benchmark. The minimum attainment level for pay for reporting measures is set at the level of complete and accurate reporting.

(4)(i) CMS will update the quality performance benchmarks every 2 years.

(ii) For newly introduced measures that transition to pay for performance in the second year of the 2-year benchmarking cycle, the benchmark

will be established for that year and updated along with the other measures at the start of the next 2-year benchmarking cycle.

(iii) CMS will use up to three years of data, as available, to set the benchmark for each quality measure.

(c) *Methodology for calculating a performance score for each measure.* (1) Performance below the minimum attainment level for a measure will receive zero points for that measure.

(2) Performance equal to or greater than the minimum attainment level for a pay-for-performance measure will receive points on a sliding scale based on the level of performance.

(3) Those measures designated as all or nothing measures will receive the maximum available points if all criteria are met and zero points if one or more of the criteria are not met.

(4) Performance at or above 90 percent or the 90th percentile of the performance benchmark earns the maximum points available for the measure.

(5) Performance equal to or greater than the minimum attainment level for pay-for-reporting measures will receive the maximum available points.

(d) *Establishing quality requirements for domains.* (1) CMS groups individual measures into four domains:

(i) Patient/care giver experience.

(ii) Care coordination/Patient safety.

(iii) Preventative health.

(iv) At-risk population.

(2) To satisfy quality requirements for a domain:

(i) The ACO must report all measures within a domain.

(ii) CMS may take the compliance actions described in § 425.216 for ACOs exhibiting poor performance on a domain, as determined by CMS under § 425.316.

(iii)(A) If the ACO achieves the minimum attainment level for at least one measure in each of the four domains, and also satisfies the requirements for realizing shared savings under subpart G of this part, the ACO may receive the proportion of those shared savings for which it qualifies.

(B) If an ACO fails to achieve the minimum attainment level on all measures in a domain, it will not be eligible to share in any savings generated.

(e) *Methodology for calculating the ACO's overall performance score.* (1) CMS scores individual measures and determines the corresponding number of points that may be earned based on the ACO's performance.

(2) CMS adds the points earned for the individual measures within the domain and divides by the total points available for the domain to determine the domain score.

(3) Domains are weighted equally and scores averaged to determine the ACO's overall performance score and sharing rate.

(4)(i) ACOs that demonstrate quality improvement on established quality measures from year to year will be eligible for up to 4 bonus points per domain.

(ii) Bonus points are awarded based on an ACO's net improvement in measures within a domain, which is calculated by determining the total number of significantly improved measures and subtracting the total number of significantly declined measures.

(iii) Up to four bonus points are awarded based on a comparison of the ACO's net improvement in performance on the measures for the domain to the total number of individual measures in the domain.

(iv) When bonus points are added to points earned for the quality measures in the domain, the total points received for the domain may not exceed the maximum total points for the domain in the absence of the quality improvement measure.

(v) If an ACO renews its participation agreement for a subsequent agreement period, quality improvement will be measured based on a comparison between performance in the first year of the new agreement period and performance in the last year of the previous agreement period.

(vi) For performance year 2017 and subsequent performance years, if an ACO receives the mean Shared Savings Program ACO quality score based on the extreme and uncontrollable circumstances policies in paragraph (f) of this section, the ACO is not eligible for bonus points awarded based on quality improvement.

(vii) For performance year 2017 and subsequent performance years, if an

ACO receives the mean Shared Savings Program ACO quality score under paragraph (f) of this section, in the next performance year for which the ACO receives a quality performance score based on its own quality reporting, quality improvement is measured based on a comparison between the performance in that year and the most recently available prior performance year in which the ACO reported quality.

(f) *Extreme and uncontrollable circumstances.* For performance year 2017 and subsequent performance years, including the applicable quality data reporting period for the performance year, CMS uses an alternative approach to calculating the quality score for ACOs affected by extreme and uncontrollable circumstances instead of the methodology specified in paragraphs (a) through (e) of this section as follows:

(1) CMS determines the ACO was affected by an extreme and uncontrollable circumstance based on either of the following:

(i) Twenty percent or more of the ACO's assigned beneficiaries reside in an area identified under the Quality Payment Program as being affected by an extreme and uncontrollable circumstance.

(A) Assignment is determined under subpart E of this part.

(B) In making this determination for performance year 2017, CMS uses the final list of beneficiaries assigned to the ACO for the performance year. For performance year 2018 and subsequent performance years, CMS uses the list of assigned beneficiaries used to generate the Web Interface quality reporting sample.

(ii) The ACO's legal entity is located in an area identified under the Quality Payment Program as being affected by an extreme and uncontrollable circumstance. An ACO's legal entity location is based on the address on file for the ACO in CMS' ACO application and management system.

(2) If CMS determines the ACO meets the requirements of paragraph (f)(1) of this section, CMS calculates the ACO's quality score as follows:

(i) The ACO's minimum quality performance score is set to equal the mean quality performance score for all Shared Savings Program ACOs for the relevant performance year.

(ii) If the ACO completely and accurately reports all quality measures, CMS uses the higher of the ACO's quality performance score or the mean quality performance score for all Shared Savings Program ACOs.

(3) CMS applies determinations made under the Quality Payment Program with respect to—

(i) Whether an extreme and uncontrollable circumstance has occurred; and

(ii) The affected areas.

(4) CMS has sole discretion to determine the time period during which an extreme and uncontrollable circumstance occurred, the percentage of the ACO's assigned beneficiaries residing in the affected areas, and the location of the ACO legal entity.

[76 FR 67973, Nov. 2, 2011, as amended at 78 FR 74823, Dec. 10, 2013; 79 FR 68008, Nov. 13, 2014; 80 FR 71386, Nov. 16, 2015; 81 FR 80560, Nov. 15, 2016; 82 FR 53370, Nov. 15, 2017; 82 FR 60918, Dec. 26, 2017; 83 FR 60093, Nov. 23, 2018; 83 FR 68069, Dec. 31, 2018; 85 FR 19291, Apr. 6, 2020; 85 FR 85040, Dec. 28, 2020]

§ 425.504 Incorporating reporting requirements related to the Physician Quality Reporting System Incentive and Payment Adjustment.

(a) *Physician quality reporting system.* (1) ACOs, on behalf of eligible professionals who bill under the TIN of an ACO participant, must submit the measures determined under § 425.500 using a CMS web interface, to qualify on behalf of their eligible professionals for the Physician Quality Reporting System incentive under the Shared Savings Program.

(2)(i) Eligible professionals who bill under the TIN of an ACO participant within an ACO may only participate under their ACO participant TIN as a group practice under the Physician Quality Reporting System Group Practice Reporting Option of the Shared Savings Program for purposes of receiving an incentive payment under the Physician Quality Reporting System.

(ii) Under the Shared Savings Program, an ACO, on behalf of eligible professionals who bill under the TIN of an

ACO participant must satisfactorily report the measures determined under Subpart F of this part during the reporting period according to the method of submission established by CMS under the Shared Savings Program in order to receive a Physician Quality Reporting System incentive under the Shared Savings Program.

(3) If eligible professionals who bill under the TIN of an ACO participant within an ACO qualify for a Physician Quality Reporting System incentive payment, each ACO participant TIN, on behalf of its ACO supplier/provider participants who are eligible professionals, will receive an incentive, for those years an incentive is available, based on the allowed charges under the Physician Fee Schedule for that TIN.

(4) ACO participant TINs and individual eligible professionals who bill under the TIN of an ACO participant cannot earn a Physician Quality Reporting System incentive outside of the Medicare Shared Savings Program.

(5) The Physician Quality Reporting System incentive under the Medicare Shared Savings Program is equal to 0.5 percent of the Secretary's estimate of the ACO's eligible professionals' total Medicare Part B Physician Fee Schedule allowed charges for covered professional services furnished during the calendar year reporting period from January 1 through December 31, for years 2012 through 2014.

(b) *Physician Quality Reporting System payment adjustment for 2015.* (1) ACOs, on behalf of eligible professionals who bill under the TIN of an ACO participant, must submit one of the ACO GPRO measures determined under § 425.500 using a CMS web interface, to satisfactorily report on behalf of their eligible professionals for purposes of the 2015 Physician Quality Reporting System payment adjustment under the Shared Savings Program.

(2)(i) Eligible professionals who bill under the TIN of an ACO participant within an ACO may only participate under their ACO participant TIN as a group practice under the Physician Quality Reporting System Group Practice Reporting Option of the Shared Savings Program for purposes of the 2015 Physician Quality Reporting System payment adjustment under the Shared Savings Program.

(ii) Under the Shared Savings Program, an ACO, on behalf of eligible professionals who bill under the TIN of an ACO participant, must satisfactorily report one of the measures determined under Subpart F of this part during the reporting period for a year, as defined in paragraph (b)(6) of this section, according to the method of submission established by CMS under the Shared Savings Program for purposes of the 2015 Physician Quality Reporting System payment adjustment.

(3) If an ACO, on behalf of eligible professionals who bill under the TIN of an ACO participant, does not satisfactorily report for purposes of a 2015 Physician Quality Reporting System payment adjustment, each eligible professional who bills under the TIN of an ACO participant, will receive a payment adjustment, as described in paragraph (b)(5) of this section.

(4) ACO participant TINs and individual eligible professionals who bill under the TIN of an ACO participant cannot satisfactorily report for purposes of a 2015 Physician Quality Reporting System payment adjustment outside of the Medicare Shared Savings Program.

(5) For eligible professionals subject to the 2015 Physician Quality Reporting System payment adjustment under the Medicare Shared Savings Program, the Medicare Part B Physician Fee Schedule amount for covered professional services furnished during the program year is equal to the applicable percent of the Medicare Part B Physician Fee Schedule amount that would otherwise apply to such services under section 1848 of the Act.

(i) The applicable percent for 2015 is 98.5 percent.

(ii) The applicable percent for 2016 and subsequent years is 98.0 percent.

(6) The reporting period for a year is the calendar year from January 1 through December 31 that occurs 2 years prior to the program year in which the payment adjustment is applied.

(c) *Physician Quality Reporting System payment adjustment for 2016.* (1) ACOs, on behalf of eligible professionals who

bill under the TIN of an ACO participant, must submit all of the ACO GPRO measures determined under § 425.500 using a CMS web interface, to satisfactorily report on behalf of their eligible professionals for purposes of the Physician Quality Reporting System payment adjustment under the Shared Savings Program for 2016.

(2) Eligible professionals who bill under the TIN of an ACO participant within an ACO may only participate under their ACO participant TIN as a group practice under the Physician Quality Reporting System Group Practice Reporting Option of the Shared Savings Program for purposes of the Physician Quality Reporting System payment adjustment under the Shared Savings Program for 2016 and subsequent years.

(3) If an ACO, on behalf of eligible professionals who bill under the TIN of an ACO participant, does not satisfactorily report for purposes of the Physician Quality Reporting System payment adjustment for 2016 and subsequent years, each eligible professional who bills under the TIN of an ACO participant, will receive a payment adjustment, as described in § 414.90(e) of this chapter.

(4) For eligible professionals subject to the Physician Quality Reporting System payment adjustment under the Medicare Shared Savings Program for 2016 and subsequent years, the Medicare Part B Physician Fee Schedule amount for covered professional services furnished during the program year is equal to the applicable percent of the Medicare Part B Physician Fee Schedule amount that would otherwise apply to such services under section 1848 of the Act, as described in § 414.90(e) of this chapter.

(5) The reporting period for a year is the calendar year from January 1 through December 31 that occurs 2 years prior to the program year in which the payment adjustment is applied.

(d) *Physician Quality Reporting System payment adjustment for 2017 and 2018.* (1) ACOs, on behalf of eligible professionals who bill under the TIN of an ACO participant, must submit all of the ACO GPRO measures determined under § 425.500 using a CMS web interface, to satisfactorily report on behalf of their eligible professionals for purposes of the Physician Quality Reporting System payment adjustment under the Shared Savings Program for 2017 and 2018.

(2) Eligible professionals who bill under the TIN of an ACO participant within an ACO participate under their ACO participant TIN as a group practice under the Physician Quality Reporting System Group Practice Reporting Option of the Shared Savings Program for purposes of the Physician Quality Reporting System payment adjustment under the Shared Savings Program for 2017 and 2018.

(3) If an ACO, on behalf of eligible professionals who bill under the TIN of an ACO participant, does not satisfactorily report for purposes of the Physician Quality Reporting System payment adjustment for 2017 or 2018, each eligible professional who bills under the TIN of an ACO participant will receive a payment adjustment, as described in § 414.90(e) of this chapter, unless such eligible professionals have reported quality measures apart from the ACO in the form and manner required by the Physician Quality Reporting System.

(4) For eligible professionals subject to the Physician Quality Reporting System payment adjustment under the Medicare Shared Savings Program for 2017 or 2018, the Medicare Part B Physician Fee Schedule amount for covered professional services furnished during the program year is equal to the applicable percent of the Medicare Part B Physician Fee Schedule amount that would otherwise apply to such services under section 1848 of the Act, as described in § 414.90(e) of this chapter.

(5) The reporting period for a year is the calendar year from January 1 through December 31 that occurs 2 years prior to the program year in which the payment adjustment is applied, unless otherwise specified by CMS under the Physician Quality Reporting System.

[76 FR 67973, Nov. 2, 2011, as amended at 77 FR 69372, Nov. 16, 2012; 78 FR 74283, Dec. 10, 2013; 80 FR 71386, Nov. 16, 2015; 81 FR 80560, Nov. 15, 2016]

§ 425.506 Incorporating reporting requirements related to adoption of certified electronic health record technology.

(a) ACOs, ACO participants, and ACO providers/suppliers are encouraged to develop a robust EHR infrastructure.

(b) For performance years 2012 through 2018, as part of the quality performance score, the quality measure regarding EHR adoption will be measured based on a sliding scale.

(c) For performance years 2012 through 2018, performance on this measure will be weighted twice that of any other measure for scoring purposes and for determining compliance with quality performance requirements for domains.

(d) Through reporting period 2016, eligible professionals participating in an ACO under the Shared Savings Program satisfy the CQM reporting component of meaningful use for the Medicare EHR Incentive Program when the following occurs:

(1) The eligible professional extracts data necessary for the ACO to satisfy the quality reporting requirements under this subpart from certified EHR technology.

(2) The ACO reports the ACO GPRO measures through a CMS web interface.

(e) For 2017 and 2018, CMS will annually assess the degree of use of certified EHR technology by eligible clinicians billing through the TINs of ACO participants for purposes of meeting the CEHRT criterion necessary for Advanced Alternative Payment Models under the Quality Payment Program.

(1) During years in which the measure is designated as pay for reporting, in order to demonstrate complete and accurate reporting, at least one eligible clinician billing through the TIN of an ACO participant must meet the reporting requirements under the Advancing Clinical Information category under the Quality Payment Program.

(2) During years in which the measure is designated as pay for performance, the quality measure regarding EHR adoption will be measured based on a sliding scale.

(f) For performance years starting on January 1, 2019 through 2024, ACOs in a track that—

(1) Does not meet the financial risk standard to be an Advanced APM must certify annually that the percentage of eligible clinicians participating in the ACO that use CEHRT to document and communicate clinical care to their patients or other health care providers meets or exceeds 50 percent; or

(2) Meets the financial risk standard to be an Advanced APM must certify annually that the percentage of eligible clinicians participating in the ACO that use CEHRT to document and communicate clinical care to their patients or other health care providers meets or exceeds the threshold established under § 414.1415(a)(1)(i) of this chapter.

[76 FR 67973, Nov. 2, 2011, as amended at 79 FR 68009, Nov. 13, 2014; 81 FR 80560, Nov. 15, 2016; 83 FR 60094, Nov. 23, 2018; 88 FR 79546, Nov. 16, 2023]

§ 425.507 Incorporating Promoting Interoperability requirements related to the Quality Payment Program for performance years beginning on or after January 1, 2025.

(a) For performance years beginning on or after January 1, 2025, unless otherwise excluded under paragraph (b) of this section, an ACO participant, ACO provider/supplier, and ACO professional that is a MIPS eligible clinician, Qualifying APM Participant (QP), or Partial Qualifying APM Participant (Partial QP) (each as defined at § 414.1305 of this chapter) must satisfy all of the following:

(1) Report the MIPS Promoting Interoperability performance category measures and requirements to MIPS according to 42 CFR part 414 subpart O at the individual, group, virtual group, or APM entity level.

(2) Earn a performance category score for the MIPS Promoting Interoperability performance category at the individual, group, virtual group, or APM entity level.

(b) An ACO participant, ACO provider/supplier, or ACO professional is excluded from the requirements specified in paragraph (a) of this section in accordance with applicable policies that exclude or otherwise exempt eligible clinicians from reporting the MIPS Promoting Interoperability performance category as set forth in 42 CFR part 414 subpart O, provided however,

that an ACO participant, ACO provider/supplier, or ACO professional cannot be excluded from the requirements specified in paragraph (a) solely on the basis of being a QP or Partial QP. Applicable exclusions may include:

(1) Low volume threshold as set forth at § 414.1310(b)(1)(iii) of this chapter.

(2) Eligible clinician as defined at § 414.1305 of this chapter who is not a MIPS eligible clinician as set forth in § 414.1310(b)(2) of this chapter.

(3) Reweighting of the MIPS Promoting Interoperability performance category to zero percent of the final score in accordance with applicable policies set forth at § 414.1380(c)(2) of this chapter.

[88 FR 79546, Nov. 16, 2023]

§ 425.508 Incorporating quality reporting requirements related to the Quality Payment Program.

(a) *For performance years (or a performance period) beginning in 2017–2020.* ACOs, on behalf of eligible clinicians who bill under the TIN of an ACO participant, must submit all of the CMS web interface measures determined under § 425.500 to satisfactorily report on behalf of their eligible clinicians for purposes of the quality performance category of the Quality Payment Program.

(b) *For performance years beginning in 2021–2024.* ACOs must submit the quality data via the APM Performance Pathway (APP) established under § 414.1367 of this chapter to satisfactorily report on behalf of the eligible clinicians who bill under the TIN of an ACO participant for purposes of the MIPS Quality performance category of the Quality Payment Program.

(c) *For performance years beginning on or after January 1, 2025.* ACOs must submit the quality data via the APM Performance Pathway (APP) on the quality measures contained in the APP Plus quality measure set established under § 414.1367 of this chapter to satisfactorily report on behalf of the eligible clinicians who bill under the TIN of an ACO participant for purposes of the MIPS Quality performance category of the Quality Payment Program.

[81 FR 80561, Nov. 15, 2016, as amended at 85 FR 85040, Dec. 28, 2020; 89 FR 98568, Dec. 9, 2024]

§ 425.510 Application of the APM Performance Pathway (APP) quality measure set or the APP Plus quality measure set (as applicable) to Shared Savings Program ACOs for performance years beginning on or after January 1, 2021.

(a) *General.* (1) CMS establishes quality performance measures to assess the quality of care furnished by the ACO. If the ACO demonstrates to CMS that it has satisfied the quality performance requirements in this subpart, and the ACO meets all other applicable requirements, the ACO is eligible to receive shared savings.

(2) CMS seeks to improve the quality of care furnished by ACOs over time by specifying higher standards, new measures, or both.

(b) *Quality reporting.* (1) For performance years beginning in 2021–2024, ACOs must report quality data on the APP quality measure set established under § 414.1367 of this chapter, according to the method of submission established by CMS.

(2) For performance years beginning on or after January 1, 2025, ACOs must report quality data on the APP Plus quality measure set established under § 414.1367 of this chapter, according to the method of submission established by CMS.

(c) *Audit and validation of data.* CMS retains the right to audit and validate quality data reported by an ACO under paragraph (b) of this section according to § 414.1390 of this chapter.

[85 FR 85041, Dec. 28, 2020, as amended at 89 FR 98568, Dec. 9, 2024]

§ 425.512 Determining the ACO quality performance standard for performance years beginning on or after January 1, 2021.

(a) *Establishing a quality performance standard*—(1) *Overall standard.* The quality performance standard is the overall standard the ACO must meet in order to be eligible to receive shared savings for a performance year. An ACO will not qualify to share in savings in any year it fails to meet the quality performance standard.

(2) For the first performance year of an ACO's first agreement period under the Shared Savings Program, the ACO will meet the quality performance

standard if it meets the requirements under this paragraph (a)(2).

(i) For performance years 2022 and 2023. If the ACO reports data via the APP and meets the data completeness requirement at § 414.1340 of this subchapter and the case minimum requirement at § 414.1380 of this subchapter on the ten CMS Web Interface measures or the three eCQMs/MIPS CQMs, and the CAHPS for MIPS survey, for the applicable performance year.

(ii) For performance year 2024. If the ACO reports data via the APP and meets the data completeness requirement at § 414.1340 of this subchapter on the ten CMS Web Interface measures or the three eCQMs/MIPS CQMs/Medicare CQMs, and the CAHPS for MIPS survey (except as specified in § 414.1380(b)(1)(vii)(B) of this subchapter), and receives a MIPS Quality performance category score under § 414.1380(b)(1) of this subchapter, for the applicable performance year.

(iii) For performance years 2025 and 2026. If the ACO reports the APP Plus quality measure set and meets the data completeness requirement at § 414.1340 of this subchapter on all eCQMs/MIPS CQMs/Medicare CQMs, and the CAHPS for MIPS survey (except as specified in § 414.1380(b)(1)(vii)(B) of this subchapter), and receives a MIPS Quality performance category score under § 414.1380(b)(1) of this subchapter, for the applicable performance year.

(iv) For performance year 2027 and subsequent performance years. If the ACO reports the APP Plus quality measure set and meets the data completeness requirement at § 414.1340 of this subchapter on all eCQMs/Medicare CQMs, and the CAHPS for MIPS survey (except as specified in § 414.1380(b)(1)(vii)(B) of this subchapter), and receives a MIPS Quality performance category score under § 414.1380(b)(1) of this subchapter, for the applicable performance year.

(3) For performance year 2021. (i) Except as specified in paragraph (a)(2) of this section, CMS designates the quality performance standard as the ACO reporting quality data via the APP established under § 414.1367 of this subchapter, according to the method of submission established by CMS and achieving a quality performance score that is equivalent to or higher than the 30th percentile across all MIPS Quality performance category scores, excluding entities/providers eligible for facility-based scoring.

(ii) If an ACO does not report any of the ten CMS Web Interface measures or any of the three eCQMs/MIPS CQMs and does not administer a CAHPS for MIPS survey under the APP, the ACO will not meet the quality performance standard.

(4) For performance years 2022 and 2023. (i) Except as specified in paragraph (a)(2) of this section, CMS designates the quality performance standard as the ACO reporting quality data via the APP established under § 414.1367 of this subchapter according to the method of submission established by CMS and either:

(A) Achieving a health equity adjusted quality performance score that is equivalent to or higher than the 30th percentile across all MIPS Quality performance category scores, excluding entities/providers eligible for facility-based scoring, or

(B) If the ACO reports the three eCQMs/MIPS CQMs in the APP measure set, meeting the data completeness requirement at § 414.1340 of this subchapter and the case minimum requirement at § 414.1380 of this subchapter for all three eCQMs/MIPS CQMs, achieving a quality performance score equivalent to or higher than the 10th percentile of the performance benchmark on at least one of the four outcome measures in the APP measure set and a quality performance score equivalent to or higher than the 30th percentile of the performance benchmark on at least one of the remaining five measures in the APP measure set.

(ii) For performance year 2023, CMS designates an alternative quality performance standard for an ACO that does not meet the criteria described in paragraphs (a)(2) or (a)(4)(i) of this section, but reports quality data via the APP established under § 414.1367 of this subchapter according to the method of submission established by CMS and achieves a quality performance score equivalent to or higher than the 10th

percentile of the performance benchmark on at least one of the four outcome measures in the APP measure set.

(iii) If an ACO does not report any of the ten CMS Web Interface measures or any of the three eCQMs/MIPS CQMs and does not administer a CAHPS for MIPS survey under the APP, the ACO will not meet the quality performance standard or the alternative quality performance standard.

(5) For performance year 2024 and subsequent performance years.

(i) Except as specified in paragraphs (a)(2) and (7) of this section, CMS designates the quality performance standard as:

(A) For performance year 2024, the ACO reporting quality data on the APP quality measure set established under §414.1367 of this subchapter, according to the method of submission established by CMS and—

(*1*) Achieving a health equity adjusted quality performance score that is equivalent to or higher than the 40th percentile across all MIPS Quality performance category scores, excluding entities/providers eligible for facility-based scoring, or

(*2*) If the ACO reports the three eCQMs/MIPS CQMs in the APP measure set, meeting the data completeness requirement at §414.1340 of this subchapter for all three eCQMs/MIPS CQMs, and achieving a quality performance score equivalent to or higher than the 10th percentile of the performance benchmark on at least one of the four outcome measures in the APP measure set and a quality performance score equivalent to or higher than the 40th percentile of the performance benchmark on at least one of the remaining five measures in the APP measure set.

(B) For performance years 2025 and 2026, the ACO reporting quality data on the APP Plus quality measure set established under §414.1367 of this subchapter, according to the method of submission established by CMS and—

(*1*) Achieving a health equity adjusted quality performance score that is equivalent to or higher than the 40th percentile across all MIPS Quality performance category scores, excluding entities/providers eligible for facility-based scoring; or

(*2*) If the ACO reports all of the eCQMs/MIPS CQMs in the APP Plus quality measure set applicable for a performance year, meeting the data completeness requirement at §414.1340 of this subchapter for all eCQMs/MIPS CQMs, and achieving a quality performance score equivalent to or higher than the 10th percentile of the performance benchmark on at least one of the outcome measures in the APP Plus quality measure set and a quality performance score equivalent to or higher than the 40th percentile of the performance benchmark on at least one of the remaining measures in the APP Plus quality measure set.

(C) For performance year 2027 and subsequent performance years, the ACO reporting quality data on the APP Plus quality measure set established under §414.1367 of this subchapter, according to the method of submission established by CMS and—

(*1*) Achieving a health equity adjusted quality performance score that is equivalent to or higher than the 40th percentile across all MIPS Quality performance category scores, excluding entities/providers eligible for facility-based scoring; or

(*2*) If the ACO reports all of the eCQMs in the APP Plus quality measure set applicable for a performance year, meeting the data completeness requirement at §414.1340 of this subchapter for all eCQMs, and achieving a quality performance score equivalent to or higher than the 10th percentile of the performance benchmark on at least one of the four outcome measures in the APP Plus quality measure set and a quality performance score equivalent to or higher than the 40th percentile of the performance benchmark on at least one of the remaining measures in the APP Plus quality measure set.

(ii) CMS designates an alternative quality performance standard for an ACO that does not meet the criteria described in paragraph (a)(2) or (a)(5)(i) of this section as the following:

(A) For performance year 2024, the ACO reports quality data on the APP quality measure set established under §414.1367 of this subchapter according

to the method of submission established by CMS and achieves a quality performance score equivalent to or higher than the 10th percentile of the performance benchmark on at least one of the four outcome measures in the APP quality measure set.

(B) For performance year 2025 and subsequent performance years, the ACO reports quality data on the APP Plus quality measure set established under § 414.1367 of this subchapter according to the method of submission established by CMS and achieves a quality performance score equivalent to or higher than the 10th percentile of the performance benchmark on at least one of the outcome measures in the APP Plus quality measure set.

(iii) An ACO will not meet the quality performance standard or the alternative quality performance standard if:

(A) For performance year 2024, the ACO does not report any of the ten CMS Web Interface measures, any of the three eCQMs/MIPS CQMs/Medicare CQMs and does not administer a CAHPS for MIPS survey (except as specified in § 414.1380(b)(1)(vii)(B) of this subchapter) under the APP.

(B) For performance years 2025 and 2026, the ACO does not report any of the eCQMs/MIPS CQMs/Medicare CQMs in the APP Plus quality measure set and does not administer a CAHPS for MIPS survey (except as specified in § 414.1380(b)(1)(vii)(B) of this subchapter).

(C) For performance year 2027 and subsequent performance years, the ACO does not report any of the eCQMs/Medicare CQMs in the APP Plus quality measure set and does not administer a CAHPS for MIPS survey (except as specified in § 414.1380(b)(1)(vii)(B) of this subchapter).

(6) For performance years 2022, 2023, and 2024, CMS designates a performance benchmark and minimum attainment level for each CMS Web Interface measure and establishes a point scale for the measure as described in § 425.502(b).

(7) CMS will use the higher of the ACO's health equity adjusted quality performance score or the equivalent of the 40th percentile MIPS Quality performance category score across all MIPS Quality performance category scores, excluding entities/providers eligible for facility-based scoring, for the relevant performance year when—

(i) For performance year 2024, if an ACO reports all of the required measures, meeting the data completeness requirement at § 414.1340 of this subchapter for each measure in the APP quality measure set and receiving a MIPS Quality performance category score as described at § 414.1380(b)(1) of this subchapter and the ACO meets either of the following:

(A) The ACO's total available measure achievement points used to calculate the ACO's MIPS Quality performance category score are reduced under § 414.1380(b)(1)(vii)(A) of this subchapter.

(B) At least one of the eCQMs/MIPS CQMs/Medicare CQMs does not have a benchmark as described at § 414.1380(b)(1)(i)(A) of this subchapter.

(ii) For performance year 2025 and subsequent performance years, if an ACO reports all of the required measures in the APP Plus quality measure set, meeting the data completeness requirement at § 414.1340 of this subchapter for each measure in the APP Plus quality measure set, and receiving a MIPS Quality performance category score as described at § 414.1380(b)(1) of this subchapter, for the relevant performance year, and the ACO meets either of the following:

(A) The ACO's total available measure achievement points used to calculate the ACO's MIPS Quality performance category score are reduced under § 414.1380(b)(1)(vii)(A) of this subchapter.

(B) At least one of the required measures in the APP Plus quality measure set does not have a benchmark as described at § 414.1380(b)(1)(i)(A) of this subchapter.

(b) *Calculation of ACO's health equity adjusted quality performance score for performance year 2023 and subsequent performance years*—(1) *For performance year 2023.* For an ACO that reports the three eCQMs/MIPS CQMs in the APP quality measure set, meeting the data completeness requirement at § 414.1340 of this subchapter for all three eCQMs/MIPS CQMs, and administers the

CAHPS for MIPS survey, CMS calculates the ACO's health equity adjusted quality performance score as the sum of the ACO's MIPS Quality performance category score for all measures in the APP quality measure set and the ACO's health equity adjustment bonus points calculated in accordance with paragraph (b)(4) of this section. The sum of these values may not exceed 100 percent.

(2) *For performance year 2024.* For an ACO that reports the three eCQMs/MIPS CQMs/Medicare CQMs in the APP quality measure set, meeting the data completeness requirement at §414.1340 of this subchapter for all three eCQMs/MIPS CQMs/Medicare CQMs, and administers the CAHPS for MIPS survey (except as specified in §414.1380(b)(1)(vii)(B) of this subchapter), CMS calculates the ACO's health equity adjusted quality performance score as the sum of the ACO's MIPS Quality performance category score for all measures in the APP quality measure set and the ACO's health equity adjustment bonus points calculated in accordance with paragraph (b)(4) of this section. The sum of these values may not exceed 100 percent.

(3) *For performance year 2025 and subsequent performance years.* For an ACO that reports all of the required measures in the APP Plus quality measure set, meeting the data completeness requirement at §414.1340 of this subchapter for all of the required measures in the APP Plus quality measure set, and administers the CAHPS for MIPS survey (except as specified in §414.1380(b)(1)(vii)(B) of this subchapter), CMS calculates the ACO's health equity adjusted quality performance score as the sum of the ACO's MIPS Quality performance category score for all measures in the APP Plus quality measure set and the ACO's health equity adjustment bonus points calculated in accordance with paragraph (b)(4) of this section. The sum of these values may not exceed 100 percent.

(4) *Calculation of ACO's health equity adjustment bonus points.* CMS calculates the ACO's health equity adjustment bonus points as follows:

(i) For each measure that an ACO is required to report for the applicable performance year, CMS groups an ACO's performance into the top, middle, or bottom third of ACO measure performers by reporting mechanism.

(ii) CMS assigns values to the ACO for its performance on each measure as follows:

(A) Values of four, two, or zero for each measure for which the ACO's performance places it in the top, middle, or bottom third of ACO measure performers, respectively.

(B) Values of zero for each measure that CMS does not evaluate because the measure is unscored or the ACO does not meet the case minimum or the minimum sample size for the measure.

(iii) CMS sums the values assigned to the ACO according to paragraph (b)(4)(ii) of this section, to calculate the ACO's measure performance scaler.

(iv) CMS calculates an underserved multiplier for the ACO.

(A)(*1*) CMS determines the proportion ranging from zero to one of the ACO's assigned beneficiary population for the performance year that is considered underserved based on the highest of either of the following:

(*i*) The proportion of the ACO's assigned beneficiaries residing in a census block group with an Area Deprivation Index (ADI) national percentile rank of at least 85. An ACO's assigned beneficiaries without an available numeric ADI national percentile rank are excluded from the calculation of the proportion of the ACO's assigned beneficiaries residing in a census block group with an ADI national percentile rank of at least 85.

(*ii*) The proportion of the ACO's assigned beneficiaries who are enrolled in the Medicare Part D low-income subsidy (LIS); or are dually eligible for Medicare and Medicaid.

(*2*) CMS calculates the proportions specified in paragraph (b)(4)(iv)(A)(*1*)(*ii*) of this section as follows:

(*i*) For performance year 2023, the proportion of the ACO's assigned beneficiaries who are enrolled in the Medicare Part D LIS or are dually eligible for Medicare and Medicaid divided by the total number of the ACO's assigned beneficiaries' person years.

(*ii*) For performance year 2024 and subsequent performance years, the proportion of the ACO's assigned beneficiaries with any months enrolled in LIS or dually eligible for Medicare and Medicaid divided by the total number of the ACO's assigned beneficiaries.

(B) If the proportion determined in accordance with paragraph (b)(4)(iv)(A) of this section is lower than 20 percent, the ACO is ineligible for health equity adjustment bonus points.

(v) Except as specified in paragraph (b)(4)(iv)(B) of this section, CMS calculates the ACO's health equity adjustment bonus points as the product of the measure performance scaler determined under paragraph (b)(4)(iii) of this section and the underserved multiplier determined under paragraph (b)(4)(iv) of this section. If the product of these values is greater than 10, the value of the ACO's health equity adjustment bonus points is set equal to 10.

(5) *Use of ACO's health equity adjusted quality performance score.* The ACO's health equity adjusted quality performance score, determined in accordance with paragraphs (b)(1) through (4) of this section, is used as follows:

(i) In determining whether the ACO meets the quality performance standard as specified under paragraphs (a)(4)(i)(A), (a)(5)(i)(A)(*1*), (a)(5)(i)(B), and (a)(7) of this section.

(ii) In determining the final sharing rate for calculating shared savings payments under the BASIC track in accordance with §425.605(d), and under the ENHANCED track in accordance with §425.610(d), for an ACO that meets the alternative quality performance standard by meeting the criteria specified in paragraph (a)(4)(ii) or (a)(5)(ii) of this section.

(iii) In determining the shared loss rate for calculating shared losses under the ENHANCED track in accordance with §425.610(f), for an ACO that meets the quality performance standard established in paragraphs (a)(2), (a)(4)(i), and (a)(5)(i) of this section or the alternative quality performance standard established in paragraph (a)(4)(ii) or (a)(5)(ii) of this section.

(iv) In determining the quality performance score for an ACO affected by extreme and uncontrollable circumstances as described in paragraphs (c)(3)(ii) through (iv) of this section.

(c) *Extreme and uncontrollable circumstances.* For performance year 2021 and subsequent performance years, including the applicable quality data reporting period for the performance year, CMS uses an alternative approach to calculating the quality score for ACOs affected by extreme and uncontrollable circumstances instead of the methodology specified in paragraph (a) of this section as follows:

(1) CMS determines the ACO was affected by an extreme and uncontrollable circumstance based on either of the following:

(i) Twenty percent or more of the ACO's assigned beneficiaries reside in an area identified under the Quality Payment Program as being affected by an extreme and uncontrollable circumstance.

(A) Assignment is determined under subpart E of this part.

(B) In making this determination, CMS uses the quarter four list of assigned beneficiaries.

(ii) The ACO's legal entity is located in an area identified under the Quality Payment Program as being affected by an extreme and uncontrollable circumstance. An ACO's legal entity location is based on the address on file for the ACO in CMS' ACO application and management system.

(2) If CMS determines the ACO meets the requirements of paragraph (c)(1) of this section, CMS calculates the ACO's quality score as follows:

(i) For performance years 2021, 2022, and 2023, the ACO's minimum quality performance score is set to the equivalent of the 30th percentile MIPS Quality performance category score across all MIPS Quality performance category scores, excluding entities/providers eligible for facility-based scoring, for the relevant performance year.

(ii) For performance year 2024 and subsequent performance years, the ACO's minimum quality performance score is set to the equivalent of the 40th percentile MIPS Quality performance category score across all MIPS Quality performance category scores, excluding entities/providers eligible for facility-based scoring, for the relevant performance year.

(3) If CMS determines the ACO meets the requirements of paragraph (c)(1) of this section and the ACO reports quality data on the APP quality measure set or the APP Plus quality measure set (as applicable), CMS calculates the ACO's quality score as follows:

(i) For performance years 2021 and 2022, if the ACO reports quality data via the APP and meets data completeness and case minimum requirements, CMS will use the higher of the ACO's quality performance score or the equivalent of the 30th percentile MIPS Quality performance category score across all MIPS Quality performance category scores, excluding entities/providers eligible for facility-based scoring, for the relevant performance year.

(ii) For performance year 2023, if the ACO reports quality data via the APP and meets data completeness and case minimum requirements, CMS will use the higher of the ACO's health equity adjusted quality performance score or the equivalent of the 30th percentile MIPS Quality performance category score across all MIPS Quality performance category scores, excluding entities/providers eligible for facility-based scoring, for the relevant performance year.

(iii) For performance year 2024 , if the ACO reports quality data via the APP and meets the data completeness requirement at § 414.1340 of this subchapter and receives a MIPS Quality performance category score under § 414.1380(b)(1) of this subchapter, CMS will use the higher of the ACO's health equity adjusted quality performance score or the equivalent of the 40th percentile MIPS Quality performance category score across all MIPS Quality performance category scores, excluding entities/providers eligible for facility-based scoring, for the relevant performance year.

(iv) For performance year 2025 and subsequent performance years, if the ACO reports the APP Plus quality measure set and meets the data completeness requirement at § 414.1340 of this subchapter and receives a MIPS Quality performance category score under § 414.1380(b)(1) of this subchapter, CMS will use the higher of the ACO's health equity adjusted quality performance score or the equivalent of the 40th percentile MIPS Quality performance category score across all MIPS Quality performance category scores, excluding entities/providers eligible for facility-based scoring, for the relevant performance year.

(4) CMS applies determinations made under the Quality Payment Program with respect to—

(i) Whether an extreme and uncontrollable circumstance has occurred; and

(ii) The affected areas.

(5) CMS has sole discretion to determine the time period during which an extreme and uncontrollable circumstance occurred, the percentage of the ACO's assigned beneficiaries residing in the affected areas, and the location of the ACO legal entity.

[85 FR 85041, Dec. 28, 2020; 86 FR 65685, Nov. 19, 2021, as amended at 87 FR 70234, Nov. 18, 2022; 88 FR 79546, Nov. 16, 2023; 89 FR 98568, Dec. 9, 2024]

Subpart G—Shared Savings and Losses

§ 425.600 Selection of risk model.

(a) An ACO may elect to operate under one of the following tracks:

(1) *Track 1.* For agreement periods beginning before July 1, 2019, an ACO in Track 1 operates under the one-sided model (as described under § 425.604) for the agreement period.

(2) *Track 2.* For agreement periods beginning before July 1, 2019, an ACO in Track 2 operates under a two-sided model (as described under § 425.606), sharing both savings and losses with the Medicare program for the agreement period.

(3) *ENHANCED track.* An ACO in the ENHANCED track operates under a two-sided model (as described under § 425.610), sharing both savings and losses with the Medicare program for the agreement period. For purposes of this part, all references to the ENHANCED track are deemed to include Track 3.

(4) *BASIC track.* For agreement periods beginning on July 1, 2019, and in subsequent years, an ACO in the BASIC track operates under either a one-sided model or a two-sided model (as described under § 425.605), either sharing savings only or sharing both savings

and losses with the Medicare program, as specified in this paragraph (a)(4).

(i) *Levels of the BASIC track's glide path*—(A) *Phase-in of levels of the risk and reward.* Under the BASIC track's glide path, the level of risk and potential reward phases in over the course of the agreement period in the following order:

(*1*) *Level A.* The ACO operates under a one-sided model as described under § 425.605(d)(1)(i).

(*2*) *Level B.* The ACO operates under a one-sided model as described under § 425.605(d)(1)(ii).

(*3*) *Level C.* The ACO operates under a two-sided model as described under § 425.605(d)(1)(iii).

(*4*) *Level D.* The ACO operates under a two-sided model as described under § 425.605(d)(1)(iv).

(*5*) *Level E.* The ACO operates under a two-sided model as described under § 425.605(d)(1)(v).

(B) *Glide path progression for agreement periods beginning on or after July 1, 2019 and before January 1, 2024.* (*1*) Experience in Track 1. (*i*) Except for an ACO that previously participated in Track 1 under paragraph (a)(1) of this section or a new ACO identified as a re-entering ACO because more than 50 percent of its ACO participants have recent prior experience in a Track 1 ACO, an ACO eligible to enter the BASIC track's glide path as determined under paragraphs (d)(1)(i) and (d)(2)(i) of this section may elect to enter its agreement period at any of the levels of risk and potential reward available under paragraphs (a)(4)(i)(A)(*1*) through (*5*) of this section.

(*ii*) An ACO that previously participated in Track 1 under paragraph (a)(1) of this section or a new ACO identified as a re-entering ACO because more than 50 percent of its ACO participants have recent prior experience in a Track 1 ACO may elect to enter its agreement period at any of the levels of risk and potential reward available under paragraphs (a)(4)(i)(A)(*2*) through (*5*) of this section.

(*2*) Automatic advancement. Unless the ACO elects to transition to a higher level of risk and potential reward within the BASIC track's glide path as provided in § 425.226(a)(2)(i), the ACO is automatically advanced to the next level of the BASIC track's glide path at the start of each subsequent performance year of the agreement period, if a higher level of risk and potential reward is available under the BASIC track.

(*i*) Exception for ACO entering the BASIC track's glide path for an agreement period beginning on July 1, 2019. The automatic advancement does not apply at the start of the second performance year for an ACO entering the BASIC track's glide path for an agreement period beginning on July 1, 2019. For performance year 2020, the ACO remains in the same level of the BASIC track's glide path that it entered for the July 1, 2019 through December 31, 2019 performance year, unless the ACO chooses to advance more quickly in accordance with § 425.226(a)(2)(i). The ACO is automatically advanced to the next level of the BASIC track's glide path at the start of performance year 2021 and all subsequent performance years of the agreement period.

(*ii*) Exception for new legal entity identified as a low revenue ACO. An exception is available for a low revenue ACO that is a new legal entity and is not identified as a re-entering ACO that enters the BASIC track's glide path at Level A under paragraph (a)(4)(i)(A)(*1*) of this section, and is automatically advanced to Level B under paragraph (a)(4)(i)(A)(*2*) of this section for performance year 2 (or performance 3 in the case of ACOs entering an agreement period beginning on July 1, 2019). Prior to the automatic advancement of the ACO to Level C under paragraph (a)(4)(i)(A)(*3*) of this section, the ACO may elect to remain in Level B under paragraph (a)(4)(i)(A)(*2*) of this section for performance year 3 (performance year 4 in the case of ACOs entering an agreement period beginning on July 1, 2019). In the case of an ACO that elects to remain in Level B for an additional performance year pursuant to the second sentence of paragraph (a)(4)(i)(B)(*2*)(*ii*) of this section, and except as provided in paragraph (a)(4)(i)(B)(2)(*vi*) of this section, the ACO is automatically advanced to Level E under paragraph (a)(4)(i)(A)(*5*) of this section at the

start of performance year 4 (or performance year 5 in the case of ACOs entering an agreement period beginning on July 1, 2019).

(*iii*) Exception for ACOs participating in the BASIC track's glide path that elect to maintain their participation level for performance year 2021. Prior to the automatic advancement for performance year 2021, an ACO that is participating in the BASIC track's glide path for performance year 2020 may elect to remain in the same level of the BASIC track's glide path that it entered for the 2020 performance year, for performance year 2021. For performance year 2022, the ACO is automatically advanced to the level of the BASIC track's glide path to which the ACO would have automatically advanced absent the election to maintain its participation level for performance year 2021, unless the ACO elects to transition to a higher level of risk and potential reward within the BASIC track's glide path as provided in § 425.226(a)(2)(i). A voluntary election by an ACO under this paragraph must be made in the form and manner and by a deadline established by CMS.

(*iv*) Exception for ACOs participating in the BASIC track's glide path that elect to maintain their participation level for performance year 2022. Prior to the automatic advancement for performance year 2022, an ACO that is participating in the BASIC track's glide path for performance year 2021 may elect to remain in the same level of the BASIC track's glide path in which it participated during the 2021 performance year, for performance year 2022. Except as provided in paragraph (a)(4)(i)(B)(*2*)(*vi*) of this section, for performance year 2023, the ACO is automatically advanced to the level of the BASIC track's glide path to which the ACO would have automatically advanced absent the election to maintain its participation level for performance year 2022 and, if applicable, the election to maintain its participation level for performance year 2021 under paragraph (a)(4)(i)(B)(*2*)(*iii*) of this section, unless the ACO elects to transition to a higher level of risk and potential reward within the BASIC track's glide path as provided in § 425.226(a)(2)(i). A voluntary election by an ACO under this paragraph must be made in the form and manner and by a deadline established by CMS.

(*v*) Prior to entering performance-based risk, an ACO must meet all requirements to participate under performance-based risk, including establishing an adequate repayment mechanism as specified under § 425.204(f) and selecting a MSR/MLR from the options specified under § 425.605(b).

(*vi*) For performance year 2023, an ACO in Level A under paragraph (a)(4)(i)(A)(*1*) of this section or in Level B under paragraph (a)(4)(i)(A)(*2*) of this section may elect to remain in the same level of the BASIC track's glide path in which it participated during performance year 2022, for the remainder of the agreement period, unless the ACO elects to transition to a higher level of risk and potential reward within the BASIC track's glide path as provided in § 425.226(a)(2)(i). If the ACO does not elect to remain under Level A or Level B, for performance year 2023, the ACO is automatically advanced to the next level of the BASIC track's glide path to which the ACO would have automatically advanced absent any election to maintain its participation level for performance year 2022 under paragraph (a)(4)(i)(B)(*2*)(*iv*) of this section and, if applicable, the election to maintain its participation level for performance year 2021 under paragraph (a)(4)(i)(B)(*2*)(*iii*) of this section, unless the ACO elects to transition to a higher level of risk and potential reward within the BASIC track's glide path as provided in § 425.226(a)(2)(i). A voluntary election by an ACO under this paragraph must be made in the form and manner and by a deadline established by CMS.

(*vii*) For performance year 2024, an ACO with an agreement period beginning January 1, 2023 in Level A under paragraph (a)(4)(i)(A)(*1*) of this section or in Level B under paragraph (a)(4)(i)(A)(*2*) of this section may elect to remain in the same level of the BASIC track's glide path in which it participated during performance year 2023, for the remainder of the agreement period, unless the ACO elects to transition to a higher level of risk and potential reward within the BASIC track's glide path as provided in

§ 425.226(a)(2)(i). If the ACO does not elect to remain under Level A or Level B, for performance year 2024, the ACO is automatically advanced to the next level of the BASIC track's glide path, unless the ACO elects to transition to a higher level of risk and potential reward within the BASIC track's glide path as provided in § 425.226(a)(2)(i). A voluntary election by an ACO under this paragraph must be made in the form and manner and by a deadline established by CMS.

(*3*) If the ACO fails to meet the requirements to participate under performance-based risk under paragraph (a)(4)(i)(B)(*2*)(*v*) of this section, the agreement is terminated.

(*4*) If, in accordance with § 425.226(a)(2)(i), the ACO elects to transition to a higher level of risk and reward available under paragraphs (a)(4)(i)(A)(*3*) through (*5*) of this section, then the automatic transition to levels of higher risk and reward specified in paragraph (a)(4)(i)(B)(*2*) of this section applies to all subsequent performance years of the agreement period.

(C) *Glide path progression for agreement periods beginning on or after January 1, 2024.* (*1*) *Level of glide path entry.* An ACO eligible to enter the BASIC track's glide path as determined under paragraph (g)(1) of this section may elect to enter its agreement period at any of the levels of risk and potential reward available under paragraphs (a)(4)(i)(A)(*1*) through (*5*) of this section.

(*2*) *Automatic advancement.* An ACO is automatically advanced to the next level of the BASIC track's glide path at the start of each subsequent performance year of the agreement period, if a higher level of risk and potential reward is available under the BASIC track, except as follows:

(*i*) The ACO elects to transition to a higher level of risk and potential reward within the BASIC track's glide path as provided in § 425.226(a)(2)(i).

(*ii*) The ACO elects to maintain its level of participation as provided in paragraph (a)(4)(i)(C)(*3*) of this section.

(*iii*) The ACO is automatically advanced to Level E pursuant to paragraph (h)(2)(i) of this section.

(*3*) *Election to remain under a one-sided model.* An eligible ACO that enters the BASIC track's glide path at Level A under paragraph (a)(4)(i)(A)(*1*) of this section and is currently at Level A may elect to remain in Level A under paragraph (a)(4)(i)(A)(*1*) of this section for all subsequent performance years of the agreement period.

(*i*) To be eligible to participate under Level A of the BASIC track as described in this paragraph, the ACO must meet the following requirements: the ACO is participating in its first agreement period under the BASIC track under paragraph (a)(4) of this section, and is not participating in an agreement period under the BASIC track as a renewing ACO (as defined at § 425.20) or a re-entering ACO (as defined in § 425.20) that previously participated in the BASIC track's glide path under paragraph (a)(4) of this section; and the ACO is inexperienced with performance-based risk Medicare ACO initiatives (as defined in § 425.20).

(*ii*) A voluntary election by an ACO under this paragraph (a)(4)(i)(C)(*3*) must be made in the form and manner and by a deadline established by CMS.

(*iii*) The ACO's election to remain in Level A applies for the entirety of the agreement period, unless the ACO elects to transition to a higher level of risk and potential reward within the BASIC track's glide path as provided in § 425.226(a)(2)(i).

(*4*) Prior to entering performance-based risk, an ACO must meet all requirements to participate under performance-based risk, including establishing an adequate repayment mechanism as specified under § 425.204(f) and selecting a MSR/MLR from the options specified under § 425.605(b).

(*5*) If the ACO fails to meet the requirements to participate under performance-based risk under paragraph (a)(4)(i)(C)(*4*) of this section, the agreement is terminated.

(*6*) If, in accordance with § 425.226(a)(2)(i), the ACO elects to transition to a higher level of risk and reward available under paragraphs (a)(4)(i)(A)(*3*) through (*5*) of this section, then the automatic transition to levels of higher risk and reward specified in paragraph (a)(4)(i)(C)(*2*) of this

section applies to all subsequent performance years of the agreement period.

(ii) *Agreement period under Level E of the BASIC track.* If an ACO enters the BASIC track and is ineligible to participate under the glide path described in paragraph (a)(4)(i) of this section, as determined under paragraph (d) or paragraph (g)(2) of this section, as applicable, Level E as described in paragraph (a)(4)(i)(A)(*5*) of this section applies to all performance years of the agreement period.

(b) For agreement periods beginning before July 1, 2019, ACOs may operate under the one-sided model for a maximum of 2 agreement periods. An ACO may not operate under the one-sided model for a second agreement period unless the—

(1) Immediately preceding agreement period was under the one-sided model; and

(2) The ACO meets the criteria established for ACOs seeking to renew their agreements under § 425.224(b).

(c) For agreement periods beginning before July 1, 2019, an ACO experiencing a net loss during a previous agreement period may reapply to participate under the conditions in § 425.202(a), except the ACO must also identify in its application the cause(s) for the net loss and specify what safeguards are in place to enable the ACO to potentially achieve savings in its next agreement period.

(d) For agreement periods beginning on or after July 1, 2019, and before January 1, 2024, CMS determines an ACO's eligibility for the Shared Savings Program participation options specified in paragraph (a) of this section as follows:

(1) If an ACO is identified as a high revenue ACO, the ACO is eligible for the participation options indicated in paragraph (a) of this section as follows:

(i) If the ACO is determined to be inexperienced with performance-based risk Medicare ACO initiatives, the ACO may enter either the BASIC track's glide path at any of the levels of risk and potential reward available under paragraphs (a)(4)(i)(A)(*1*) through (*5*) of this section, except as provided in paragraph (a)(4)(i)(B) of this section, or the ENHANCED track under paragraph (a)(3) of this section.

(ii) If the ACO is determined to be experienced with performance-based risk Medicare ACO initiatives:

(A) The ACO may enter the ENHANCED track under paragraph (a)(3) of this section except as provided in paragraph (d)(1)(ii)(B) of this section.

(B) An ACO in a first or second agreement period beginning in 2016 or 2017 identified as experienced with performance-based risk Medicare ACO initiatives based on participation in the Track 1+ Model may renew for a consecutive agreement period beginning on July 1, 2019, or January 1, 2020 (respectively), under either the BASIC track Level E under paragraph (a)(4)(i)(A)(*5*) of this section, or the ENHANCED track under paragraph (a)(3) of this section.

(2) If an ACO is identified as a low revenue ACO, the ACO is eligible for the participation options indicated in paragraph (a) of this section as follows:

(i) If the ACO is determined to be inexperienced with performance-based risk Medicare ACO initiatives, the ACO may enter either the BASIC track's glide path at any of the levels of risk and potential reward available under paragraphs (a)(4)(i)(A)(*1*) through (*5*) of this section, except as provided in paragraph (a)(4)(i)(B) of this section, or the ENHANCED track under paragraph (a)(3) of this section.

(ii) If the ACO is determined to be experienced with performance-based risk Medicare ACO initiatives, the ACO may enter under either the BASIC track Level E under paragraph (a)(4)(i)(A)(*5*) of this section, except as provided in paragraph (d)(3) of this section, or the ENHANCED track under paragraph (a)(3) of this section.

(3) Low revenue ACOs may participate under the BASIC track for a maximum of two agreement periods. A low revenue ACO may only participate in the BASIC track for a second agreement period if it satisfies either of the following:

(i) The ACO is the same legal entity as a current or previous ACO that previously entered into a participation agreement for participation in the BASIC track only one time.

(ii) For a new ACO identified as a reentering ACO, the ACO in which the majority of the new ACO's participants

were participating previously entered into a participation agreement for participation in the BASIC track only one time.

(e) For performance years beginning on or after July 1, 2019 and before January 1, 2024, CMS monitors low revenue ACOs identified as experienced with performance-based risk Medicare ACO initiatives, during an agreement period in the BASIC track, for changes in the revenue of ACO participants that would cause the ACO to be considered a high revenue ACO and ineligible for participation in the BASIC track. If the ACO meets the definition of a high revenue ACO (as specified in § 425.20)—

(1) The ACO is permitted to complete the remainder of its current performance year under the BASIC track, but is ineligible to continue participation in the BASIC track after the end of that performance year if it continues to meet the definition of a high revenue ACO; and

(2) CMS takes compliance action as specified in §§ 425.216 and 425.218, up to and including termination of the participation agreement, to ensure the ACO does not continue in the BASIC track for subsequent performance years of the agreement period if it continues to meet the definition of a high revenue ACO.

(f) For agreement periods beginning on July 1, 2019, and in subsequent years, CMS determines the agreement period an ACO is entering for purposes of applying program requirements that phase-in over multiple agreement periods, as follows:

(1) An ACO entering an initial agreement period is considered to be entering a first agreement period in the Shared Savings Program.

(2) A re-entering ACO is considered to be entering a new agreement period in the Shared Savings Program as follows—

(i) An ACO whose participation agreement expired without having been renewed re-enters the program under the next consecutive agreement period in the Shared Savings Program;

(ii) An ACO whose participation agreement was terminated under § 425.218 or § 425.220 re-enters the program at the start of the same agreement period in which it was participating at the time of termination from the Shared Savings Program, beginning with the first performance year of that agreement period; or

(iii) A new ACO identified as a re-entering ACO enters the program in an agreement period that is determined based on the prior participation of the ACO in which the majority of the new ACO's participants were participating.

(A) If the participation agreement of the ACO used in this determination expired without having been renewed or was terminated, the agreement period of the re-entering ACO is determined in accordance with paragraph (f)(2)(i) or (ii) of this section, as applicable.

(B) If the ACO used in this determination is currently participating in the program, the new ACO is considered to be entering into the same agreement period as this currently participating ACO, beginning with the first performance year of that agreement period.

(3) A renewing ACO is considered to be entering the next consecutive agreement period in the Shared Savings Program.

(4) For purposes of this paragraph (f), program requirements that phase in over multiple agreement periods are as follows:

(i) The quality performance standard as described in § 425.502(a) or § 425.512(a), as applicable.

(ii) The weight used in calculating the regional adjustment to the ACO's historical benchmark as described in §§ 425.601(f), and 425.656(e).

(iii) The use of equal weights to weight each benchmark year as specified in §§ 425.601(e), and 425.652(c)(2).

(g) For agreement periods beginning on or after January 1, 2024, CMS determines an ACO's eligibility for the Shared Savings Program participation options specified in paragraph (a) of this section as follows:

(1) If an ACO is determined to be inexperienced with performance-based risk Medicare ACO initiatives, the ACO may enter either the BASIC track's glide path at any of the levels of risk and potential reward under paragraphs (a)(4)(i)(A)(*1*) through (*5*) of this section, or the ENHANCED track under paragraph (a)(3) of this section.

(i) An ACO that is inexperienced with performance-based risk Medicare ACO initiatives may participate under the BASIC track's glide path for a maximum of two agreement periods, as specified in paragraph (a)(4)(i)(C) of this section.

(ii) An ACO that enters an agreement under the BASIC track's glide path at either Level A under paragraph (a)(4)(i)(A)(*1*) of this section or Level B under paragraph (a)(4)(i)(A)(*2*) of this section is deemed to have completed one agreement under the BASIC track's glide path and is only eligible to enter a second agreement under the BASIC track's glide path if the ACO continues to meet the definition of inexperienced with performance-based risk Medicare ACO initiatives and satisfies either of the following:

(A) The ACO is the same legal entity as a current or previous ACO that previously entered into a participation agreement for participation in the BASIC track's glide path only one time.

(B) For a new ACO identified as a reentering ACO, the ACO in which the majority of the new ACO's participants were participating previously entered into a participation agreement for participation in the BASIC track's glide path only one time.

(iii) An ACO that is determined to be inexperienced with performance-based risk Medicare ACO initiatives but is not eligible to enter the BASIC track's glide path as specified in paragraph (a)(4)(i)(C) of this section may enter either the BASIC track Level E under paragraph (a)(4)(i)(A)(*5*) of this section for all performance years of the agreement period, or the ENHANCED track under paragraph (a)(3) of this section.

(2) If an ACO is determined to be experienced with performance-based risk Medicare ACO initiatives, the ACO may enter either the BASIC track Level E under paragraph (a)(4)(i)(A)(*5*) of this section for all performance years of the agreement period, or the ENHANCED track under paragraph (a)(3) of this section.

(h)(1) For performance years beginning on or after January 1, 2024, CMS monitors ACOs identified as inexperienced with performance-based risk Medicare ACO initiatives and participating in the BASIC track under a one-sided model during an agreement period pursuant to an election under paragraph (a)(4)(i)(B)(*2*)(*vi*), paragraph (a)(4)(i)(B)(*2*)(*vii*), or paragraph (a)(4)(i)(C)(*3*) of this section for changes to their certified list of ACO participants that would cause the ACO to be considered experienced with performance-based risk Medicare ACO initiatives and ineligible for participation in a one-sided model.

(2) If the ACO meets the definition of experienced with performance-based risk Medicare ACO initiatives (under § 425.20)—

(i) The ACO is permitted to complete the performance year for which it met the definition of experienced with performance-based risk Medicare ACO initiatives in a one-sided model of the BASIC track, but is ineligible to continue participation in the one-sided model after the end of that performance year if it continues to meet the definition of experienced with performance-based risk Medicare ACO initiatives. The ACO will be automatically advanced to Level E within the BASIC track under paragraph (a)(4)(i)(A)(*5*) of this section at the start of the next performance year and will remain in Level E for all subsequent performance years of the agreement period; and

(ii) Prior to entering performance-based risk, the ACO must meet all requirements to participate under performance-based risk, including establishing an adequate repayment mechanism as specified under § 425.204(f) and selecting a MSR/MLR from the options specified under § 425.605(b), in accordance with paragraph (a)(4)(i)(B)(*2*)(*v*) of this section or paragraph (a)(4)(i)(C)(*4*) of this section, as applicable. If the ACO fails to meet the requirements to participate under performance-based risk, the agreement is terminated in accordance with paragraph (a)(4)(i)(B)(*3*) of this section or paragraph (a)(4)(i)(C)(*5*) of this section, as applicable.

[76 FR 67973, Nov. 2, 2011, as amended at 80 FR 32841, June 9, 2015; 83 FR 68069, Dec. 31, 2018; 85 FR 27625, May 8, 2020; 85 FR 85041, Dec. 28, 2020; 86 FR 45521, Aug. 13, 2021; 87 FR 70235, Nov. 18, 2022; 88 FR 79547, Nov. 16, 2023]

§ 425.601 Establishing, adjusting, and updating the benchmark for agreement periods beginning on or after July 1, 2019, and before January 1, 2024.

(a) *Computing per capita Medicare Part A and Part B benchmark expenditures for an ACO's first agreement period.* For agreement periods beginning on July 1, 2019, and in subsequent years, in computing an ACO's historical benchmark for its first agreement period under the Shared Savings Program, CMS determines the per capita Parts A and B fee-for-service expenditures for beneficiaries that would have been assigned to the ACO in any of the 3 most recent years prior to the start of the agreement period using the ACO participant TINs identified before the start of the agreement period as required under § 425.118(a) and the beneficiary assignment methodology selected by the ACO for the first performance year of the agreement period as required under § 425.400(a)(4)(ii). CMS does all of the following:

(1) Calculates the payment amounts included in Parts A and B fee-for-service claims using a 3-month claims run out with a completion factor.

(i) This calculation excludes indirect medical education (IME) and disproportionate share hospital (DSH) payments, and the supplemental payment for IHS/Tribal hospitals and Puerto Rico hospitals.

(ii) This calculation includes individually beneficiary identifiable final payments made under a demonstration, pilot or time limited program.

(2) Makes separate expenditure calculations for each of the following populations of beneficiaries: ESRD, disabled, aged/dual eligible Medicare and Medicaid beneficiaries and aged/non-dual eligible Medicare and Medicaid beneficiaries.

(3) Adjusts expenditures for changes in severity and case mix using prospective HCC risk scores.

(4) Truncates an assigned beneficiary's total annual Parts A and B fee-for-service per capita expenditures at the 99th percentile of national Medicare fee-for-service expenditures for assignable beneficiaries identified for the 12-month calendar year corresponding to each benchmark year in order to minimize variation from catastrophically large claims.

(5) Trends forward expenditures for each benchmark year (BY1 and BY2) to the third benchmark year (BY3) dollars using a blend of national and regional growth rates.

(i) To trend forward the benchmark, CMS makes separate calculations for expenditure categories for each of the following populations of beneficiaries:

(A) ESRD.

(B) Disabled.

(C) Aged/dual eligible Medicare and Medicaid beneficiaries.

(D) Aged/non-dual eligible Medicare and Medicaid beneficiaries.

(ii) National growth rates are computed using CMS Office of the Actuary national Medicare expenditure data for each of the years making up the historical benchmark for assignable beneficiaries identified for the 12-month calendar year corresponding to each benchmark year.

(iii) Regional growth rates are computed using expenditures for the ACO's regional service area for each of the years making up the historical benchmark as follows:

(A) Determine the counties included in the ACO's regional service area based on the ACO's assigned beneficiary population for the relevant benchmark year.

(B) Determine the ACO's regional expenditures as specified under paragraphs (c) and (d) of this section.

(iv) The national and regional growth rates are blended together by taking a weighted average of the two. The weight applied to the—

(A) National growth rate is calculated as the share of assignable beneficiaries in the ACO's regional service area for BY3 that are assigned to the ACO in BY3, as calculated in paragraph (a)(5)(v) of this section; and

(B) Regional growth rate is equal to 1 minus the weight applied to the national growth rate.

(v) CMS calculates the share of assignable beneficiaries in the ACO's regional service area that are assigned to the ACO by doing all of the following:

(A) Calculating the county-level share of assignable beneficiaries that are assigned to the ACO for each county in the ACO's regional service area.

(B) Weighting the county-level shares according to the ACO's proportion of assigned beneficiaries in the county, determined by the number of the ACO's assigned beneficiaries residing in the county in relation to the ACO's total number of assigned beneficiaries.

(C) Aggregating the weighted county-level shares for all counties in the ACO's regional service area.

(6) Restates BY1 and BY2 trended and risk adjusted expenditures using BY3 proportions of ESRD, disabled, aged/dual eligible Medicare and Medicaid beneficiaries and aged/non-dual eligible Medicare and Medicaid beneficiaries.

(7) Weights each year of the benchmark for an ACO's initial agreement period using the following percentages:

(i) BY3 at 60 percent.

(ii) BY2 at 30 percent.

(iii) BY1 at 10 percent.

(8) Adjusts the historical benchmark based on the ACO's regional service area expenditures, making separate calculations for the following populations of beneficiaries: ESRD, disabled, aged/dual eligible Medicare and Medicaid beneficiaries, and aged/non-dual eligible Medicare and Medicaid beneficiaries. CMS does all of the following:

(i) Calculates an average per capita amount of expenditures for the ACO's regional service area as follows:

(A) Determines the counties included in the ACO's regional service area based on the ACO's BY3 assigned beneficiary population.

(B) Determines the ACO's regional expenditures as specified under paragraphs (c) and (d) of this section for BY3.

(C) Adjusts for differences in severity and case mix between the ACO's assigned beneficiary population and the assignable beneficiary population for the ACO's regional service area identified for the 12-month calendar year that corresponds to BY3.

(ii) Calculates the adjustment as follows:

(A) Determines the difference between the average per capita amount of expenditures for the ACO's regional service area as specified under paragraph (a)(8)(i) of this section and the average per capita amount of the ACO's historical benchmark determined under paragraphs (a)(1) through (7) of this section, for each of the following populations of beneficiaries:

(*1*) ESRD.

(*2*) Disabled.

(*3*) Aged/dual eligible for Medicare and Medicaid.

(*4*) Aged/non-dual eligible for Medicare and Medicaid.

(B) Applies a percentage, as determined in paragraph (f) of this section.

(C) Caps the per capita dollar amount for each Medicare enrollment type (ESRD, Disabled, Aged/dual eligible Medicare and Medicaid beneficiaries, Aged/non-dual eligible Medicare and Medicaid beneficiaries) calculated under paragraph (a)(8)(ii)(B) of this section at a dollar amount equal to 5 percent of national per capita expenditures for Parts A and B services under the original Medicare fee-for-service program in BY3 for assignable beneficiaries in that enrollment type identified for the 12-month calendar year corresponding to BY3 using data from the CMS Office of the Actuary.

(*1*) For positive adjustments, the per capita dollar amount for a Medicare enrollment type is capped at 5 percent of the national per capita expenditure amount for the enrollment type for BY3.

(*2*) For negative adjustments, the per capita dollar amount for a Medicare enrollment type is capped at negative 5 percent of the national per capita expenditure amount for the enrollment type for BY3.

(9) For the second and each subsequent performance year during the term of the agreement period, the ACO's benchmark is adjusted for the following, as applicable: For the addition and removal of ACO participants or ACO providers/suppliers in accordance with §425.118(b), for a change to the ACO's beneficiary assignment methodology selection under §425.226(a)(1), for a change to the beneficiary assignment methodology specified in subpart E of this part, for changes in values used in benchmark calculations as a result of issuance of a revised initial determination under §425.315, and for changes in values used in benchmark calculations as a result of the performance year being affected

by significant, anomalous, and highly suspect billing under § 425.672. To adjust the benchmark, CMS does the following:

(i) Takes into account the expenditures of beneficiaries who would have been assigned to the ACO in any of the 3 most recent years prior to the start of the agreement period.

(ii) Redetermines the regional adjustment amount under paragraph (a)(8) of this section, according to the ACO's assigned beneficiaries for BY3.

(iii) Recalculates benchmark year expenditures to account for the impact of improper payments, for the benchmark year corresponding to a performance year for which CMS issued a revised initial determination under § 425.315. In recalculating expenditures for the benchmark year, CMS applies the calculation methodology applied in recalculating expenditures for the corresponding performance year in accordance with § 425.674.

(iv) Recalculates expenditures used in Shared Savings Program benchmark calculations under this section, to exclude the same HCPCS or CPT codes identified as displaying significant, anomalous, and highly suspect billing patterns in calculation of performance year expenditures, in accordance with § 425.672.

(10) The historical benchmark is further adjusted at the time of reconciliation for a performance year to account for changes in severity and case mix of the ACO's assigned beneficiary population as described under §§ 425.605(a), 425.609(c), and 425.610(a).

(b) *Updating the benchmark.* For all agreement periods beginning on July 1, 2019, and in subsequent years, CMS updates the historical benchmark annually for each year of the agreement period using a blend of national and regional growth rates.

(1) To update the benchmark, CMS makes separate calculations for expenditure categories for each of the following populations of beneficiaries:

(i) ESRD.

(ii) Disabled.

(iii) Aged/dual eligible Medicare and Medicaid beneficiaries.

(iv) Aged/non-dual eligible Medicare and Medicaid beneficiaries.

(2) National growth rates are computed using CMS Office of the Actuary national Medicare expenditure data for BY3 and the performance year for assignable beneficiaries identified for the 12-month calendar year corresponding to each year.

(3) Regional growth rates are computed using expenditures for the ACO's regional service area for BY3 and the performance year, computed as follows:

(i) Determine the counties included in the ACO's regional service area based on the ACO's assigned beneficiary population for the year.

(ii) Determine the ACO's regional expenditures as specified under paragraphs (c) and (d) of this section.

(4) The national and regional growth rates are blended together by taking a weighted average of the two. The weight applied to the—

(i) National growth rate is calculated as the share of assignable beneficiaries in the ACO's regional service area that are assigned to the ACO for the applicable performance year as specified in paragraph (a)(5)(v) of this section; and

(ii) Regional growth rate is equal to 1 minus the weight applied to the national growth rate.

(c) *Calculating county expenditures.* For all agreement periods beginning on July 1, 2019, and in subsequent years, CMS does all of the following to determine risk adjusted county fee-for-service expenditures for use in calculating the ACO's regional fee-for-service expenditures:

(1)(i) Determines average county fee-for-service expenditures based on expenditures for the assignable population of beneficiaries in each county in the ACO's regional service area, where assignable beneficiaries are identified for the 12-month calendar year corresponding to the relevant benchmark or performance year.

(ii) Makes separate expenditure calculations for each of the following populations of beneficiaries:

(A) ESRD.

(B) Disabled.

(C) Aged/dual eligible Medicare and Medicaid beneficiaries.

(D) Aged/non-dual eligible Medicare and Medicaid beneficiaries.

(2) Calculates assignable beneficiary expenditures using the payment

amounts included in Parts A and B fee-for-service claims with dates of service in the 12-month calendar year for the relevant benchmark or performance year, using a 3-month claims run out with a completion factor. The calculation—

(i) Excludes IME and DSH payments, and the supplemental payment for IHS/Tribal hospitals and Puerto Rico hospitals; and

(ii) Considers individually beneficiary identifiable final payments made under a demonstration, pilot or time limited program.

(3) Truncates a beneficiary's total annual Parts A and B fee-for-service per capita expenditures at the 99th percentile of national Medicare fee-for-service expenditures for assignable beneficiaries identified for the 12-month calendar year that corresponds to the relevant benchmark or performance year, in order to minimize variation from catastrophically large claims.

(4) Adjusts fee-for-service expenditures for severity and case mix of assignable beneficiaries in the county using prospective HCC risk scores. The calculation is made according to the following populations of beneficiaries:

(i) ESRD.

(ii) Disabled.

(iii) Aged/dual eligible Medicare and Medicaid beneficiaries.

(iv) Aged/non-dual eligible Medicare and Medicaid beneficiaries.

(d) *Calculating regional expenditures.* For all agreement periods beginning on July 1, 2019, and in subsequent years, CMS calculates an ACO's risk adjusted regional expenditures by:

(1) Weighting the risk-adjusted county-level fee-for-service expenditures determined under paragraph (c) of this section according to the ACO's proportion of assigned beneficiaries in the county, determined by the number of the ACO's assigned beneficiaries in the applicable population (according to Medicare enrollment type) residing in the county in relation to the ACO's total number of assigned beneficiaries in the applicable population (according to Medicare enrollment type) for the relevant benchmark or performance year for each of the following populations of beneficiaries:

(i) ESRD.

(ii) Disabled.

(iii) Aged/dual eligible Medicare and Medicaid beneficiaries.

(iv) Aged/non-dual eligible Medicare and Medicaid beneficiaries.

(2) Aggregating the values determined under paragraph (d)(1) of this section for each population of beneficiaries (according to Medicare enrollment type) across all counties within the ACO's regional service area.

(e) *Resetting the benchmark.* (1) An ACO's benchmark is reset at the start of each subsequent agreement period.

(2) For second or subsequent agreements periods beginning on July 1, 2019, and in subsequent years, CMS establishes, adjusts, and updates the rebased historical benchmark in accordance with paragraphs (a) through (d) of this section with the following modifications:

(i) Rather than weighting each year of the benchmark using the percentages provided in paragraph (a)(7) of this section, each benchmark year is weighted equally.

(ii) For a renewing ACO or re-entering ACO whose prior agreement period benchmark was calculated according to §425.603(c), to determine the weight used in the regional adjustment calculation described in paragraph (f) of this section, CMS considers the agreement period the ACO is entering into according to §425.600(f) in combination with either of the following—

(A) The weight previously applied to calculate the regional adjustment to the ACO's benchmark under §425.603(c)(9) in its most recent prior agreement period; or

(B) For a new ACO identified as a re-entering ACO, CMS considers the weight previously applied to calculate the regional adjustment to the benchmark under §425.603(c)(9) in its most recent prior agreement period of the ACO in which the majority of the new ACO's participants were participating previously.

(f) *Phase-in of weights used in regional adjustment calculation.* (1) The first time that an ACO's benchmark is adjusted based on the ACO's regional service area expenditures, CMS calculates the regional adjustment as follows:

(i) Using 35 percent of the difference between the average per capita amount of expenditures for the ACO's regional service area and the average per capita amount of the ACO's initial or rebased historical benchmark, if the ACO is determined to have lower spending than the ACO's regional service area.

(ii) Using 15 percent of the difference between the average per capita amount of expenditures for the ACO's regional service area and the average per capita amount of the ACO's initial or rebased historical benchmark, if the ACO is determined to have higher spending than the ACO's regional service area.

(2) The second time that an ACO's benchmark is adjusted based on the ACO's regional service area expenditures, CMS calculates the regional adjustment as follows:

(i) Using 50 percent of the difference between the average per capita amount of expenditures for the ACO's regional service area and the average per capita amount of the ACO's rebased historical benchmark if the ACO is determined to have lower spending than the ACO's regional service area.

(ii) Using 25 percent of the difference between the average per capita amount of expenditures for the ACO's regional service area and the average per capita amount of the ACO's rebased historical benchmark if the ACO is determined to have higher spending than the ACO's regional service area.

(3) The third time that an ACO's benchmark is adjusted based on the ACO's regional service area expenditures, CMS calculates the regional adjustment as follows:

(i) Using 50 percent of the difference between the average per capita amount of expenditures for the ACO's regional service area and the average per capita amount of the ACO's rebased historical benchmark if the ACO is determined to have lower spending than the ACO's regional service area.

(ii) Using 35 percent of the difference between the average per capita amount of expenditures for the ACO's regional service area and the average per capita amount of the ACO's rebased historical benchmark if the ACO is determined to have higher spending than the ACO's regional service area.

(4) The fourth or subsequent time that an ACO's benchmark is adjusted based on the ACO's regional service area expenditures, CMS calculates the regional adjustment to the historical benchmark using 50 percent of the difference between the average per capita amount of expenditures for the ACO's regional service area and the average per capita amount of the ACO's rebased historical benchmark.

(5) To determine if an ACO has lower or higher spending compared to the ACO's regional service area, CMS does the following:

(i) Multiplies the difference between the average per capita amount of expenditures for the ACO's regional service area and the average per capita amount of the ACO's historical benchmark for each population of beneficiaries (ESRD, Disabled, Aged/dual eligible Medicare and Medicaid beneficiaries, Aged/non-dual eligible Medicare and Medicaid beneficiaries) as calculated under either paragraph (a)(8)(ii)(A) or (e) of this section by the applicable proportion of the ACO's assigned beneficiary population (ESRD, Disabled, Aged/dual eligible Medicare and Medicaid beneficiaries, Aged/non-dual eligible Medicare and Medicaid beneficiaries) for BY3 of the historical benchmark.

(ii) Sums the amounts determined in paragraph (f)(5)(i) of this section across the populations of beneficiaries (ESRD, Disabled, Aged/dual eligible Medicare and Medicaid beneficiaries, Aged/non-dual eligible Medicare and Medicaid beneficiaries).

(iii) If the resulting sum is a net positive value, the ACO is considered to have lower spending compared to the ACO's regional service area. If the resulting sum is a net negative value, the ACO is considered to have higher spending compared to the ACO's regional service area.

(iv) If during the term of the agreement period CMS adjusts the ACO's benchmark, as specified in paragraph (a)(9) of this section, CMS redetermines whether the ACO is considered to have lower spending or higher spending compared to the ACO's regional service area for purposes of determining the percentage in paragraphs (f)(1) through (3) of this section used in calculating

the adjustment under either paragraph (a)(8) or (e) of this section.

(g) *July 1, 2019 through December 31, 2019 performance year.* In determining performance for the July 1, 2019 through December 31, 2019 performance year described in § 425.609(c), CMS does all of the following:

(1) When adjusting the benchmark using the methodology set forth in paragraph (a)(10) of this section and § 425.609(c), CMS adjusts for severity and case mix between BY3 and CY 2019.

(2) When updating the benchmark using the methodology set forth in paragraph (b) of this section and § 425.609(c), CMS updates the benchmark based on growth between BY3 and CY 2019.

[83 FR 68071, Dec. 31, 2018, as amended at 85 FR 85042, Dec. 28, 2020; 87 FR 70237, Nov. 18, 2022; 88 FR 79547, Nov. 16, 2023; 89 FR 98570, Dec. 9, 2024]

§ 425.602 Establishing, adjusting, and updating the benchmark for an ACO's first agreement period beginning on or before January 1, 2018.

(a) *Computing per capita Medicare Part A and Part B benchmark expenditures.* For agreement periods beginning on or before January 1, 2018, in computing an ACO's fixed historical benchmark that is adjusted for historical growth and beneficiary characteristics, including health status, CMS determines the per capita Parts A and B fee-for-service expenditures for beneficiaries that would have been assigned to the ACO in any of the 3 most recent years prior to the agreement period using the ACO participants' TINs identified at the start of the agreement period. CMS does all of the following:

(1) Calculates the payment amounts included in Parts A and B fee-for-service claims using a 3-month claims run out with a completion factor.

(i) This calculation excludes indirect medical education (IME) and disproportionate share hospital (DSH) payments.

(ii) This calculation considers individually beneficiary identifiable payments made under a demonstration, pilot or time limited program.

(A) For agreement periods beginning before 2018, this calculation considers all individually beneficiary identifiable payments, including interim payments, made under a demonstration, pilot or time limited program.

(B) For agreement periods beginning in 2018, this calculation considers individually beneficiary identifiable final payments made under a demonstration, pilot or time limited program.

(C) For the 2018 performance year and subsequent performance years in agreement periods beginning in 2015, 2016 and 2017, the benchmark is adjusted to reflect only individually beneficiary identifiable final payments made under a demonstration, pilot or time limited program.

(2) Makes separate expenditure calculations for each of the following populations of beneficiaries: ESRD, disabled, aged/dual eligible Medicare and Medicaid beneficiaries and aged/non-dual eligible Medicare and Medicaid beneficiaries.

(3) Adjusts expenditures for changes in severity and case mix using prospective HCC risk scores.

(4) Truncation of expenditures:

(i) For agreement periods beginning before 2017—

(A) Truncates an assigned beneficiary's total annual Parts A and B fee-for-service per capita expenditures at the 99th percentile of national Medicare fee-for-service expenditures as determined for each benchmark year in order to minimize variation from catastrophically large claims; and

(B) For the 2017 performance year and any subsequent performance years in agreement periods beginning in 2014, 2015 and 2016, the benchmark is adjusted to reflect the use of assignable beneficiaries in determining the 99th percentile of Medicare fee-for-service expenditures for purposes of truncating expenditures for assigned beneficiaries during each benchmark year as specified in paragraph (a)(4)(ii) of this section.

(ii) For agreement periods beginning in 2017 and 2018, truncates an assigned beneficiary's total annual Parts A and B fee-for-service per capita expenditures at the 99th percentile of national Medicare fee-for-service expenditures for assignable beneficiaries identified for the 12-month calendar year corresponding to each benchmark year in order to minimize variation from catastrophically large claims.

(5) Trending expenditures:

(i) For agreement periods beginning before 2017—

(A) Using CMS Office of the Actuary national Medicare expenditure data for each of the years making up the historical benchmark, determines national growth rates and trends expenditures for each benchmark year (BY1 and BY2) to the third benchmark year (BY3) dollars.

(B) To trend forward the benchmark, CMS makes separate calculations for expenditure categories for each of the following populations of beneficiaries:

(*1*) ESRD.

(*2*) Disabled.

(*3*) Aged/dual eligible Medicare and Medicaid beneficiaries.

(*4*) Aged/non-dual eligible Medicare and Medicaid beneficiaries.

(C) For the 2017 performance year and any subsequent performance years in agreement periods beginning in 2014, 2015 and 2016, the benchmark is adjusted to reflect the use of assignable beneficiaries to perform each of these calculations as specified in paragraph (a)(5)(ii) of this section.

(ii) For agreement periods beginning in 2017 and 2018—

(A) Using CMS Office of the Actuary national Medicare expenditure data for each of the years making up the historical benchmark, determines national growth rates for assignable beneficiaries identified for the 12-month calendar year corresponding to each benchmark year, and trends expenditures for each benchmark year (BY1 and BY2) to the third benchmark year (BY3) dollars.

(B) To trend forward the benchmark, CMS makes separate calculations for expenditure categories for each of the following populations of beneficiaries:

(*1*) ESRD.

(*2*) Disabled.

(*3*) Aged/dual eligible Medicare and Medicaid beneficiaries.

(*4*) Aged/non-dual eligible Medicare and Medicaid beneficiaries.

(6) Restates BY1 and BY2 trended and risk adjusted expenditures in BY3 proportions of ESRD, disabled, aged/dual eligible Medicare and Medicaid beneficiaries and aged/non-dual eligible Medicare and Medicaid beneficiaries.

(7) Weights each year of the benchmark for the initial agreement period using the following percentages:

(i) BY3 at 60 percent.

(ii) BY2 at 30 percent.

(iii) BY1 at 10 percent.

(8) The ACO's benchmark is adjusted for the addition and removal of ACO participants or ACO providers/suppliers in accordance with § 425.118(b) and for a change to the beneficiary assignment methodology specified in subpart E of this part, as applicable, to take into account the expenditures for beneficiaries who would have been assigned to the ACO in any of the 3 most recent years prior to the start of the agreement period.

(9) The historical benchmark is further adjusted at the time of reconciliation for a performance year to account for changes in severity and case mix for newly and continuously assigned beneficiaries using prospective HCC risk scores and demographic factors as described under §§ 425.604(a)(1) through (3), 425.606(a)(1) through (3), and 425.610(a)(1) through (3).

(b) *Updating the benchmark.* CMS updates the historical benchmark annually for each year of the agreement period based on the flat dollar equivalent of the projected absolute amount of growth in national per capita expenditures for Parts A and B services under the original Medicare fee-for-service program.

(1) For performance years before 2017, CMS updates the historical benchmark annually for each year of the agreement period based on the flat dollar equivalent of the projected absolute amount of growth in national per capita expenditures for Parts A and B services under the original Medicare fee-for-service program.

(i) CMS updates the fixed benchmark by the projected absolute amount of growth in national per capita expenditures for Parts A and B services under the original Medicare fee-for-service program using data from CMS' Office of the Actuary.

(ii) To update the benchmark, CMS makes expenditure calculations for separate categories for each of the following populations of beneficiaries:

(A) ESRD.

(B) Disabled.

(C) Aged/dual eligible Medicare and Medicaid beneficiaries.

(D) Aged/non-dual eligible Medicare and Medicaid beneficiaries.

(2) For the 2017 performance year and subsequent performance years, CMS updates the historical benchmark annually for each year of the agreement period based on the flat dollar equivalent of the projected absolute amount of growth in national per capita expenditures for Parts A and B services under the original Medicare fee-for-service program for assignable beneficiaries identified for the 12-month calendar year corresponding to the year for which the update is calculated.

(i) CMS updates the fixed benchmark by the projected absolute amount of growth in national per capita expenditures for Parts A and B services under the original Medicare fee-for-service program for assignable beneficiaries identified for the 12-month calendar year corresponding to the year for which the update is being calculated using data from CMS' Office of the Actuary.

(ii) To update the benchmark, CMS makes expenditure calculations for separate categories for each of the following populations of beneficiaries:

(A) ESRD.

(B) Disabled.

(C) Aged/dual eligible Medicare and Medicaid beneficiaries.

(D) Aged/non-dual eligible Medicare and Medicaid beneficiaries.

(c) *January 1, 2019 through June 30, 2019 performance year*. In determining performance for the January 1, 2019 through June 30, 2019 performance year described in § 425.609(b) CMS does all of the following:

(1) When adjusting the benchmark using the methodology set forth in paragraph (a)(9) of this section and § 425.609(b), CMS adjusts for severity and case mix between BY3 and CY 2019.

(2) When updating the benchmark using the methodology set forth in paragraph (b) of this section and § 425.609(b), CMS updates the benchmark based on growth between BY3 and CY 2019.

[76 FR 67973, Nov. 2, 2011, as amended at 80 FR 32842, June 9, 2015; 81 FR 38014, June 10, 2016; 82 FR 53370, Nov. 15, 2017; 83 FR 60094, Nov. 23, 2018; 83 FR 68074, Dec. 31, 2018; 85 FR 85042, Dec. 28, 2020]

§ 425.603 Resetting, adjusting, and updating the benchmark for a subsequent agreement period beginning on or before January 1, 2019.

(a) An ACO's benchmark is reset at the start of each subsequent agreement period.

(b) For second agreement periods beginning in 2016, CMS establishes, adjusts, and updates the rebased historical benchmark in accordance with § 425.602(a) and (b) with the following modifications:

(1) Rather than weighting each year of the benchmark using the percentages provided at § 425.602(a)(7), each benchmark year is weighted equally.

(2) An additional adjustment is made to account for the average per capita amount of savings generated during the ACO's previous agreement period. The adjustment is limited to the average number of assigned beneficiaries (expressed as person years) under the ACO's first agreement period.

(c) For second or subsequent agreement periods beginning in 2017, 2018 and on January 1, 2019, CMS establishes the rebased historical benchmark by determining the per capita Parts A and B fee-for-service expenditures for beneficiaries who would have been assigned to the ACO in any of the 3 most recent years before the agreement period using the certified ACO participant list submitted before the start of the agreement period as required under § 425.118. CMS does all of the following:

(1) Calculates the payment amounts included in Parts A and B fee-for-service claims using a 3-month claims run out with a completion factor. The calculation—

(i) Excludes IME and DSH payments; and

(ii) Considers individually beneficiary identifiable payments made under a demonstration, pilot or time limited program.

(A) For agreement periods beginning before 2018, considers all individually

beneficiary identifiable payments, including interim payments, made under a demonstration, pilot or time limited program.

(B) For agreement periods beginning in 2018 and on January 1, 2019, considers individually beneficiary identifiable final payments made under a demonstration, pilot or time limited program.

(C) For the 2018 and 2019 performance years in agreement periods beginning in 2017, the benchmark is adjusted to reflect only individually beneficiary identifiable final payments made under a demonstration, pilot or time limited program.

(2) Makes separate expenditure calculations for each of the following populations of beneficiaries:

(i) ESRD.

(ii) Disabled.

(iii) Aged/dual eligible Medicare and Medicaid beneficiaries.

(iv) Aged/non-dual eligible Medicare and Medicaid beneficiaries.

(3) Adjusts expenditures for changes in severity and case mix using prospective HCC risk scores.

(4) Truncates an assigned beneficiary's total annual Parts A and B fee-for-service per capita expenditures at the 99th percentile of national Medicare fee-for-service expenditures for assignable beneficiaries identified for the 12-month calendar year corresponding to each benchmark year in order to minimize variation from catastrophically large claims.

(5) Trends forward expenditures for each benchmark year (BY1 and BY2) to the third benchmark year (BY3) dollars using regional growth rates based on expenditures for the ACO's regional service area as determined under paragraphs (e) and (f) of this section, making separate expenditure calculations for each of the following populations of beneficiaries:

(i) ESRD.

(ii) Disabled.

(iii) Aged/dual eligible Medicare and Medicaid beneficiaries.

(iv) Aged/non-dual eligible Medicare and Medicaid beneficiaries.

(6) Restates BY1 and BY2 trended and risk-adjusted expenditures in BY3 proportions of the following populations of beneficiaries:

(i) ESRD.

(ii) Disabled.

(iii) Aged/dual eligible Medicare and Medicaid beneficiaries.

(iv) Aged/non-dual eligible Medicare and Medicaid beneficiaries.

(7) Weights each benchmark year equally.

(8) The ACO's benchmark is adjusted for the following, as applicable: For the addition and removal of ACO participants or ACO providers/suppliers in accordance with §425.118(b), and for a change to the beneficiary assignment methodology specified in subpart E of this part. To adjust the benchmark, CMS does the following:

(i) Takes into account the expenditures for beneficiaries who would have been assigned to the ACO in any of the 3 most recent years prior to the start of the agreement period.

(ii) Redetermines the regional adjustment amount under paragraph (c)(9) of this section, according to the ACO's assigned beneficiaries for BY3.

(9) Adjusts the historical benchmark based on the ACO's regional service area expenditures, making separate calculations for the following populations of beneficiaries: ESRD, disabled, aged/dual eligible Medicare and Medicaid beneficiaries, and aged/non-dual eligible Medicare and Medicaid beneficiaries. CMS does all of the following:

(i) Calculates an average per capita amount of expenditures for the ACO's regional service area as follows:

(A) Determines the counties included in the ACO's regional service area based on the ACO's BY3 assigned beneficiary population.

(B) Determines the ACO's regional expenditures as specified under paragraphs (e) and (f) of this section for BY3.

(C) Adjusts for differences in severity and case mix between the ACO's assigned beneficiary population and the assignable beneficiary population for the ACO's regional service area identified for the 12-month calendar year that corresponds to BY3.

(ii) Calculates the adjustment as follows:

(A) Determines the difference between the average per capita amount of expenditures for the ACO's regional

service area as specified under paragraph (c)(9)(i) of this section and the average per capita amount of the ACO's rebased historical benchmark determined under paragraphs (c)(1) through)(8) of this section, for each of the following populations of beneficiaries:

(*1*) ESRD.

(*2*) Disabled.

(*3*) Aged/dual eligible Medicare and Medicaid beneficiaries.

(*4*) Aged/non-dual eligible Medicare and Medicaid beneficiaries.

(B) Applies a percentage, determined as follows:

(*1*) The first time an ACO's benchmark is rebased using the methodology described under paragraph (c) of this section, CMS calculates the regional adjustment as follows:

(*i*) Using 35 percent of the difference between the average per capita amount of expenditures for the ACO's regional service area and the average per capita amount of the ACO's rebased historical benchmark, if the ACO is determined to have lower spending than the ACO's regional service area;

(*ii*) Using 25 percent of the difference between the average per capita amount of expenditures for the ACO's regional service area and the average per capita amount of the ACO's rebased historical benchmark, if the ACO is determined to have higher spending than the ACO's regional service area.

(*2*) The second time that an ACO's benchmark is rebased using the methodology described under paragraph (c) of this section, CMS calculates the regional adjustment to the historical benchmark as follows:

(*i*) Using 70 percent of the difference between the average per capita amount of expenditures for the ACO's regional service area and the average per capita amount of the ACO's rebased historical benchmark, unless the Secretary determines a lower weight should be applied, if the ACO is determined to have lower spending than the ACO's regional service area;

(*ii*) Using 50 percent of the difference between the average per capita amount of expenditures for the ACO's regional service area and the average per capita amount of the ACO's rebased historical benchmark, if the ACO is determined to have higher spending than the ACO's regional service area.

(*3*) The third or subsequent time that an ACO's benchmark is rebased using the methodology described under paragraph (c) of this section, CMS calculates the regional adjustment to the historical benchmark using 70 percent of the difference between the average per capita amount of expenditures for the ACO's regional service area and the average per capita amount of the ACO's rebased historical benchmark, unless the Secretary determines a lower weight should be applied.

(*4*) To determine if an ACO has lower or higher spending compared to the ACO's regional service area, CMS does the following:

(*i*) Multiplies the difference between the average per capita amount of expenditures for the ACO's regional service area and the average per capita amount of the ACO's rebased historical benchmark for each population of beneficiaries (ESRD, Disabled, Aged/dual eligible Medicare and Medicaid beneficiaries, Aged/non-dual eligible Medicare and Medicaid beneficiaries) as calculated under paragraph (c)(9)(ii)(A) of this section by the applicable proportion of the ACO's assigned beneficiary population (ESRD, Disabled, Aged/dual eligible Medicare and Medicaid beneficiaries, Aged/non-dual eligible Medicare and Medicaid beneficiaries) for benchmark year 3 of the rebased historical benchmark.

(*ii*) Sums the amounts determined in paragraph (c)(9)(ii)(B)(*4*)(*i*) of this section across the populations of beneficiaries (ESRD, Disabled, Aged/dual eligible Medicare and Medicaid beneficiaries, Aged/non-dual eligible Medicare and Medicaid beneficiaries).

(*iii*) If the resulting sum is a net positive value, the ACO is considered to have lower spending compared to the ACO's regional service area. If the resulting sum is a net negative value, the ACO is considered to have higher spending compared to the ACO's regional service area.

(*iv*) If CMS adjusts the ACO's benchmark, as specified in paragraph (c)(8) of this section, CMS redetermines whether the ACO is considered to have lower spending or higher spending compared to the ACO's regional service area for

purposes of determining the percentage used in calculating the adjustment in paragraphs (c)(9)(ii)(B)(*1*) and (*2*) of this section.

(10) The historical benchmark is further adjusted at the time of reconciliation for a performance year to account for changes in severity and case mix for newly and continuously assigned beneficiaries using prospective HCC risk scores and demographic factors as described under §§ 425.604(a)(1) through (3), 425.606(a)(1) through (3), and 425.610(a)(1) through (3).

(d) For second or subsequent agreement periods beginning in 2017, 2018 and on January 1, 2019, CMS updates the rebased historical benchmark under paragraph (c) of this section, annually for each year of the agreement period by the growth in risk adjusted regional per beneficiary FFS spending for the ACO's regional service area by doing all of the following:

(1) Determining the counties included in the ACO's regional service area based on the ACO's assigned beneficiary population used to determine financial reconciliation for the relevant performance year.

(2) Determining growth rates based on expenditures for counties in the ACO's regional service area calculated under paragraphs (e) and (f) of this section, for the performance year compared to BY3 for each of the following populations of beneficiaries:

(i) ESRD.

(ii) Disabled.

(iii) Aged/dual eligible Medicare and Medicaid beneficiaries.

(iv) Aged/non-dual eligible Medicare and Medicaid beneficiaries.

(3) Updating the benchmark by making separate calculations for each of the following populations of beneficiaries:

(i) ESRD.

(ii) Disabled.

(iii) Aged/dual eligible Medicare and Medicaid beneficiaries.

(iv) Aged/non-dual eligible Medicare and Medicaid beneficiaries.

(e) For second or subsequent agreement periods beginning in 2017, 2018 and on January 1, 2019, CMS does all of the following to determine risk adjusted county fee-for-service expenditures for use in calculating the ACO's regional fee-for-service expenditures:

(1)(i) Determines average county fee-for-service expenditures based on expenditures for the assignable population of beneficiaries in each county, where assignable beneficiaries are identified for the 12-month calendar year corresponding to the relevant benchmark or performance year.

(ii) Makes separate expenditure calculations for each of the following populations of beneficiaries:

(A) ESRD.

(B) Disabled.

(C) Aged/dual eligible Medicare and Medicaid beneficiaries.

(D) Aged/non-dual eligible Medicare and Medicaid beneficiaries.

(2) Calculates assignable beneficiary expenditures using the payment amounts included in Parts A and B fee-for-service claims with dates of service in the 12-month calendar year for the relevant benchmark or performance year, using a 3-month claims run out with a completion factor. The calculation—

(i) Excludes IME and DSH payments; and

(ii) Considers individually beneficiary identifiable payments made under a demonstration, pilot or time limited program.

(A) For agreement periods beginning before 2018, considers all individually beneficiary identifiable payments, including interim payments, made under a demonstration, pilot or time limited program.

(B) For agreement periods beginning in 2018 and on January 1, 2019, considers individually beneficiary identifiable final payments made under a demonstration, pilot or time limited program.

(C) For the 2018 and 2019 performance years in agreement periods beginning in 2017, risk adjusted county fee-for-service expenditures are adjusted to reflect only individually beneficiary identifiable final payments made under a demonstration, pilot or time limited program.

(3) Truncates a beneficiary's total annual Parts A and B fee-for-service per capita expenditures at the 99th percentile of national Medicare fee-for-service expenditures for assignable

beneficiaries identified for the 12-month calendar year that corresponds to the relevant benchmark or performance year, in order to minimize variation from catastrophically large claims.

(4) Adjusts fee-for-service expenditures for severity and case mix of assignable beneficiaries in the county using prospective CMS–HCC risk scores. The calculation is made according to the following populations of beneficiaries:

(i) ESRD.

(ii) Disabled.

(iii) Aged/dual eligible Medicare and Medicaid beneficiaries.

(iv) Aged/non-dual eligible Medicare and Medicaid beneficiaries.

(f) For second or subsequent agreement periods beginning in 2017, 2018, and on January 1, 2019, CMS calculates an ACO's risk adjusted regional expenditures by—

(1) Weighting the risk-adjusted county-level fee-for-service expenditures determined under paragraph (e) of this section according to the ACO's proportion of assigned beneficiaries in the county, determined by the number of the ACO's assigned beneficiaries in the applicable population (according to Medicare enrollment type) residing in the county in relation to the ACO's total number of assigned beneficiaries in the applicable population (according to Medicare enrollment type) for the relevant benchmark or performance year for each of the following populations of beneficiaries:

(i) ESRD.

(ii) Disabled.

(iii) Aged/dual eligible Medicare and Medicaid beneficiaries.

(iv) Aged/non-dual eligible Medicare and Medicaid beneficiaries.

(2) Aggregating the values determined under paragraph (f)(1) of this section for each population of beneficiaries (according to Medicare enrollment type) across all counties within the ACO's regional service area; and

(3) Weighting the aggregate expenditure values determined for each population of beneficiaries (according to Medicare enrollment type) under paragraph (f)(2) of this section by a weight reflecting the proportion of the ACO's overall beneficiary population in the applicable Medicare enrollment type for the relevant benchmark or performance year.

(g) In determining performance for the January 1, 2019 through June 30, 2019 performance year described in § 425.609(b) CMS does all of the following:

(1) When adjusting the benchmark using the methodology set forth in paragraph (c)(10) of this section and § 425.609(b), CMS adjusts for severity and case mix between BY3 and CY 2019.

(2) When updating the benchmark using the methodology set forth in paragraph (d) of this section and § 425.609(b), CMS updates the benchmark based on growth between BY3 and CY 2019.

[81 FR 38014, June 10, 2016, as amended at 82 FR 53370, Nov. 15, 2017; 83 FR 60094, Nov. 23, 2018; 83 FR 68074, Dec. 31, 2018; 85 FR 85042, Dec. 28, 2020]

§ 425.604 Calculation of savings under the one-sided model.

(a) *Savings determination.* For each performance year, CMS determines whether the estimated average per capita Medicare expenditures under the ACO for Medicare fee-for-service beneficiaries for Parts A and B services are below the applicable updated benchmark determined under § 425.602 or § 425.603.

(1) *Newly assigned beneficiaries.* CMS uses an ACO's HCC prospective risk score to adjust the benchmark for changes in severity and case mix in this population.

(2) *Continuously assigned beneficiaries.* (i) CMS uses demographic factors to adjust the benchmark for changes in the continuously assigned population.

(ii) If the prospective HCC risk score is lower in the performance year for this population, CMS will adjust the benchmark for changes in severity and case mix in this population using this lower prospective HCC risk score.

(3) Assigned beneficiary changes in demographics and health status are used to adjust benchmark expenditures as described in § 425.602(a) or § 425.603(c). In adjusting the benchmark for health status and demographic changes CMS makes adjustments for separate categories for each of the following populations of beneficiaries:

(i) ESRD.

(ii) Disabled.

(iii) Aged/dual eligible Medicare and Medicaid beneficiaries.

(iv) Aged/non-dual eligible Medicare and Medicaid beneficiaries.

(4)(i) For performance years before 2017 to minimize variation from catastrophically large claims, CMS truncates an assigned beneficiary's total annual Parts A and B fee-for-service per capita expenditures at the 99th percentile of national Medicare fee-for-service expenditures as determined for each performance year.

(ii) For the 2017 performance year and subsequent performance years, to minimize variation from catastrophically large claims, CMS truncates an assigned beneficiary's total annual Parts A and B fee-for-service per capita expenditures at the 99th percentile of national Medicare fee-for-service expenditures as determined for the applicable performance year for assignable beneficiaries identified for the 12-month calendar year corresponding to the performance year.

(5) CMS uses a 3 month claims run out with a completion factor to calculate an ACO's per capita expenditures for each performance year.

(6) Calculations of the ACO's expenditures will include the payment amounts included in Part A and B fee-for-service claims.

(i) These calculations will exclude indirect medical education (IME) and disproportionate share hospital (DSH) payments.

(ii) These calculations will take into consideration individually beneficiary identifiable payments made under a demonstration, pilot or time limited program.

(A) For performance years beginning before 2018, these calculations will take into consideration all individually beneficiary identifiable payments, including interim payments, made under a demonstration, pilot or time limited program.

(B) For performance year 2018 and subsequent performance years, these calculations will take into consideration individually beneficiary identifiable final payments made under a demonstration, pilot or time limited program.

(7) In order to qualify for a shared savings payment, the ACO's average per capita Medicare expenditures for the performance year must be below the applicable updated benchmark by at least the minimum savings rate established for the ACO under paragraph (b) of this section.

(b) *Minimum savings rate (MSR).* CMS uses a sliding scale, based on the number of beneficiaries assigned to the ACO under subpart E of this part, to establish the MSR for an ACO participating under the one-sided model. The MSR under the one-sided model for an ACO based on the number of assigned beneficiaries is as follows:

Number of Beneficiaries	MSR (low end of assigned beneficiaries) (percent)	MSR (high end of assigned beneficiaries) (percent)
1 – 499	≥12.2	
500 – 999	12.2	8.7
1,000 – 2,999	8.7	5.0
3,000 – 4,999	5.0	3.9
5,000 – 5,999	3.9	3.6
6,000 – 6,999	3.6	3.4
7,000 – 7,999	3.4	3.2
8,000 – 8,999	3.2	3.1
9,000 – 9,999	3.1	3.0
10,000 – 14,999	3.0	2.7
15,000 – 19,999	2.7	2.5
20,000 – 49,999	2.5	2.2
50,000 – 59,999	2.2	2.0
60,000 +	2.0	2.0

(c) *Qualification for shared savings payment*—(1) *For performance years (or a performance period) beginning on or before January 1, 2020.* In order to qualify for shared savings, an ACO must meet or exceed its minimum savings rate determined under paragraph (b) of this section, meet the minimum quality performance standards established under § 425.502, and otherwise maintain its eligibility to participate in the Shared Savings Program under this part.

(2) *For the performance year beginning on January 1, 2021.* To qualify for shared savings, an ACO must meet or exceed its minimum savings rate determined under paragraph (b) of this section, meet the quality performance standard established under § 425.512, and otherwise maintain its eligibility to participate in the Shared Savings Program under this part.

(d) *Final sharing rate*—(1) *For performance years (or a performance period) beginning on or before January 1, 2020.* An ACO that meets all the requirements for receiving shared savings payments under the one-sided model will receive a shared savings payment of up to 50 percent of all savings under the updated benchmark, as determined on the basis of its quality performance under § 425.502 (up to the performance payment limit described in paragraph (e)(2) of this section).

(2) *For the performance year beginning on January 1, 2021.* An ACO that meets all the requirements for receiving shared savings payments under Track 1 will receive a shared savings payment of 50 percent of all the savings under the updated benchmark (up to the performance payment limit described in paragraph (e)(2) of this section).

(e) *Performance payment.* (1) If an ACO qualifies for savings by meeting or exceeding the MSR, the final sharing rate will apply to an ACO's savings on a first dollar basis.

(2) The amount of shared savings an eligible ACO receives under the one-sided model may not exceed 10 percent of its updated benchmark.

(f) *Notification of savings.* CMS notifies an ACO in writing regarding whether the ACO qualifies for a shared savings payment, and if so, the amount of the payment due.

(g) *January 1, 2019 through June 30, 2019 performance year.* Shared savings for the January 1, 2019 through June 30,

2019 performance year are calculated as described in § 425.609.

[76 FR 67973, Nov. 2, 2011, as amended at 81 FR 38016, June 10, 2016; 82 FR 53370, Nov. 15, 2017; 83 FR 60094, Nov. 23, 2018; 83 FR 68074, Dec. 31, 2018; 85 FR 85042, Dec. 28, 2020]

§ 425.605 Calculation of shared savings and losses under the BASIC track.

(a) *General rules.* For each performance year, CMS determines whether the estimated average per capita Medicare Parts A and B fee-for-service expenditures for Medicare fee-for-service beneficiaries assigned to the ACO are above or below the updated benchmark determined under § 425.601 or § 425.652, as applicable. In order to qualify for a shared savings payment under the BASIC track, or to be responsible for sharing losses with CMS, an ACO's average per capita Medicare Parts A and B fee-for-service expenditures for its assigned beneficiary population for the performance year must be below or above the updated benchmark, respectively, by at least the minimum savings or loss rate under paragraph (b) of this section except as provided in paragraph (h) of this section.

(1) CMS uses an ACO's prospective HCC risk score to adjust the benchmark for changes in severity and case mix in the assigned beneficiary population between BY3 and the performance year.

(i) For agreement periods beginning before January 1, 2024:

(A) Positive adjustments in prospective HCC risk scores are subject to a cap of 3 percent.

(B) This cap is the maximum increase in risk scores for each agreement period, such that any positive adjustment between BY3 and any performance year in the agreement period cannot be larger than 3 percent.

(ii) For agreement periods beginning on January 1, 2024, and in subsequent years:

(A) Positive adjustments in prospective HCC risk scores are subject to a cap equal to the ACO's aggregate growth in demographic risk scores between BY3 and the performance year (positive or negative) plus 3 percentage points.

(B) The cap described in paragraph (a)(1)(ii)(A) of this section will apply to prospective HCC risk score growth for a population described in paragraph (a)(2) of this section only if the ACO's aggregate growth in prospective HCC risk scores between BY3 and the performance year across all of the populations described in paragraph (a)(2) of this section exceeds this cap. If the cap described in paragraph (a)(1)(ii)(A) of this section is determined to apply, the value of the cap is the maximum increase in risk scores for the applicable performance year, such that any positive adjustment between BY3 and the performance year cannot be larger than the value of the cap for any of the populations described in paragraph (a)(2) of this section.

(C) The aggregate growth in demographic risk scores for purposes of paragraph (a)(1)(ii)(A) of this section and the aggregate growth in prospective hierarchical condition category (HCC) risk scores for purposes of paragraph (a)(1)(ii)(B) of this section is calculated by taking a weighted average of the growth in demographic risk scores or prospective HCC risk scores, as applicable, across the populations described in paragraph (a)(2) of this section. When calculating the weighted average growth in demographic risk scores or prospective HCC risk scores, as applicable, the weight applied to the growth in risk scores (expressed as a ratio of the ACO's performance year risk score to the ACO's BY3 risk score) for each Medicare enrollment type is equal to the product of the ACO's historical benchmark expenditures, adjusted in accordance with § 425.652(a)(8), for that enrollment type and the ACO's performance year assigned beneficiary person years for that enrollment type.

(2) In risk adjusting the benchmark as described in §§ 425.601(a)(10) and 425.652(a)(10), CMS makes separate adjustments for each of the following populations of beneficiaries:

(i) ESRD.

(ii) Disabled.

(iii) Aged/dual eligible Medicare and Medicaid beneficiaries.

(iv) Aged/non-dual eligible Medicare and Medicaid beneficiaries.

(3) To minimize variation from catastrophically large claims, CMS truncates an assigned beneficiary's total annual Medicare Parts A and B fee-for-

service per capita expenditures at the 99th percentile of national Medicare Parts A and B fee-for-service expenditures as determined for the applicable performance year for assignable beneficiaries identified for the 12-month calendar year corresponding to the performance year.

(4) CMS uses a 3-month claims run out with a completion factor to calculate an ACO's per capita expenditures for each performance year.

(5) Calculations of the ACO's expenditures include the payment amounts included in Medicare Parts A and B fee-for-service claims.

(i) These calculations exclude indirect medical education (IME) and disproportionate share hospital (DSH) payments, and the supplemental payment for IHS/Tribal hospitals and Puerto Rico hospitals.

(ii) These calculations take into consideration individually beneficiary identifiable final payments made under a demonstration, pilot or time limited program.

(6) In order to qualify for a shared savings payment, the ACO's average per capita Medicare Parts A and B fee-for-service expenditures for the performance year must be below the applicable updated benchmark by at least the minimum savings rate established for the ACO under paragraph (b) of this section except as provided in paragraph (h) of this section.

(b) *Minimum savings or loss rate.* (1) For ACOs under a one-sided model of the BASIC track's glide path, as specified under paragraphs (d)(1)(i) and (ii) of this section, CMS uses a sliding scale, based on the number of beneficiaries assigned to the ACO under subpart E of this part, to establish the MSR for the ACO as follows:

Number of Beneficiaries	MSR (low end of assigned beneficiaries) (percent)	MSR (high end of assigned beneficiaries) (percent)
1 – 499	≥12.2	
500 – 999	12.2	8.7
1,000 – 2,999	8.7	5.0
3,000 – 4,999	5.0	3.9
5,000 – 5,999	3.9	3.6
6,000 – 6,999	3.6	3.4
7,000 – 7,999	3.4	3.2
8,000 – 8,999	3.2	3.1
9,000 – 9,999	3.1	3.0
10,000 – 14,999	3.0	2.7
15,000 – 19,999	2.7	2.5
20,000 – 49,999	2.5	2.2
50,000 – 59,999	2.2	2.0
60,000 +	2.0	2.0

(2) Prior to entering a two-sided model of the BASIC track, the ACO must select the MSR/MLR. For an ACO making this selection as part of an application for, or renewal of, participation in a two-sided model of the BASIC track, the selection applies for the duration of the agreement period under the BASIC track. For an ACO making this selection during an agreement period, as part of the application cycle prior to entering a two-sided model of the BASIC track, the selection applies for the remaining duration of the applicable agreement period under the BASIC track.

(i) The ACO must choose from the following options for establishing the MSR/MLR:

(A) Zero percent MSR/MLR.

(B) Symmetrical MSR/MLR in a 0.5 percent increment between 0.5 and 2.0 percent.

(C) Symmetrical MSR/MLR that varies, based on the number of beneficiaries assigned to the ACO under subpart E of this part. The MSR is the same as the MSR that would apply under paragraph (b)(1) of this section for an ACO under a one-sided model of the BASIC track's glide path, and is based on the number of assigned beneficiaries. The MLR under the BASIC track is equal to the negative MSR.

(ii) The ACO selects its MSR/MLR as part of one the following:

(A) Application for, or renewal of, program participation in a two-sided model of the BASIC track.

(B) Election to participate in a two-sided model of the BASIC track during an agreement period under § 425.226.

(C) Automatic transition from Level B to Level C of the BASIC track's glide path under § 425.600(a)(4)(i).

(D) Automatic transition from Level B to Level E of the BASIC track's glide path under § 425.600(a)(4)(i)(B)(*2*)(*ii*).

(E) Automatic transition from Level A to Level E of the BASIC track's glide path under § 425.600(h)(2).

(3) Except as provided in paragraph (h) of this section, in order to qualify for a shared savings payment, an ACO's average per capita Medicare Parts A and B fee-for-service expenditures for its assigned beneficiary population for the performance year must be below its updated benchmark by at least the MSR established for the ACO.

(4) To be responsible for sharing losses with the Medicare program, an ACO's average per capita Medicare Parts A and B fee-for-service expenditures for its assigned beneficiary population for the performance year must be above its updated benchmark costs for the year by at least the MLR established for the ACO.

(c) *Qualification for shared savings payment*—(1) *For performance years beginning on or before January 1, 2020.* To qualify for shared savings, an ACO must meet the minimum savings rate requirement established under paragraph (b) of this section, meet the minimum quality performance standards established under § 425.502, and otherwise maintain its eligibility to participate in the Shared Savings Program under this part.

(2) *For performance years beginning on or after January 1, 2021.* To qualify for shared savings, an ACO must—

(i) Meet either the minimum savings rate requirement established under paragraph (b) of this section, or the criteria described in paragraph (h) of this section;

(ii) Meet either the quality performance standard or alternative quality performance standard established under § 425.512; and

(iii) Otherwise maintain its eligibility to participate in the Shared Savings Program under this part.

(d) *Levels of risk and potential reward.* (1) The following levels of risk and potential reward apply to an ACO in the BASIC track, as permitted under § 425.600(d) or § 425.600(g).

(i) *Level A (one-sided model)*—(A)*Final sharing rate—(1) For performance years beginning on or before January 1, 2020.* An ACO that meets all the requirements for receiving shared savings payments under the BASIC track, Level A, receives a shared savings payment of up to 40 percent of all the savings under the updated benchmark, as determined on the basis of its quality performance under § 425.502 (up to the performance payment limit described in paragraph (d)(1)(i)(B) of this section).

(*2*) *For performance years beginning on January 1, 2021, or January 1, 2022.* An ACO that meets all the requirements for receiving shared savings payments under the BASIC track, Level A, receives a shared savings payment of 40 percent of all the savings under the updated benchmark (up to the performance payment limit described in paragraph (d)(1)(i)(B) of this section).

(*3*) *For the performance year beginning on January 1, 2023.* An ACO that meets all the requirements for receiving shared savings payments under the BASIC track, Level A, receives a shared savings payment equal to a percentage of all the savings under the updated benchmark (up to the performance payment limit described in paragraph (d)(1)(i)(B) of this section). The percentage is as follows:

(*i*) 40 percent for an ACO that meets the quality performance standard by

meeting the criteria specified in § 425.512(a)(2) or (a)(4)(i).

(*ii*) 40 percent multiplied by the ACO's health equity adjusted quality performance score calculated according to § 425.512(b) for an ACO that meets the alternative quality performance standard by meeting the criteria specified in § 425.512(a)(4)(ii).

(*4*) *For performance years beginning on or after January 1, 2024.* An ACO that meets all the requirements for receiving shared savings payments under the BASIC track, Level A, receives a shared savings payment equal to a percentage of all the savings under the updated benchmark (up to the performance payment limit described in paragraph (d)(1)(i)(B) of this section). Except as provided in paragraph (h) of this section, the percentage is as follows:

(*i*) 40 percent for an ACO that meets the quality performance standard by meeting the criteria specified in § 425.512(a)(2) or (a)(5)(i).

(*ii*) 40 percent multiplied by the ACO's health equity adjusted quality performance score calculated according to § 425.512(b) for an ACO that meets the alternative quality performance standard by meeting the criteria specified in § 425.512(a)(5)(ii).

(B) *Performance payment.* (*1*) If an ACO qualifies for savings by meeting or exceeding the MSR, or as provided in paragraph (h) of this section, the final sharing rate specified in paragraph (d)(1)(i)(A) of this section applies to an ACO's savings on a first dollar basis.

(*2*) The amount of shared savings an eligible ACO receives under the BASIC track, Level A, may not exceed 10 percent of its updated benchmark.

(ii) *Level B (one-sided model)*—(A) *Final sharing rate—(1) For performance years beginning on or before January 1, 2020.* An ACO that meets all the requirements for receiving shared savings payments under the BASIC track, Level B, receives a shared savings payment of up to 40 percent of all the savings under the updated benchmark, as determined on the basis of its quality performance under § 425.502 (up to the performance payment limit described in paragraph (d)(1)(ii)(B) of this section).

(*2*) (*2*) *For performance years beginning on January 1, 2021, or January 1, 2022.* An ACO that meets all the requirements for receiving shared savings payments under the BASIC track, Level B, receives a shared savings payment of 40 percent of all the savings under the updated benchmark (up to the performance payment limit described in paragraph (d)(1)(ii)(B) of this section).

(*3*) *For the performance year beginning on January 1, 2023.* An ACO that meets all the requirements for receiving shared savings payments under the BASIC track, Level B, receives a shared savings payment equal to a percentage of all the savings under the updated benchmark (up to the performance payment limit described in paragraph (d)(1)(ii)(B) of this section). The percentage is as follows:

(*i*) 40 percent for an ACO that meets the quality performance standard by meeting the criteria specified in § 425.512(a)(2) or (a)(4)(i).

(*ii*) 40 percent multiplied by the ACO's health equity adjusted quality performance score calculated according to § 425.512(b) for an ACO that meets the alternative quality performance standard by meeting the criteria specified in § 425.512(a)(4)(ii).

(*4*) *For performance years beginning on or after January 1, 2024.* An ACO that meets all the requirements for receiving shared savings payments under the BASIC track, Level B, receives a shared savings payment equal to a percentage of all the savings under the updated benchmark (up to the performance payment limit described in paragraph (d)(1)(ii)(B) of this section). Except as provided in paragraph (h) of this section, the percentage is as follows:

(*i*) 40 percent for an ACO that meets the quality performance standard by meeting the criteria specified in § 425.512(a)(2) or (a)(5)(i).

(*ii*) 40 percent multiplied by the ACO's health equity adjusted quality performance score calculated according to § 425.512(b) for an ACO that meets the alternative quality performance standard by meeting the criteria specified in § 425.512(a)(5)(ii).

(B) *Performance payment.* (*1*) If an ACO qualifies for savings by meeting or exceeding the MSR, or as provided in

paragraph (h) of this section, the final sharing rate specified in paragraph (d)(1)(ii)(A) of this section applies to an ACO's savings on a first dollar basis.

(*2*) The amount of shared savings an eligible ACO receives under the BASIC track, Level B, may not exceed 10 percent of its updated benchmark.

(iii) *Level C (two-sided model)*—(A) *Final sharing rate*—(*1*) *For performance years beginning on or before January 1, 2020.* An ACO that meets all the requirements for receiving shared savings payments under the BASIC track, Level C, receives a shared savings payment of up to 50 percent of all the savings under the updated benchmark, as determined on the basis of its quality performance under § 425.502 (up to the performance payment limit described in paragraph (d)(1)(iii)(B) of this section).

(*2*) *For performance years beginning on January 1, 2021, or January 1, 2022.* An ACO that meets all the requirements for receiving shared savings payments under the BASIC track, Level C, receives a shared savings payment of 50 percent of all the savings under the updated benchmark (up to the performance payment limit described in paragraph (d)(1)(iii)(B) of this section).

(*3*) *For the performance year beginning on January 1, 2023.* An ACO that meets all the requirements for receiving shared savings payments under the BASIC track, Level C, receives a shared savings payment equal to a percentage of all the savings under the updated benchmark (up to the performance payment limit described in paragraph (d)(1)(iii)(B) of this section). The percentage is as follows:

(*i*) 50 percent for an ACO that meets the quality performance standard by meeting the criteria specified in § 425.512(a)(2) or (a)(4)(i).

(*ii*) 50 percent multiplied by the ACO's health equity adjusted quality performance score calculated according to § 425.512(b) for an ACO that meets the alternative quality performance standard by meeting the criteria specified in § 425.512(a)(4)(ii).

(*4*) *For performance years beginning on or after January 1, 2024.* An ACO that meets all the requirements for receiving shared savings payments under the BASIC track, Level C, receives a shared savings payment equal to a percentage of all the savings under the updated benchmark (up to the performance payment limit described in paragraph (d)(1)(iii)(B) of this section). Except as provided in paragraph (h) of this section, the percentage is as follows:

(*i*) 50 percent for an ACO that meets the quality performance standard by meeting the criteria specified in § 425.512(a)(2) or (a)(5)(i).

(*ii*) 50 percent multiplied by the ACO's health equity adjusted quality performance score calculated according to § 425.512(b) for an ACO that meets the alternative quality performance standard by meeting the criteria specified in § 425.512(a)(5)(ii).

(B) *Performance payment.* (*1*) If an ACO qualifies for savings by meeting or exceeding the MSR, or as provided in paragraph (h) of this section, the final sharing rate specified in paragraph (d)(1)(iii)(A) of this section applies to an ACO's savings on a first dollar basis.

(*2*) The amount of shared savings an eligible ACO receives under the BASIC track, Level C may not exceed 10 percent of its updated benchmark.

(C) *Shared loss rate.* For an ACO that is required to share losses with the Medicare program for expenditures over the updated benchmark, the amount of shared losses is determined based on a fixed 30 percent loss sharing rate.

(D) *Loss recoupment limit.* (*1*) Except as provided in paragraph (d)(1)(iii)(D)(*2*) of this section, the amount of shared losses for which an eligible ACO is liable may not exceed 2 percent of total Medicare Parts A and B fee-for-service revenue of the ACO participants in the ACO.

(*2*) Instead of the revenue-based loss recoupment limit determined under paragraph (d)(1)(iii)(D)(*1*) of this section, the loss recoupment limit for the ACO is 1 percent of the ACO's updated benchmark as determined under § 425.601 or § 425.652, if the amount determined under paragraph (d)(1)(iii)(D)(*1*) of this section exceeds the amount that is 1 percent of the ACO's updated benchmark as determined under § 425.601 or § 425.652.

(iv) *Level D (two-sided model)*—(A) *Final sharing rate*—(*1*) *For performance*

years beginning on or before January 1, 2020. An ACO that meets all the requirements for receiving shared savings payments under the BASIC track, Level D, receives a shared savings payment of up to 50 percent of all the savings under the updated benchmark, as determined on the basis of its quality performance under § 425.502 (up to the performance payment limit described in paragraph (d)(1)(iv)(B) of this section).

(*2*) *For performance years beginning on January 1, 2021, or January 1, 2022*. An ACO that meets all the requirements for receiving shared savings payments under the BASIC track, Level D, receives a shared savings payment of 50 percent of all the savings under the updated benchmark (up to the performance payment limit described in paragraph (d)(1)(iv)(B) of this section).

(*3*) *For the performance year beginning on January 1, 2023*. An ACO that meets all the requirements for receiving shared savings payments under the BASIC track, Level D, receives a shared savings payment equal to a percentage of all the savings under the updated benchmark (up to the performance payment limit described in paragraph (d)(1)(iv)(B) of this section). The percentage is as follows:

(*i*) 50 percent for an ACO that meets the quality performance standard by meeting the criteria specified in § 425.512(a)(2) or (a)(4)(i).

(*ii*) 50 percent multiplied by the ACO's health equity adjusted quality performance score calculated according to § 425.512(b) for an ACO that meets the alternative quality performance standard by meeting the criteria specified in § 425.512(a)(4)(ii).

(*4*) *For performance years beginning on or after January 1, 2024*. An ACO that meets all the requirements for receiving shared savings payments under the BASIC track, Level D, receives a shared savings payment equal to a percentage of all the savings under the updated benchmark (up to the performance payment limit described in paragraph (d)(1)(iv)(B) of this section). Except as provided in paragraph (h) of this section, the percentage is as follows:

(*i*) 50 percent for an ACO that meets the quality performance standard by meeting the criteria specified in § 425.512(a)(2) or (a)(5)(i).

(*ii*) 50 percent multiplied by the ACO's health equity adjusted quality performance score calculated according to § 425.512(b) for an ACO that meets the alternative quality performance standard by meeting the criteria specified in § 425.512(a)(5)(ii).

(B) *Performance payment*. (*1*) If an ACO qualifies for savings by meeting or exceeding the MSR, or as provided in paragraph (h) of this section, the final sharing rate specified in paragraph (d)(1)(iv)(A) of this section applies to an ACO's savings on a first dollar basis.

(*2*) The amount of shared savings an eligible ACO receives under the BASIC track, Level D, may not exceed 10 percent of its updated benchmark.

(C) *Shared loss rate*. For an ACO that is required to share losses with the Medicare program for expenditures over the updated benchmark, the amount of shared losses is determined based on a fixed 30 percent loss sharing rate.

(D) *Loss recoupment limit*. (*1*) Except as provided in paragraph (d)(1)(iv)(D)(*2*) of this section, the amount of shared losses for which an eligible ACO is liable may not exceed 4 percent of total Medicare Parts A and B fee-for-service revenue of the ACO participants in the ACO.

(*2*) Instead of the revenue-based loss recoupment limit determined under paragraph (d)(1)(iv)(D)(*1*) of this section, the loss recoupment limit for the ACO is 2 percent of the ACO's updated benchmark as determined under § 425.601 or § 425.652, if the amount determined under paragraph (d)(1)(iv)(D)(*1*) of this section exceeds the amount that is 2 percent of the ACO's updated benchmark as determined under § 425.601 or § 425.652.

(v) *Level E (two-sided model)*—(A) *Final sharing rate—(1) For performance years beginning on or before January 1, 2020*. An ACO that meets all the requirements for receiving shared savings payments under the BASIC track, Level E, receives a shared savings payment of up to 50 percent of all the savings under the updated benchmark, as determined on the basis of its quality performance under § 425.502 (up to the performance payment limit described

in paragraph (d)(1)(v)(B) of this section).

(*2*) *For performance years beginning on January 1, 2021, or January 1, 2022.* An ACO that meets all the requirements for receiving shared savings payments under the BASIC track, Level E, receives a shared savings payment of 50 percent of all the savings under the updated benchmark (up to the performance payment limit described in paragraph (d)(1)(v)(B) of this section).

(*3*) *For the performance year beginning on January 1, 2023.* An ACO that meets all the requirements for receiving shared savings payments under the BASIC track, Level E, receives a shared savings payment equal to a percentage of all the savings under the updated benchmark (up to the performance payment limit described in paragraph (d)(1)(v)(B) of this section). The percentage is as follows:

(*i*) 50 percent for an ACO that meets the quality performance standard by meeting the criteria specified in § 425.512(a)(2) or (a)(4)(i).

(*ii*) 50 percent multiplied by the ACO's health equity adjusted quality performance score calculated according to § 425.512(b) for an ACO that meets the alternative quality performance standard by meeting the criteria specified in § 425.512(a)(4)(ii).

(*4*) *For performance years beginning on or after January 1, 2024.* An ACO that meets all the requirements for receiving shared savings payments under the BASIC track, Level E, receives a shared savings payment equal to a percentage of all the savings under the updated benchmark (up to the performance payment limit described in paragraph (d)(1)(v)(B) of this section). Except as provided in paragraph (h) of this section, the percentage is as follows:

(*i*) 50 percent for an ACO that that meets the quality performance standard by meeting the criteria specified in § 425.512(a)(2) or (a)(5)(i).

(*ii*) 50 percent multiplied by the ACO's health equity adjusted quality performance score calculated according to § 425.512(b) for an ACO that meets the alternative quality performance standard by meeting the criteria specified in § 425.512(a)(5)(ii).

(B) *Performance payment.* (*1*) If an ACO qualifies for savings by meeting or exceeding the MSR, or as provided in paragraph (h) of this section, the final sharing rate specified in paragraph (d)(1)(v)(A) of this section applies to an ACO's savings on a first dollar basis.

(*2*) The amount of shared savings an eligible ACO receives under the BASIC track, Level E, may not exceed 10 percent of its updated benchmark.

(C) *Shared loss rate.* For an ACO that is required to share losses with the Medicare program for expenditures over the updated benchmark, the amount of shared losses is determined based on a fixed 30 percent loss sharing rate.

(D) *Loss recoupment limit.* (*1*) Except as provided in paragraph (d)(1)(v)(D)(*2*) of this section, the amount of shared losses for which an eligible ACO is liable may not exceed the percentage, as specified in § 414.1415(c)(3)(i)(A) of this chapter, of total Medicare Parts A and B fee-for-service revenue of the ACO participants in the ACO.

(*2*) Instead of the revenue-based loss recoupment limit determined under paragraph (d)(1)(v)(D)(*1*) of this section, the loss recoupment limit for the ACO is 1 percentage point higher than the percentage, as specified in § 414.1415(c)(3)(i)(B) of this chapter, based on the ACO's updated benchmark as determined under § 425.601 or § 425.652, if the amount determined under paragraph (d)(1)(v)(D)(*1*) of this section exceeds this percentage of the ACO's updated benchmark as determined under § 425.601 or § 425.652.

(2) Level E risk and reward as specified in paragraph (d)(1)(v) of this section applies to an ACO eligible to enter the BASIC track that is determined to be experienced with performance-based risk Medicare ACO initiatives as specified under § 425.600(d) or § 425.600(g).

(e) *Notification of savings and losses.* (1) CMS notifies an ACO in writing regarding whether the ACO qualifies for a shared savings payment, and if so, the amount of the payment due.

(2) CMS provides written notification to an ACO of the amount of shared losses, if any, that it must repay to the program.

(3) If an ACO has shared losses, the ACO must make payment in full to

CMS within 90 days of receipt of notification.

(f) *Extreme and uncontrollable circumstances.* The following adjustment is made in calculating the amount of shared losses, after the application of the shared loss rate and the loss recoupment limit.

(1) CMS determines the percentage of the ACO's performance year assigned beneficiary population affected by an extreme and uncontrollable circumstance.

(2) CMS reduces the amount of the ACO's shared losses by an amount determined by multiplying the shared losses by the percentage of the total months in the performance year affected by an extreme and uncontrollable circumstance, and the percentage of the ACO's assigned beneficiaries who reside in an area affected by an extreme and uncontrollable circumstance.

(i) For an ACO that is liable for a pro-rated share of losses under §425.221(b)(2)(ii), the amount of shared losses determined for the performance year during which the termination becomes effective is adjusted according to this paragraph (f)(2).

(ii) [Reserved]

(3) CMS applies determinations made under the Quality Payment Program with respect to—

(i) Whether an extreme and uncontrollable circumstance has occurred; and

(ii) The affected areas.

(4) CMS has sole discretion to determine the time period during which an extreme and uncontrollable circumstance occurred and the percentage of the ACO's assigned beneficiaries residing in the affected areas.

(g) *July 1, 2019 through December 31, 2019 performance year.* Shared savings or shared losses for the July 1, 2019 through December 31, 2019 performance year are calculated as described in §425.609.

(h) *Calculation of shared savings for certain BASIC track ACOs not meeting MSR requirement.* An ACO that does not meet the minimum savings rate requirement established under paragraph (b) of this section but meets the other criteria described in paragraphs (c)(2)(ii) and (iii) of this section may qualify for a shared savings payment as provided in this paragraph.

(1) To qualify for a shared savings payment under this paragraph, an ACO must meet all of the following criteria:

(i) The ACO has average per capita Medicare Parts A and B fee-for-service expenditures for the performance year below the updated benchmark determined under §425.652.

(ii) The ACO is a low revenue ACO as defined in §425.20 as determined at the time of financial reconciliation for the performance year.

(iii) The ACO has at least 5,000 assigned beneficiaries for the relevant performance year as determined at the time of financial reconciliation for the performance year.

(iv) The ACO is participating in an agreement period beginning on January 1, 2024, or in subsequent years.

(2) The ACO's shared savings payment will be calculated as described in paragraph (d) of this section according to the ACO's applicable level of the BASIC track with the exception that the final sharing rate applied will equal one-half of the applicable percentage described in paragraph (d)(1)(i)(A)(*4*), (d)(1)(ii)(A)(*4*), (d)(1)(iii)(A)(*4*), (d)(1)(iv)(A)(*4*), or (d)(1)(v)(A)(*4*) of this section.

[83 FR 68075, Dec. 31, 2018, as amended at 85 FR 85042, Dec. 28, 2020; 87 FR 70237, Nov. 18, 2022; 89 FR 98571, Dec. 9, 2024]

§425.606 Calculation of shared savings and losses under Track 2.

(a) *General rule.* For each performance year, CMS determines whether the estimated average per capita Medicare expenditures under the ACO for Medicare fee-for-service beneficiaries for Parts A and B services are above or below the updated benchmark determined under §425.602 or §425.603. In order to qualify for a shared savings payment under Track 2, or to be responsible for sharing losses with CMS, an ACO's average per capita Medicare expenditures under the ACO for Medicare fee-for-service beneficiaries for Parts A and B services for the performance year must be below or above the updated benchmark, respectively, by at least the minimum savings or loss rate under paragraph (b) of this section.

(1) *Newly assigned beneficiaries.* CMS uses an ACO's HCC prospective risk score to adjust the benchmark for changes in severity and case mix in this population.

(2) *Continuously assigned beneficiaries.* (i) CMS uses demographic factors to adjust the benchmark for changes in the continuously assigned beneficiary population.

(ii) If the prospective HCC risk score is lower in the performance year for this population, CMS will adjust the benchmark for changes in severity and case mix for this population using this lower prospective HCC risk score.

(3) Assigned beneficiary changes in demographics and health status are used to adjust benchmark expenditures as described in § 425.602(a) or § 425.603(c). In adjusting the benchmark for health status and demographic changes CMS makes separate adjustments for each of the following populations of beneficiaries:

(i) ESRD.

(ii) Disabled.

(iii) Aged/dual eligible Medicare and Medicaid beneficiaries.

(iv) Aged/non-dual eligible Medicare and Medicaid beneficiaries.

(4)(i) For performance years before 2017 to minimize variation from catastrophically large claims, CMS truncates an assigned beneficiary's total annual Parts A and B fee-for-service per capita expenditures at the 99th percentile of national Medicare fee-for-service expenditures as determined for each performance year.

(ii) For the 2017 performance year and subsequent performance years, to minimize variation from catastrophically large claims, CMS truncates an assigned beneficiary's total annual Parts A and B fee-for-service per capita expenditures at the 99th percentile of national Medicare fee-for-service expenditures as determined for the applicable performance year for assignable beneficiaries identified for the 12-month calendar year corresponding to the performance year.

(5) CMS uses a 3 month claims run out with a completion factor to calculate an ACO's per capita expenditures for each performance year.

(6) Calculations of the ACO's expenditures will include the payment amounts included in Part A and B fee-for-service claims.

(i) These calculations will exclude indirect medical education (IME) and disproportionate share hospital (DSH) payments.

(ii) These calculations will take into consideration individually beneficiary identifiable payments made under a demonstration, pilot or time limited program.

(A) For performance years beginning before 2018, these calculations will take into consideration all individually beneficiary identifiable payments, including interim payments, made under a demonstration, pilot or time limited program.

(B) For performance year 2018 and subsequent performance years, these calculations will take into consideration individually beneficiary identifiable final payments made under a demonstration, pilot or time limited program.

(7) In order to qualify for a shared savings payment, the ACO's average per capita Medicare expenditures for the performance year must be below the applicable updated benchmark by at least the minimum savings rate established for the ACO under paragraph (b) of this section.

(b) *Minimum savings or loss rate.* (1)(i) For agreement periods beginning in 2012 through 2015, the ACO's MSR and MLR are set at 2 percent.

(ii) For agreement periods beginning in 2016 and subsequent years, as part of the ACO's application for, or renewal of, program participation, the ACO must choose from the following options for establishing the MSR/MLR for the duration of the agreement period:

(A) Zero percent MSR/MLR.

(B) Symmetrical MSR/MLR in a 0.5 percent increment between 0.5–2.0 percent.

(C) Symmetrical MSR/MLR that varies, based on the number of beneficiaries assigned to the ACO under subpart E of this part. The MSR for an ACO under Track 2 is the same as the MSR that would apply in the one-sided model under § 425.604(b) and is based on the number of assigned beneficiaries. The MLR under Track 2 is equal to the negative MSR.

(2) To qualify for shared savings under Track 2, an ACO's average per capita Medicare expenditures for the performance year must be below its updated benchmark costs for the year by at least the MSR established for the ACO.

(3) To be responsible for sharing losses with the Medicare program, an ACO's average per capita Medicare expenditures for the performance year must be above its updated benchmark costs for the year by at least the MLR established for the ACO.

(c) *Qualification for shared savings payment*—(1) *For performance years (or a performance period) beginning on or before January 1, 2020.* To qualify for shared savings, an ACO must meet the minimum savings rate requirement established under paragraph (b) of this section, meet the minimum quality performance standards established under §425.502, and otherwise maintain its eligibility to participate in the Shared Savings Program under this part.

(2) *For the performance year beginning on January 1, 2021.* To qualify for shared savings, an ACO must meet the minimum savings rate requirement established under paragraph (b) of this section, meet the quality performance standard established under §425.512, and otherwise maintain its eligibility to participate in the Shared Savings Program under this part.

(d) *Final sharing rate*—(1) *For performance years (or a performance period) beginning on or before January 1, 2020.* An ACO that meets all the requirements for receiving shared savings payments under Track 2 will receive a shared savings payment of up to 60 percent of all the savings under the updated benchmark, as determined on the basis of its quality performance under §425.502 (up to the performance payment limit described in paragraph (e)(2) of this section).

(2) *For the performance year beginning on January 1, 2021.* An ACO that meets all the requirements for receiving shared savings payments under Track 2 will receive a shared savings payment of 60 percent of all the savings under the updated benchmark (up to the performance payment limit described in paragraph (e)(2) of this section).

(e) *Performance payment.* (1) If an ACO qualifies for savings by meeting or exceeding the MSR, the final sharing rate will apply to an ACO's savings on a first dollar basis.

(2) The amount of shared savings an eligible ACO receives under Track 2 may not exceed 15 percent of its updated benchmark.

(f) *Shared loss rate*—(1) *For performance years (or a performance period) beginning on or before January 1, 2020.* For an ACO that is required to share losses with the Medicare program for expenditures over the updated benchmark, the amount of shared losses is determined based on the inverse of its final sharing rate described in paragraph (d)(1) of this section (that is, 1 minus the final shared savings rate determined under paragraph (d)(1) of this section). The shared loss rate—

(i) May not exceed 60 percent; and

(ii) May not be less than 40 percent.

(2) *For the performance year beginning on January 1, 2021.* For an ACO that is required to share losses with the Medicare program for expenditures over the updated benchmark, the amount of shared losses is determined as follows:

(i) If the ACO meets the quality performance standard established in §425.512, CMS determines the shared loss rate as follows:

(A) Calculate the quotient of the MIPS Quality performance category points earned divided by the total MIPS Quality performance category points available.

(B) Calculate the product of the quotient determined in paragraph (f)(2)(i)(A) of this section and 60 percent.

(C) Calculate the shared loss rate as 1 minus the product determined in paragraph (f)(2)(i)(B) of this section. The shared loss rate—

(*1*) May not exceed 60 percent; and

(*2*) May not be less than 40 percent.

(ii) If the ACO fails to meet the quality performance standard established in §425.512, the shared loss rate is 60 percent.

(g) *Loss recoupment limit.* The amount of shared losses for which an eligible ACO is liable may not exceed the following percentages of its updated benchmark as determined under §425.602 or §425.603:

(1) 5 percent in the first performance year of participation in Track 2 under the Shared Savings Program.

(2) 7.5 percent in the second performance year.

(3) 10 percent in the third and any subsequent performance year.

(h) *Notification of savings and losses.* (1) CMS notifies an ACO in writing regarding whether the ACO qualifies for a shared savings payment, and if so, the amount of the payment due.

(2) CMS provides written notification to an ACO of the amount of shared losses, if any, that it must repay to the program.

(3) If an ACO has shared losses, the ACO must make payment in full to CMS within 90 days of receipt of notification.

(i) *Extreme and uncontrollable circumstances.* For performance year 2017 and subsequent performance years, the following adjustment is made in calculating the amount of shared losses, after the application of the shared loss rate in paragraph (f) of this section and the loss recoupment limit in paragraph (g) of this section.

(1) CMS determines the percentage of the ACO's performance year assigned beneficiary population affected by an extreme and uncontrollable circumstance.

(2) CMS reduces the amount of the ACO's shared losses by an amount determined by multiplying the shared losses by the percentage of the total months in the performance year affected by an extreme and uncontrollable circumstance, and the percentage of the ACO's assigned beneficiaries who reside in an area affected by an extreme and uncontrollable circumstance.

(i) For an ACO that is liable for a pro-rated share of losses under § 425.221(b)(2)(ii) or (b)(3)(i), the amount of shared losses determined for the performance year during which the termination becomes effective is adjusted according to this paragraph (i)(2).

(ii) [Reserved]

(3) CMS applies determinations made under the Quality Payment Program with respect to—

(i) Whether an extreme and uncontrollable circumstance has occurred; and

(ii) The affected areas.

(4) CMS has sole discretion to determine the time period during which an extreme and uncontrollable circumstance occurred and the percentage of the ACO's assigned beneficiaries residing in the affected areas.

(j) *January 1, 2019 through June 30, 2019.* Shared savings or shared losses for the January 1, 2019 through June 30, 2019 performance year are calculated as described in § 425.609.

[76 FR 67973, Nov. 2, 2011, as amended at 80 FR 32842, June 9, 2015; 81 FR 38017, June 10, 2016; 82 FR 53370, Nov. 15, 2017; 82 FR 60918, Dec. 26, 2017; 83 FR 60094, Nov. 23, 2018; 83 FR 68077, Dec. 31, 2018; 85 FR 85043, Dec. 28, 2020]

§ 425.608 Determining first year performance for ACOs beginning April 1 or July 1, 2012.

(a) For April 1 and July 1, 2012 starters, first year (defined as 21 and 18 months respectively) performance will be based on an optional interim payment calculation (based on the ACO's first 12 months of participation) and a final reconciliation at the end of the ACO's first performance year. Unless stated otherwise, for purposes of the interim payment calculation and first year reconciliation, the methodology under subpart E of this part for assigning beneficiaries and the methodology described in § 425.602 through § 425.606 for calculating shared savings and losses will apply, and quality performance will be assessed as described in subpart F of this part.

(b) In the interim payment calculation, based on the ACO's first 12 months of performance—

(1) CMS compares the first 12 months of per capita beneficiary expenditures to a historical benchmark updated for the period which includes the ACO's first 12 months of participation, taking into account changes in health status and demographics; and

(2) Quality performance is based on GPRO quality data reported for CY 2012.

(c)(1) The interim payment calculation is reconciled with the ACO's performance for its complete first performance year, defined as 21 months for April 1, 2012 starters and 18 months for July 1, 2012 starters.

(2) The first year reconciliation takes into account expenditures spanning the entire 21 or 18 months of the first performance year.

(3) First performance year expenditures are summed over beneficiaries assigned in two overlapping 12 month assignment windows.

(i) The first window will be the first 12 months used for interim payment calculation.

(ii) The second window will be CY2013.

(4) Expenditures for the first performance year are the sum of aggregate expenditure dollars accounting for the ACO's first 6 or 9 months of performance within CY 2012 for beneficiaries assigned for the interim payment calculation and aggregate dollars calculated for CY2013 for beneficiaries assigned for CY 2013.

(5) Adjustments for health status and demographic changes are performed as described in § 425.604 through § 425.606 with the following exceptions:

(i) Beneficiaries from the CY2013 assignment window are identified as continuously assigned or newly assigned relative to the previous calendar year.

(ii) The adjustment factor identified for purposes of the interim payment calculation is applied to the 6 months or 9 months of the ACO's first performance year that lie within CY2012.

(6) The updated benchmark, stated in aggregate dollars, is the sum of the interim updated benchmark for the average fraction of expenditures incurred in the latter 6 or 9 months of CY 2012 and an updated aggregate benchmark representing CY 2013.

(7) A savings percentage (based on a comparison of summed expenditures to summed updated benchmark dollars) for the ACO's 18 or 21 month performance year is compared to the ACO's MSR or MLR. The reconciled amount of the shared savings or losses owed to or by the ACO for the performance year is net of any interim payments of shared savings or losses.

(8) Quality performance for the first year reconciliation is based on complete and accurate reporting, of all required quality measures, for CYs 2012 and 2013.

(d) An ACO with a start date of April 1, 2012 or July 1, 2012 has the option to request an interim payment calculation based on quality and financial performance for its first 12 months of program participation. As required under § 425.204(f), the ACO requesting an interim payment calculation must have a mechanism in place to pay back the interim payment if final reconciliation determines an overpayment.

(e) Unless otherwise stated, program requirements which apply in the course of a performance year apply to the interim payment calculation and first year reconciliation.

§ 425.609 Determining performance for 6-month performance years during CY 2019.

(a) *General.* An ACO's financial and quality performance for a 6-month performance year during 2019 are determined as described in this section.

(b) *January 2019 through June 2019.* For ACOs participating in a 6-month performance year from January 1, 2019, through June 30, 2019, under § 425.200(b)(2)(ii)(B) and for ACOs eligible for pro-rated shared savings or liable for pro-rated shared losses in accordance with § 425.221(b)(3)(i) for the performance period from January 1, 2019, through June 30, 2019, CMS reconciles the ACO for the period from January 1, 2019, through June 30, 2019, after the conclusion of CY 2019, based on the 12-month calendar year and prorates shared savings or shared losses to reflect the ACO's participation from January 1, 2019, through June 30, 2019. CMS does all of the following to determine financial and quality performance:

(1) Uses the ACO participant list in effect for the performance year beginning January 1, 2019, to determine beneficiary assignment, using claims for the entire calendar year, as specified in §§ 425.402 and 425.404, and according to the ACO's track as specified in § 425.400.

(i) For ACOs under preliminary prospective assignment with retrospective reconciliation the assignment window is CY 2019.

(ii) For ACOs under prospective assignment—

(A) Medicare fee-for-service beneficiaries are prospectively assigned to the ACO based on the beneficiary's use

of primary care services in the most recent 12 months for which data are available; and

(B) Beneficiaries remain prospectively assigned to the ACO at the end of CY 2019 if they do not meet any of the exclusion criteria under § 425.401(b) during the calendar year.

(2) Uses the ACO's quality performance for the 2019 reporting period to determine the ACO's quality performance score as specified in § 425.502.

(i) The ACO participant list finalized for the first performance year of the ACO's agreement period beginning on July 1, 2019, is used to determine the quality reporting samples for the 2019 reporting year for the following ACOs:

(A) An ACO that extends its participation agreement for a 6-month performance year from January 1, 2019, through June 30, 2019, under § 425.200(b)(2)(ii)(B), and enters a new agreement period beginning on July 1, 2019.

(B) An ACO that participates in the program for the first 6 months of a 12-month performance year during 2019 and is eligible for pro-rated shared savings or liable for pro-rated shared losses in accordance with § 425.221(b)(3)(i).

(ii) The ACO's latest certified ACO participant list is used to determine the quality reporting samples for the 2019 reporting year for an ACO that extends its participation agreement for the 6-month performance year from January 1, 2019, through June 30, 2019, under § 425.200(b)(2)(ii)(B), and does not enter a new agreement period beginning on July 1, 2019.

(3) Uses the methodology for calculating shared savings or shared losses applicable to the ACO under the terms of the participation agreement that was in effect on January 1, 2019.

(i) The ACO's historical benchmark is determined according to either § 425.602 (first agreement period) or § 425.603 (second agreement period) except as follows:

(A) The benchmark is adjusted for changes in severity and case mix between BY3 and CY 2019 using the methodology that accounts separately for newly and continuously assigned beneficiaries using prospective HCC risk scores and demographic factors as described under §§ 425.604(a)(1) through (3), 425.606(a)(1) through (3), and 425.610(a)(1) through (3).

(B) The benchmark is updated to CY 2019 according to the methodology described under § 425.602(b), § 425.603(b), or § 425.603(d), based on whether the ACO is in its first or second agreement period, and for an ACO in a second agreement period, the date on which that agreement period began.

(ii) The ACO's financial performance is determined based on the track the ACO is participating under during the performance year starting on January 1, 2019 (§ 425.604, § 425.606 or § 425.610), unless otherwise specified. In determining ACO financial performance, CMS does all of the following:

(A) Average per capita Medicare Parts A and B fee-for-service expenditures for CY 2019 are calculated for the ACO's performance year assigned beneficiary population identified in paragraph (b)(1) of this section.

(B) Expenditures calculated in paragraph (b)(3)(ii)(A) of this section are compared to the ACO's updated benchmark determined according to paragraph (b)(3)(i) of this section.

(C)(*1*) The ACO's performance year assigned beneficiary population identified in paragraph (b)(1) of this section is used to determine the MSR for Track 1 ACOs and the variable MSR/MLR for ACOs in a two-sided model that selected this option at the start of their agreement period. For two-sided model ACOs that selected a fixed MSR/MLR at the start of the ACO's agreement period, this fixed MSR/MLR is applied. In the event an ACO's performance year assigned population identified in paragraph (b)(1) of this section is below 5,000 beneficiaries, the MSR/MLR is determined according to § 425.110(b).

(*2*) To qualify for shared savings an ACO must do all of the following:

(*i*) Have average per capita Medicare Parts A and B fee-for-service expenditures for its assigned beneficiary population for CY 2019 below its updated benchmark costs for the year by at least the MSR established for the ACO based on the track the ACO is participating under during the performance year starting on January 1, 2019

(§ 425.604, § 425.606 or § 425.610) and paragraph (b)(3)(ii)(C)(*1*) of this section.

(*ii*) Meet the minimum quality performance standards established under § 425.502 and according to paragraph (b)(2) of this section.

(*iii*) Otherwise maintain its eligibility to participate in the Shared Savings Program under this part.

(*3*) To be responsible for sharing losses with the Medicare program, an ACO's average per capita Medicare Parts A and B fee-for-service expenditures for its assigned beneficiary population for CY 2019 must be above its updated benchmark costs for the year by at least the MLR established for the ACO based on the track the ACO is participating under during the performance year starting on January 1, 2019 (§ 425.606 or § 425.610) and paragraph (b)(3)(ii)(C)(*1*) of this section.

(D) For an ACO that meets all the requirements to receive a shared savings payment under paragraph (b)(3)(ii)(C)(*2*) of this section—

(*1*) The final sharing rate, determined based on the track the ACO is participating under during the performance year starting on January 1, 2019 (§ 425.604, § 425.606 or § 425.610), is applied to all savings under the updated benchmark specified under paragraph (b)(3)(i) of this section, not to exceed the performance payment limit for the ACO based on its track; and

(*2*) After applying the applicable performance payment limit, CMS prorates any shared savings amount determined under paragraph (b)(3)(ii)(D)(*1*) of this section by multiplying the amount by one-half, which represents the fraction of the calendar year covered by the period from January 1, 2019, through June 30, 2019.

(E) For an ACO responsible for shared losses under paragraph (b)(3)(ii)(C)(*3*) of this section—

(*1*) The shared loss rate, determined based on the track the ACO is participating under during the performance year starting on January 1, 2019 (§ 425.606 or § 425.610), is applied to all losses under the updated benchmark specified under paragraph (b)(3)(i) of this section, not to exceed the loss recoupment limit for the ACO based on its track; and

(*2*) After applying the applicable loss recoupment limit, CMS pro-rates any shared losses amount determined under paragraph (b)(3)(ii)(E)(*1*) of this section by multiplying the amount by one-half, which represents the fraction of the calendar year covered by the period from January 1, 2019, through June 30, 2019.

(c) *July 2019 through December 2019.* For ACOs entering an agreement period beginning on July 1, 2019, the ACO's first performance year is from July 1, 2019, through December 31, 2019, as specified in § 425.200(c)(3). CMS reconciles the ACO for the period from July 1, 2019, through December 31, 2019, after the conclusion of CY 2019, based on the 12-month calendar year and prorates shared savings or shared losses to reflect the ACO's participation from July 1, 2019, through December 31, 2019. CMS does all of the following to determine financial and quality performance:

(1) Uses the ACO participant list in effect for the performance year beginning on July 1, 2019, to determine beneficiary assignment, using claims for the entire calendar year, consistent with the methodology the ACO selected at the start of its agreement period under § 425.400(a)(4)(ii).

(i) For ACOs under preliminary prospective assignment with retrospective reconciliation the assignment window is CY 2019.

(ii) For ACOs under prospective assignment—

(A) The assignment window is the same as the assignment window that applies under paragraph (b)(1)(ii)(A) of this section for ACOs under prospective assignment for the 6-month performance year from January 1, 2019, through June 30, 2019; and

(B) Beneficiaries remain prospectively assigned to the ACO at the end of CY 2019 if they do not meet any of the exclusion criteria under § 425.401(b) during the calendar year.

(2) Uses the ACO's quality performance for the 2019 reporting period to determine the ACO's quality performance score as specified in § 425.502. The ACO participant list finalized for the first performance year of the ACO's agreement period beginning on July 1, 2019,

is used to determine the quality reporting samples for the 2019 reporting year for all ACOs.

(3) Uses the methodology for calculating shared savings or shared loses applicable to the ACO for its first performance year under its agreement period beginning on July 1, 2019.

(i) The ACO's historical benchmark is determined according to § 425.601 except as follows:

(A) The benchmark is adjusted for changes in severity and case mix between BY3 and CY 2019 based on growth in prospective HCC risk scores, subject to a cap of positive 3 percent as described under § 425.605(a)(1) or § 425.610(a)(2).

(B) The benchmark is updated to CY 2019 according to the methodology described under § 425.601(b).

(ii) The ACO's financial performance is determined based on the track the ACO is participating under during the performance year starting on July 1, 2019 (§ 425.605 (BASIC track) or § 425.610 (ENHANCED track)), unless otherwise specified. In determining ACO financial performance, CMS does all of the following:

(A) Average per capita Medicare Parts A and B fee-for-service expenditures for CY 2019 are calculated for the ACO's performance year assigned beneficiary population identified in paragraph (c)(1) of this section.

(B) Expenditures calculated in paragraph (c)(3)(ii)(A) of this section are compared to the ACO's updated benchmark determined according to paragraph (c)(3)(i) of this section.

(C)(*1*) The ACO's performance year assigned beneficiary population identified in paragraph (c)(1) of this section is used to determine the MSR for ACOs in BASIC track Level A or Level B, and the variable MSR/MLR for ACOs in a two-sided model that selected this option at the start of their agreement period. In the event a two-sided model ACO selected a fixed MSR/MLR at the start of its agreement period, and the ACO's performance year assigned population identified in paragraph (c)(1) of this section is below 5,000 beneficiaries, the MSR/MLR is determined based on the number of assigned beneficiaries as specified in § 425.110(b)(3)(iii).

(*2*) To qualify for shared savings an ACO must do all of the following:

(*i*) Have average per capita Medicare Parts A and B fee-for-service expenditures for its assigned beneficiary population for CY 2019 below its updated benchmark costs for the year by at least the MSR established for the ACO based on the track the ACO is participating under during the performance year starting on July 1, 2019 (§ 425.605 or § 425.610) and paragraph (c)(3)(ii)(C)(*1*) of this section.

(*ii*) Meet the minimum quality performance standards established under § 425.502 and according to paragraph (c)(2) of this section.

(*iii*) Otherwise maintain its eligibility to participate in the Shared Savings Program under this part.

(*3*) To be responsible for sharing losses with the Medicare program, an ACO's average per capita Medicare Parts A and B fee-for-service expenditures for its assigned beneficiary population for CY 2019 must be above its updated benchmark costs for the year by at least the MLR established for the ACO based on the track the ACO is participating under during the performance year starting on July 1, 2019 (§ 425.605 or § 425.610) and paragraph (c)(3)(ii)(C)(*1*) of this section.

(D) For an ACO that meets all the requirements to receive a shared savings payment under paragraph (c)(3)(ii)(C)(*2*) of this section—

(*1*) The final sharing rate, determined based on the track the ACO is participating under during the performance year starting on July 1, 2019 (§ 425.605 or § 425.610), is applied to all savings under the updated benchmark specified under paragraph (c)(3)(i) of this section, not to exceed the performance payment limit for the ACO based on its track; and

(*2*) After applying the applicable performance payment limit, CMS prorates any shared savings amount determined under paragraph (c)(3)(ii)(D)(*1*) of this section by multiplying the amount by one-half, which represents the fraction of the calendar year covered by the July 1, 2019 through December 31, 2019 performance year.

(E) For an ACO responsible for shared losses under paragraph (c)(3)(ii)(C)(*3*) of this section—

(*1*) The shared loss rate, determined based on the track the ACO is participating under during the performance year starting on July 1, 2019 (§ 425.605 or § 425.610), is applied to all losses under the updated benchmark specified under paragraph (c)(3)(i) of this section, not to exceed the loss recoupment limit for the ACO based on its track; and

(*2*) After applying the applicable loss recoupment limit, CMS pro-rates any shared losses amount determined under paragraph (c)(3)(ii)(E)(*1*) of this section by multiplying the amount by one-half, which represents the fraction of the calendar year covered by the July 1, 2019 through December 31, 2019 performance year.

(d) *Extreme and uncontrollable circumstances.* For ACOs affected by extreme and uncontrollable circumstances during CY 2019—

(1) In calculating the amount of shared losses owed, CMS makes adjustments to the amount determined in paragraph (b)(3)(ii)(E)(*1*) or (c)(3)(ii)(E)(*1*) of this section, as specified in § 425.605(f), § 425.606(i), or § 425.610(i), as applicable; and

(2) In determining the ACO's quality performance score for the 2019 quality reporting period, CMS uses the alternative scoring methodology specified in § 425.502(f).

(e) *Notification of savings and losses.* (1) CMS notifies the ACO of shared savings or shared losses separately for the January 1, 2019 through June 30, 2019 performance year (or performance period) and the July 1, 2019 through December 31, 2019 performance year, consistent with the notification requirements specified in §§ 425.604(f), 425.605(e), 425.606(h), and 425.610(h), as applicable:

(i) CMS notifies an ACO in writing regarding whether the ACO qualifies for a shared savings payment, and if so, the amount of the payment due.

(ii) CMS provides written notification to an ACO of the amount of shared losses, if any, that it must repay to the program.

(iii) If an ACO has shared losses, the ACO must make payment in full to CMS within 90 days of receipt of notification.

(2) If an ACO is reconciled for both the January 1, 2019 through June 30, 2019 performance year (or performance period) and the July 1, 2019 through December 31, 2019 performance year, CMS issues a separate notice of shared savings or shared losses for each performance year (or performance period), and if the ACO has shared savings for one performance year (or performance period) and shared losses for the other performance year (or performance period), CMS reduces the amount of shared savings by the amount of shared losses.

(i) If any amount of shared savings remains after completely repaying the amount of shared losses owed, the ACO is eligible to receive payment for the remainder of the shared savings.

(ii) If the amount of shared losses owed exceeds the amount of shared savings earned, the ACO is accountable for payment of the remaining balance of shared losses in full.

[83 FR 60094, Nov. 23, 2018, as amended at 83 FR 68078, Dec. 31, 2018]

§ 425.610 Calculation of shared savings and losses under the ENHANCED track.≤

(a) *General rule.* For each performance year, CMS determines whether the estimated average per capita Medicare expenditures under the ACO for Medicare fee-for-service beneficiaries for Parts A and B services are above or below the updated benchmark determined under § 425.601, 425.602, 425.603, or 425.652. In order to qualify for a shared savings payment under the ENHANCED track, or to be responsible for sharing losses with CMS, an ACO's average per capita Medicare expenditures under the ACO for Medicare fee-for-service beneficiaries for Parts A and B services for the performance year must be below or above the updated benchmark, respectively, by at least the minimum savings or loss rate under paragraph (b) of this section.

(1) Risk adjustment for ACOs in agreement periods beginning on or before January 1, 2019. CMS does the following to adjust the benchmark each performance year:

(i) *Newly assigned beneficiaries.* CMS uses an ACO's prospective HCC risk score to adjust the benchmark for changes in severity and case mix in this population.

(ii) *Continuously assigned beneficiaries.* (A) CMS uses demographic factors to adjust the benchmark for changes in the continuously assigned beneficiary population.

(B) If the prospective HCC risk score is lower in the performance year for this population, CMS adjusts the benchmark for changes in severity and case mix for this population using this lower prospective HCC risk score.

(2) Risk adjustment for ACOs in agreement periods beginning on July 1, 2019, and in subsequent years. CMS uses an ACO's prospective HCC risk score to adjust the benchmark for changes in severity and case mix in the assigned beneficiary population between BY3 and the performance year.

(i) For agreement periods beginning before January 1, 2024:

(A) Positive adjustments in prospective HCC risk scores are subject to a cap of 3 percent.

(B) This cap is the maximum increase in risk scores for each agreement period, such that any positive adjustment between BY3 and any performance year in the agreement period cannot be larger than 3 percent.

(ii) For agreement periods beginning on January 1, 2024, and in subsequent years:

(A) Positive adjustments in prospective HCC risk scores are subject to a cap equal to the ACO's aggregate growth in demographic risk scores between BY3 and the performance year (positive or negative) plus 3 percentage points.

(B) The cap described in paragraph (a)(2)(ii)(A) of this section will apply to prospective HCC risk score growth for a population described in paragraph (a)(3) of this section only if the ACO's aggregate growth in prospective HCC risk scores between BY3 and the performance year across all of the populations described in paragraph (a)(3) of this section exceeds this cap. If the cap described in paragraph (a)(2)(ii)(A) of this section is determined to apply, the value of the cap is the maximum increase in risk scores for the applicable performance year, such that any positive adjustment between BY3 and the performance year cannot be larger than the value of the cap for any of the populations described in paragraph (a)(3) of this section.

(C) The aggregate growth in demographic risk scores for purposes of paragraph (a)(2)(ii)(A) of this section and the aggregate growth in prospective HCC risk scores for purposes of paragraph (a)(2)(ii)(B) of this section is calculated by taking a weighted average of the growth in demographic risk scores or prospective HCC risk scores, as applicable, across the populations described in paragraph (a)(3) of this section. When calculating the weighted average growth in demographic risk scores or prospective HCC risk scores, as applicable, the weight applied to the growth in risk scores (expressed as a ratio of the ACO's performance year risk score to the ACO's BY3 risk score) for each Medicare enrollment type is equal to the product of the ACO's historical benchmark expenditures, adjusted in accordance with § 425.652(a)(8), for that enrollment type and the ACO's performance year assigned beneficiary person years for that enrollment type.

(3) In risk adjusting the benchmark as described in §§ 425.601(a)(10), 425.602(a)(9), 425.603(c)(10), and 425.652(a)(10) CMS makes separate adjustments for each of the following populations of beneficiaries:

(i) ESRD.

(ii) Disabled.

(iii) Aged/dual eligible Medicare and Medicaid beneficiaries.

(iv) Aged/non-dual eligible Medicare and Medicaid beneficiaries.

(4)(i) For performance years before 2017 to minimize variation from catastrophically large claims, CMS truncates an assigned beneficiary's total annual Parts A and B fee-for-service per capita expenditures at the 99th percentile of national Medicare fee-for-service expenditures as determined for each performance year.

(ii) For the 2017 performance year and subsequent performance years, to minimize variation from catastrophically large claims, CMS truncates an assigned beneficiary's total annual Parts A and B fee-for-service per capita expenditures at the 99th percentile of national Medicare fee-for-service expenditures as determined for the applicable performance year for assignable beneficiaries identified for the 12-

month calendar year corresponding to the performance year.

(5) CMS uses a 3-month claims run out with a completion factor to calculate an ACO's per capita expenditures for each performance year.

(6) Calculations of the ACO's expenditures will include the payment amounts included in Part A and B fee-for-service claims.

(i) These calculations will exclude indirect medical education (IME) and disproportionate share hospital (DSH) payments, and the supplemental payment for IHS/Tribal hospitals and Puerto Rico hospitals.

(ii) These calculations will take into consideration individually beneficiary identifiable payments made under a demonstration, pilot or time limited program.

(A) For performance years beginning before 2018, these calculations will take into consideration all individually beneficiary identifiable payments, including interim payments, made under a demonstration, pilot or time limited program.

(B) For performance year 2018 and subsequent performance years, these calculations will take into consideration individually beneficiary identifiable final payments made under a demonstration, pilot or time limited program.

(7) In order to qualify for a shared savings payment, the ACO's average per capita Medicare expenditures for the performance year must be below the applicable updated benchmark by at least the minimum savings rate established for the ACO under paragraph (b) of this section.

(b) *Minimum savings or loss rate.* (1) As part of the ACO's application for, or renewal of, program participation, the ACO must choose from the following options for establishing the MSR/MLR for the duration of the agreement period:

(i) Zero percent MSR/MLR

(ii) Symmetrical MSR/MLR in a 0.5 percent increment between 0.5–2.0 percent.

(iii) Symmetrical MSR/MLR that varies, based on the number of beneficiaries assigned to the ACO under subpart E of this part. The MSR for an ACO under the ENHANCED track is the same as the MSR that would apply in the one-sided model under either §425.604(b) (for ACOs entering an agreement period on or before January 1, 2019) or §425.605(b)(1) (for ACOs entering an agreement period on July 1, 2019, and in subsequent years) and is based on the number of assigned beneficiaries. The MLR under the ENHANCED track is equal to the negative MSR.

(2) To qualify for shared savings under the ENHANCED track, an ACO's average per capita Medicare expenditures for the performance year must be below its updated benchmark costs for the year by at least the MSR established for the ACO.

(3) To be responsible for sharing losses with the Medicare program, an ACO's average per capita Medicare expenditures for the performance year must be above its updated benchmark costs for the year by at least the MLR established for the ACO.

(c) *Qualification for shared savings payment*—(1) *For performance years (or a performance period) beginning on or before January 1, 2020.* To qualify for shared savings, an ACO must meet the minimum savings rate requirement established under paragraph (b) of this section, meet the minimum quality performance standards established under §425.502, and otherwise maintain its eligibility to participate in the Shared Savings Program under this part.

(2) *For performance years beginning on or after January 1, 2021.* To qualify for shared savings, an ACO must meet the minimum savings rate requirement established under paragraph (b) of this section, meet the quality performance standard established under §425.512, and otherwise maintain its eligibility to participate in the Shared Savings Program under this part.

(d) *Final sharing rate*—(1) *For performance years (or a performance period) beginning on or before January 1, 2020.* An ACO that meets all the requirements for receiving shared savings payments under the ENHANCED track will receive a shared savings payment of up to 75 percent of all the savings under the updated benchmark, as determined on the basis of its quality performance under §425.502 (up to the performance

payment limit described in paragraph (e)(2) of this section).

(2) *For performance years beginning on January 1, 2021, or January 1, 2022.* An ACO that meets all the requirements for receiving shared savings payments under the ENHANCED track will receive a shared savings payment of 75 percent of all the savings under the updated benchmark (up to the performance payment limit described in paragraph (e)(2) of this section).

(3) *For the performance year beginning on January 1, 2023.* An ACO that meets all the requirements for receiving shared savings payments under the ENHANCED track will receive a shared savings payment equal to a percentage of all the savings under the updated benchmark (up to the performance payment limit described in paragraph (e)(2) of this section). The percentage is as follows:

(i) 75 percent for an ACO that meets the quality performance standard by meeting the criteria specified in § 425.512(a)(2) or (a)(4)(i).

(ii) 75 percent multiplied by the ACO's health equity adjusted quality performance score calculated according to § 425.512(b) for an ACO that meets the alternative quality performance standard by meeting the criteria specified in § 425.512(a)(4)(ii).

(4) *For performance years beginning on or after January 1, 2024.* An ACO that meets all the requirements for receiving shared savings payments under the ENHANCED track will receive a shared savings payment equal to a percentage of all the savings under the updated benchmark (up to the performance payment limit described in paragraph (e)(2) of this section). The percentage is as follows:

(i) 75 percent for an ACO that meets the quality performance standard by meeting the criteria specified in § 425.512(a)(2) or (a)(5)(i).

(ii) 75 percent multiplied by the ACO's health equity adjusted quality performance score calculated according to § 425.512(b) for an ACO that meets the alternative quality performance standard by meeting the criteria specified in § 425.512(a)(5)(ii).

(e) *Performance payment.* (1) If an ACO qualifies for savings by meeting or exceeding the MSR, the final sharing rate will apply to an ACO's savings on a first dollar basis.

(2) The amount of shared savings an eligible ACO receives under the ENHANCED track may not exceed 20 percent of its updated benchmark.

(f) *Shared loss rate*—(1) *For performance years (or a performance period) beginning on or before January 1, 2020.* For an ACO that is required to share losses with the Medicare program for expenditures over the updated benchmark, the amount of shared losses is determined based on the inverse of its final sharing rate described in paragraph (d)(1) of this section (that is, 1 minus the final shared savings rate determined under paragraph (d)(1) of this section). The shared loss rate—

(i) May not exceed 75 percent; and

(ii) May not be less than 40 percent.

(2) *For performance years beginning on January 1, 2021, or January 1, 2022.* For an ACO that is required to share losses with the Medicare program for expenditures over the updated benchmark, the amount of shared losses is determined as follows:

(i) If the ACO meets the quality performance standard established in § 425.512, CMS determines the shared loss rate as follows:

(A) Calculate the quotient of the MIPS Quality performance category points earned divided by the total MIPS Quality performance category points available.

(B) Calculate the product of the quotient determined in paragraph (f)(2)(i)(A) of this section, and 75 percent.

(C) Calculate the shared loss rate as 1 minus the product determined in paragraph (f)(2)(i)(B) of this section. The shared loss rate—

(*1*) May not exceed 75 percent; and

(*2*) May not be less than 40 percent.

(ii) If the ACO fails to meet the quality performance standard established in § 425.512, the shared loss rate is 75 percent.

(3) *For the performance year beginning on January 1, 2023.* For an ACO that is required to share losses with the Medicare program for expenditures over the updated benchmark, the amount of shared losses is determined as follows:

(i) If the ACO meets either the quality performance standard established

in §425.512 applicable for the performance year by meeting the criteria specified in §425.512(a)(2) or (a)(4)(i), or the alternative quality performance standard established in §425.512(a)(4)(ii), CMS determines the shared loss rate as follows:

(A) Calculate the product of 75 percent and the ACO's health equity adjusted quality performance score calculated according to §425.512(b).

(B) Calculate the shared loss rate as 1 minus the product determined in paragraph (f)(3)(i)(A) of this section. The shared loss rate—

(*1*) May not exceed 75 percent; and

(*2*) May not be less than 40 percent.

(ii) If the ACO fails to meet either the quality performance standard or the alternative quality performance standard established in §425.512 applicable for the performance year, the shared loss rate is 75 percent.

(4) *For performance years beginning on or after January 1, 2024.* For an ACO that is required to share losses with the Medicare program for expenditures over the updated benchmark, the amount of shared losses is determined as follows:

(i) If the ACO meets either the quality performance standard established in §425.512 applicable for the performance year by meeting the criteria specified in §425.512(a)(2) or (a)(5)(i), or the alternative quality performance standard established in §425.512(a)(5)(ii), CMS determines the shared loss rate as follows:

(A) Calculate the product of 75 percent and the ACO's health equity adjusted quality performance score calculated according to §425.512(b).

(B) Calculate the shared loss rate as 1 minus the product determined in paragraph (f)(4)(i)(A) of this section. The shared loss rate—

(*1*) May not exceed 75 percent; and

(*2*) May not be less than 40 percent.

(ii) If the ACO fails to meet either the quality performance standard or the alternative quality performance standard established in §425.512 for the applicable performance year, the shared loss rate is 75 percent.

(g) *Loss recoupment limit.* The amount of shared losses for which an eligible ACO is liable may not exceed 15 percent of its updated benchmark as determined under §425.601, 425.602, 425.603 or 425.652.

(h) *Notification of savings and losses.* (1) CMS notifies an ACO in writing regarding whether the ACO qualifies for a shared savings payment, and if so, the amount of the payment due.

(2) CMS provides written notification to an ACO of the amount of shared losses, if any, that it must repay to the program.

(3) If an ACO has shared losses, the ACO must make payment in full to CMS within 90 days of receipt of notification.

(i) *Extreme and uncontrollable circumstances.* For performance year 2017 and subsequent performance years, the following adjustment is made in calculating the amount of shared losses, after the application of the shared loss rate in paragraph (f) of this section and the loss recoupment limit in paragraph (g) of this section.

(1) CMS determines the percentage of the ACO's performance year assigned beneficiary population affected by an extreme and uncontrollable circumstance.

(2) CMS reduces the amount of the ACO's shared losses by an amount determined by multiplying the shared losses by the percentage of the total months in the performance year affected by an extreme and uncontrollable circumstance, and the percentage of the ACO's assigned beneficiaries who reside in an area affected by an extreme and uncontrollable circumstance.

(i) For an ACO that is liable for a pro-rated share of losses under §425.221(b)(2)(ii) or (b)(3)(i), the amount of shared losses determined for the performance year during which the termination becomes effective is adjusted according to this paragraph (i)(2).

(ii) [Reserved]

(3) CMS applies determinations made under the Quality Payment Program with respect to—

(i) Whether an extreme and uncontrollable circumstance has occurred; and

(ii) The affected areas.

(4) CMS has sole discretion to determine the time period during which an extreme and uncontrollable circumstance occurred and the percentage

of the ACO's assigned beneficiaries residing in the affected areas.

(j) *January 1, 2019 through June 30, 2019 performance year.* Shared savings or shared losses for the January 1, 2019 through June 30, 2019 performance year are calculated as described in § 425.609.

(k) *July 1, 2019 through December 31, 2019 performance year.* Shared savings or shared losses for the July 1, 2019 through December 31, 2019 performance year are calculated as described in § 425.609.

[80 FR 32842, June 9, 2015, as amended at 81 FR 38017, June 10, 2016; 82 FR 53370, Nov. 15, 2017; 82 FR 60918, Dec. 26, 2017; 83 FR 60096, Nov. 23, 2018; 83 FR 68079, Dec. 31, 2018; 85 FR 85044, Dec. 28, 2020; 87 FR 70240, Nov. 18, 2022; 89 FR 98571, Dec. 9, 2024]

EDITORIAL NOTE: At 81 FR 38017, June 10, 2016, in § 425.610, paragraph (a)(2)(ii), the phrase ''adjust for changes'' was removed, and in its place the phrase ''adjust the benchmark for changes'' was added, however, the phrase ''adjust for changes'' does not appear in this paragraph, so the amendment could not be incorporated.

§ 425.611 Adjustments to Shared Savings Program calculations to address the COVID–19 pandemic.

(a) *General.* This section describes adjustments CMS makes to Shared Savings Program calculations to address the impact of the COVID–19 pandemic.

(b) *Episodes of care for treatment of COVID–19.* (1) CMS identifies an episode of care for treatment of COVID–19 based on either of the following:

(i) Discharges for inpatient services eligible for the 20 percent adjustment under section 1886(d)(4)(C) of the Act.

(ii) Discharges for acute care inpatient services for treatment of COVID–19 from facilities that are not paid under the inpatient prospective payment system, such as CAHs, when the date of discharge occurs within the Public Health Emergency as defined in § 400.200 of this chapter.

(2) CMS defines the episode of care as starting in the month in which the inpatient stay begins as identified by the admission date, all months during the inpatient stay, and the month following the end of the inpatient stay as indicated by the discharge date.

(c) *Applicability of adjustments.* Notwithstanding any other provision in this part, CMS adjusts the following Shared Savings Program calculations to exclude all Parts A and B fee-for-service payment amounts for a beneficiary's episode of care for treatment of COVID–19 as described in paragraph (b) of this section:

(1) Calculation of Medicare Parts A and B fee-for-service expenditures for an ACO's assigned beneficiaries for all purposes including the following: Establishing, adjusting, updating, and resetting the ACO's historical benchmark and determining performance year expenditures.

(2) Calculation of fee-for-service expenditures for assignable beneficiaries as used in determining county-level fee-for-service expenditures and national Medicare fee-for-service expenditures, including the following calculations:

(i) Determining average county fee-for-service expenditures based on expenditures for the assignable population of beneficiaries in each county in the ACO's regional service area according to §§ 425.601(c), 425.603(e), and 425.654(a) for purposes of calculating the ACO's regional fee-for-service expenditures.

(ii) Determining the 99th percentile of national Medicare fee-for-service expenditures for assignable beneficiaries for purposes of the following:

(A) Truncating assigned beneficiary expenditures used in calculating benchmark expenditures under §§ 425.601(a)(4), 425.602(a)(4), 425.603(c)(4), and 425.652(a)(4), and performance year expenditures under §§ 425.604(a)(4), 425.605(a)(3), 425.606(a)(4), and 425.610(a)(4).

(B) Truncating expenditures for assignable beneficiaries in each county for purposes of determining county fee-for-service expenditures according to §§ 425.601(c)(3), 425.603(e)(3), and 425.654(a)(3).

(iii) Determining national per capita expenditures for Parts A and B services under the original Medicare fee-for-service program for assignable beneficiaries for purposes of capping the regional adjustment to the ACO's historical benchmark according to §§ 425.601(a)(8)(ii)(C) and 425.656(c)(3), and capping the prior savings adjustment according to § 425.658(c)(1)(ii).

(iv) Determining the flat dollar equivalent of the projected absolute amount of growth in national per capita expenditures for Parts A and B services under the original Medicare fee-for-service program for assignable beneficiaries, for purposes of updating the ACO's historical benchmark according to § 425.602(b)(2).

(v) Determining national growth rates that are used as part of the blended growth rates used to trend forward BY1 and BY2 expenditures to BY3 according to §§ 425.601(a)(5)(ii) and 425.652(a)(5)(ii) and as part of the blended growth rates used to trend the benchmark and update the benchmark according to §§ 425.601(b)(2) and 425.652(b)(2)(i).

(3) Calculation of Medicare Parts A and B fee-for-service revenue of ACO participants for purposes of calculating the ACO's loss recoupment limit under the BASIC track as specified in § 425.605(d).

(4) Calculation of total Medicare Parts A and B fee-for-service revenue of ACO participants and total Medicare Parts A and B fee-for-service expenditures for the ACO's assigned beneficiaries for purposes of identifying whether an ACO is a high revenue ACO or low revenue ACO, as defined under § 425.20, determining an ACO's eligibility for participation options according to § 425.600(d), and determining an ACO's eligibility to receive advance investment payments according to § 425.630.

(5) Calculation or recalculation of the amount of the ACO's repayment mechanism arrangement according to § 425.204(f)(4).

[85 FR 27625, May 8, 2020, as amended at 85 FR 85044, Dec. 28, 2020; 87 FR 70241, Nov. 18, 2022; 88 FR 79548, Nov. 16, 2023]

§ 425.612 Waivers of payment rules or other Medicare requirements.

(a) *General.* CMS may waive certain payment rules or other Medicare requirements as determined necessary to carry out the Shared Savings Program under this part.

(1) *SNF 3-day rule.* For performance year 2017 and subsequent performance years, CMS waives the requirement in section 1861(i) of the Act for a 3-day inpatient hospital stay prior to a Medicare-covered post-hospital extended care service for eligible beneficiaries assigned to ACOs participating in a two-sided model and as provided in paragraph (a)(1)(iv) of this section during a grace period for beneficiaries excluded from prospective assignment to an ACO in a two-sided model, who receive otherwise covered post-hospital extended care services furnished by an eligible SNF that has entered into a written agreement to partner with the ACO for purposes of this waiver. Eligible SNFs include providers furnishing SNF services under swing bed agreements. All other provisions of the statute and regulations regarding Medicare Part A post-hospital extended care services continue to apply. ACOs identified under paragraph (a)(1)(vi) of this section may request to use the SNF 3-day rule waiver for performance years beginning on July 1, 2019, and in subsequent years.

(i) ACOs must submit to CMS supplemental application information sufficient to demonstrate the ACO has the capacity to identify and manage beneficiaries who would be either directly admitted to a SNF or admitted to a SNF after an inpatient hospitalization of fewer than 3-days in the form and manner specified by CMS. Application materials include but are not limited to, the following:

(A) An attestation that it has established and will make available to CMS upon request the following narratives describing how the ACO plans to implement the waiver:

(*1*) A communication plan between the ACO and its SNF affiliates.

(*2*) A care management plan for beneficiaries admitted to a SNF affiliate.

(*3*) A beneficiary evaluation and admission plan approved by the ACO medical director and the healthcare professional responsible for the ACO's quality improvement and assurance processes under § 425.112.

(B) A list of SNFs with whom the ACO will partner along with executed written SNF affiliate agreements between the ACO and each listed SNF.

(ii) In order to be eligible to receive covered SNF services under the waiver, a beneficiary must meet the following requirements:

(A) In the case of a beneficiary who is assigned to an ACO that has selected preliminary prospective assignment with retrospective reconciliation under § 425.400(a)(2), the beneficiary must appear on the list of preliminarily prospectively assigned beneficiaries at the beginning of the performance year or on the first, second, or third quarterly preliminary prospective assignment list for the performance year in which they are admitted to the eligible SNF, and the SNF services must be provided after the beneficiary first appeared on the preliminary prospective assignment list for the performance year.

(B) In the case of a beneficiary who is assigned to an ACO that has selected prospective assignment under § 425.400(a)(3), the beneficiary must be prospectively assigned to the ACO for the performance year in which they are admitted to the eligible SNF.

(C) Does not reside in a SNF or other long-term care setting.

(D) Is medically stable.

(E) Does not require inpatient or further inpatient hospital evaluation or treatment.

(F) Have certain and confirmed diagnoses.

(G) Have an identified skilled nursing or rehabilitation need that cannot be provided as an outpatient.

(H) Have been evaluated and approved for admission to the SNF within 3 days prior to the SNF admission by an ACO provider/supplier who is a physician, consistent with the ACO's beneficiary evaluation and admission plan.

(iii) SNFs eligible to partner and enter into written agreements with ACOs for purposes of this waiver must do the following:

(A) Providers eligible to be included in the CMS 5-star Quality Rating System must have and maintain an overall rating of 3 or higher.

(B) Sign a SNF affiliate agreement with the ACO that includes elements determined by CMS including but not limited to the following:

(*1*) Agreement to comply with the requirements and conditions of this part, including but not limited to those specified in the participation agreement with CMS.

(*2*) Effective dates of the SNF affiliate agreement.

(*3*) Agreement to implement and comply with the ACO's beneficiary evaluation and admission plan and the care management plan.

(*4*) Agreement to validate the eligibility of a beneficiary to receive covered SNF services in accordance with the waiver prior to admission.

(*5*) Remedial processes and penalties that will apply for non-compliance.

(iv) For a beneficiary who was included on the ACO's prospective assignment list or preliminary prospective assignment list at the beginning of the performance year or on the first, second, or third quarterly preliminary prospective assignment list for the performance year, for an ACO for which a waiver of the SNF 3-day rule has been approved under paragraph (a)(1) of this section, but who was subsequently removed from the assignment list for the performance year, CMS makes payment for SNF services furnished to the beneficiary by a SNF affiliate if the following conditions are met:

(A)(*1*) The beneficiary was prospectively assigned to an ACO that selected prospective assignment under § 425.400(a)(3) at the beginning of the applicable performance year, but was excluded in the most recent quarterly update to the assignment list under § 425.401(b), and the beneficiary was admitted to a SNF affiliate within 90 days following the date that CMS delivered the quarterly exclusion list to the ACO; or

(*2*) The beneficiary was identified as preliminarily prospectively assigned to an ACO that has selected preliminary prospective assignment with retrospective reconciliation under § 425.400(a)(2) in the report provided under § 425.702(c)(1)(ii)(A) at the beginning of the performance year or for the first, second, or third quarter of the performance year, the SNF services were provided after the beneficiary first appeared on the preliminary prospective assignment list for the performance year, and the beneficiary meets the criteria to be assigned to an ACO under § 425.401(a)(1) and (2).

(B) But for the beneficiary's removal from the ACO's assignment list, CMS would have made payment to the SNF affiliate for such services under the

waiver under paragraph (a)(1) of this section.

(v) The following beneficiary protections apply when a beneficiary receives SNF services without a prior 3-day inpatient hospital stay from a SNF affiliate that intended to provide services under a SNF 3-day rule waiver under paragraph (a)(1) of this section, the SNF affiliate services were non-covered only because the SNF affiliate stay was not preceded by a qualifying hospital stay under section 1861(i) of the Act, and in the case of a beneficiary where the ACO selected one of the following:

(A) Prospective assignment under §425.400(a)(3), the beneficiary was not prospectively assigned to the ACO for the performance year in which they received the SNF services, or was prospectively assigned but was later excluded and the 90-day grace period, described in paragraph (a)(1)(iv)(A) of this section, has lapsed.

(B) Preliminary prospective assignment with retrospective reconciliation under §425.400(a)(2), the beneficiary was not identified as preliminarily prospectively assigned to the ACO for the performance year in the report provided under §425.702(c)(1)(ii)(A) at the beginning of the performance year or for the first, second, or third quarter of the performance year before the SNF services were provided to the beneficiary.

(C) A SNF is presumed to intend to provide services pursuant to the SNF 3-day rule waiver under paragraph (a)(1) of this section if the SNF submitting the claim is a SNF affiliate of an ACO for which such a waiver has been approved.

(D) CMS makes no payments for SNF services to a SNF affiliate of an ACO for which a waiver of the SNF 3-day rule has been approved when the SNF affiliate admits a FFS beneficiary who was not prospectively or preliminarily prospectively assigned to the ACO prior to the SNF admission or was prospectively assigned but was later excluded and the 90-day grace period under paragraph (a)(1)(iv)(A) of this section has lapsed.

(E) In the event that CMS makes no payment for SNF services furnished by a SNF affiliate as a result of paragraph (a)(1)(v)(D) of this section and the only reason the claim was non-covered is due to the lack of a qualifying inpatient stay, the following beneficiary protections will apply:

(*1*) The SNF must not charge the beneficiary for the expenses incurred for such services; and

(*2*) The SNF must return to the beneficiary any monies collected for such services; and

(*3*) The ACO may be required to submit a corrective action plan under §425.216(b) for CMS approval. If after being given an opportunity to act upon the corrective action plan the ACO fails to come into compliance with the requirements of paragraph (a)(1), approval for the SNF 3-day rule waiver under this section will be terminated as provided under paragraph (d) of this section.

(vi) The following ACOs may request to use the SNF 3-day rule waiver:

(A) An ACO participating in performance-based risk within the BASIC track under §425.605.

(B) An ACO participating in the ENHANCED track under §425.610.

(2) [Reserved]

(b) *Review and determination of request to use waivers.* (1) In order to obtain a determination regarding whether the ACO may use waivers under this section, an ACO must submit a waiver request to CMS in the form and manner and by a deadline specified by CMS.

(2) An ACO executive who has the authority to legally bind the ACO must certify to the best of his or her knowledge, information, and belief that the information contained in the waiver request submitted under paragraph (b)(1) of this section is accurate, complete, and truthful.

(3) CMS evaluates an ACO's waiver request to determine whether it satisfies the requirements of this part and approves or denies waiver requests accordingly. Waiver requests are approved or denied on the basis of the following:

(i) Information contained in and submitted with the waiver request by a deadline specified by CMS.

(ii) Supplemental information submitted by a deadline specified by CMS in response to a CMS request for information.

(iii) Screening of the ACO, ACO participants, ACO providers/suppliers, and

other individuals or entities providing services to Medicare beneficiaries in accordance with the terms of the waiver.

(iv) Other information available to CMS.

(4) CMS may deny a waiver request if an ACO fails to submit requested information by the deadlines established by CMS.

(c) *Effective and termination date of waivers.* (1) Waivers are effective upon CMS notification of approval for the waiver or the start date of the participation agreement, whichever is later.

(2) Waivers do not extend beyond the end of the participation agreement.

(3) If CMS terminates the participation agreement under § 425.218, the waiver ends on the date specified by CMS in the termination notice.

(4) If the ACO terminates the participation agreement, the waiver ends on the effective date of termination as specified in the written notification required under § 425.220.

(d) *Monitoring and termination of waivers.* (1) ACOs with approved waivers are required to post their use of the waiver as part of public reporting under § 425.308.

(2) CMS monitors and audits the use of such waivers in accordance with § 425.316.

(3) CMS reserves the right to deny or revoke a waiver if an ACO, its ACO participants, ACO providers/suppliers or other individuals or entities providing services to Medicare beneficiaries are not in compliance with the requirements of this part or if any of the following occur:

(i) The waiver is not used as described in the ACO's waiver request under paragraph (b)(1) of this section.

(ii) The ACO does not successfully meet the quality reporting standard under subpart F of this part.

(iii) CMS identifies a program integrity issue affecting the ACO's use of the waiver.

(4) CMS reserves the right to take compliance action, including termination, against an ACO for noncompliance with program rules, including misuse of a waiver under this section, as specified at §§ 425.216 and 425.218.

(e) *Other rules governing use of waivers.* (1) Waivers under this section do not protect financial or other arrangements between or among ACOs, ACO participants, ACO providers/suppliers, or other individual or entities providing services to Medicare beneficiaries from liability under the fraud and abuse laws or any other applicable laws.

(2) Waivers under this section do not protect any person or entity from liability for any violation of law or regulation for any conduct other than the conduct permitted by a waiver under paragraph (a) of this section.

(3) ACOs must ensure compliance with all claims submission requirements, except those expressly waived under paragraph (a) of this section.

(f) *Waiver for payment for telehealth services.* For performance year 2020 and subsequent performance years, CMS waives the originating site requirements in section 1834(m)(4)(C)(i) and (ii) of the Act and makes payment for telehealth services furnished to a beneficiary, if the following conditions are met:

(1) The beneficiary was prospectively assigned to an ACO that is an applicable ACO for purposes of § 425.613 at the beginning of the applicable performance year, but the beneficiary was excluded in the most recent quarterly update to the prospective assignment list under § 425.401(b).

(2) The telehealth services are provided by a physician or practitioner billing under the TIN of an ACO participant in the ACO within 90 days following the date CMS delivers the quarterly exclusion list to the ACO.

(3) But for the beneficiary's exclusion from the ACO's prospective assignment list, CMS would have made payment to the ACO participant for such services under § 425.613.

[80 FR 32843, June 9, 2015, as amended at 81 FR 80561, Nov. 15, 2016; 82 FR 53371, Nov. 15, 2017; 83 FR 68080, Dec. 31, 2018; 84 FR 63204, Nov. 15, 2019; 87 FR 70242, Nov. 18, 2022]

§ 425.613 Telehealth services.

(a) *General.* Payment is available for otherwise covered telehealth services furnished on or after January 1, 2020, by a physician or other practitioner billing through the TIN of an ACO participant in an applicable ACO, without regard to the geographic requirements

under section 1834(m)(4)(C)(i) of the Act, in accordance with the requirements of this section.

(1) For purposes of this section:

(i) An applicable ACO is an ACO that is participating under a two-sided model under § 425.600 and has elected prospective assignment under § 425.400(a)(3) for the performance year.

(ii) The home of the beneficiary is treated as an originating site under section 1834(m)(4)(C)(ii) of the Act.

(2) For payment to be made under this section, the following requirements must be met:

(i) The beneficiary is prospectively assigned to the ACO for the performance year in which the beneficiary received the telehealth service.

(ii) The physician or practitioner who furnishes the telehealth service must bill under the TIN of an ACO participant that is included on the certified ACO participant list under § 425.118 for the performance year in which the service is rendered.

(iii) The originating site must comply with applicable State licensing requirements.

(iv) When the originating site is the beneficiary's home, the telehealth services must not be inappropriate to furnish in the home setting. Services that are typically furnished in an inpatient setting may not be furnished as a telehealth service when the originating site is the beneficiary's home.

(v) CMS does not pay a facility fee when the originating site is the beneficiary's home.

(b) *Beneficiary protections.* (1) When a beneficiary who is not prospectively assigned to an applicable ACO or in a 90-day grace period under § 425.612(f) receives a telehealth service from a physician or practitioner billing through the TIN of an ACO participant participating in an applicable ACO, CMS makes no payment for the telehealth service to the ACO participant.

(2) In the event that CMS makes no payment for a telehealth service furnished by a physician or practitioner billing through the TIN of an ACO participant, and the only reason the claim was non-covered is because the beneficiary is not prospectively assigned to the ACO or in the 90-day grace period under § 425.612(f), all of the following beneficiary protections apply:

(i) The ACO participant must not charge the beneficiary for the expenses incurred for such service.

(ii) The ACO participant must return to the beneficiary any monies collected for such service.

(iii) The ACO may be required to submit a corrective action plan under § 425.216(b) for CMS approval. If the ACO is required to submit a corrective action plan and, after being given an opportunity to act upon the corrective action plan, the ACO fails to implement the corrective action plan or demonstrate improved performance upon completion of the corrective action plan, CMS may terminate the participation agreement as specified under § 425.216(b)(2).

(c) *Termination date for purposes of payment for telehealth services.* (1) Payment for telehealth services under paragraph (a) of this section does not extend beyond the end of the applicable ACO's participation agreement.

(2) If CMS terminates the participation agreement under § 425.218, payment for telehealth services under paragraph (a) of this section is not made with respect to telehealth services furnished beginning on the date specified by CMS in the termination notice.

(3) If the ACO terminates the participation agreement, payment for telehealth services under paragraph (a) of this section is not made with respect to telehealth services furnished beginning on the effective date of termination as specified in the written notification required under § 425.220.

(d) *Monitoring of telehealth services.* (1) CMS monitors and audits the use of telehealth services by the ACO and its ACO participants and ACO providers/suppliers, in accordance with § 425.316.

(2) CMS reserves the right to take compliance action, up to and including termination of the participation agreement, as specified in §§ 425.216 and 425.218, with respect to an applicable ACO for non-compliance with program requirements, including inappropriate use of telehealth services.

[83 FR 68081, Dec. 31, 2018]

§§ 425.614–425.629 [Reserved]

§ 425.630 Option to receive advance investment payments.

(a) *Purpose.* Advance investment payments are intended to encourage low-revenue ACOs that are inexperienced with risk to participate in the Shared Savings Program and to provide additional resources to such ACOs in order to support care improvement for underserved beneficiaries.

(b) *Eligibility.* An ACO is eligible to receive advance investment payments as specified in this section if CMS determines that all of the following criteria are met:

(1) The ACO is not a renewing or a reentering ACO.

(2) CMS has determined that the ACO is eligible to participate in the Shared Savings Program.

(3) The ACO is inexperienced with performance-based risk Medicare ACO initiatives during its first 2 performance years and participates in the BASIC track's glide path as follows:

(i) For performance year 1, the ACO must participate in Level A of the BASIC track's glide path.

(ii) For performance year 2, the ACO may participate in Level A of the BASIC track's glide path (in accordance with § 425.600(a)(4)(i)(C)(*3*)) or Level B.

(iii) For performance years 3 through 5, the ACO may participate in Level A of the BASIC track's glide path (in accordance with § 425.600(a)(4)(i)(C)(*3*)), or Levels B through E.

(4) The ACO is a low revenue ACO.

(c) *Application procedure.* To obtain a determination regarding whether an ACO may receive advance investment payments, the ACO must submit to CMS complete supplemental information as part of its application to participate in the Shared Savings Program (filed pursuant to § 425.202) in the form and manner and by a deadline specified by CMS.

(d) *Application contents and review.* (1) *General.* An ACO must submit to CMS supplemental application information sufficient for CMS to determine whether the ACO is eligible to receive advance investment payments. In addition, the ACO must submit a proposed spend plan as part of the supplemental application information.

(2) *Spend plan.* The spend plan must:

(i) Describe how the ACO will spend its advance investment payments during the agreement period to build care coordination capabilities (including coordination with community-based organizations, as appropriate), address specific health disparities, and meet other criteria under this section.

(ii) Identify the categories of goods and services that will be purchased with advance investment payment funds (including any allowable uses under paragraph (e) of this section), the dollar amounts to be spent on the various categories, and such other information as may be specified by CMS.

(iii) State that the ACO has established a separate designated account for the deposit and expenditure of all advance investment payments in accordance with paragraph (e)(4) of this section.

(3) *CMS review.* CMS will review the supplemental application information to determine whether an ACO meets the eligibility criteria and other requirements for advance investment payments and will approve or deny the advance investment payment application accordingly. CMS may review an ACO's spend plan at any time and require the ACO to modify its spend plan to comply with the requirements of this paragraph (d) and paragraph (e) of this section.

(e) *Use and management of advance investment payments*—(1) *Allowable uses.* An ACO must use an advance investment payment to improve the quality and efficiency of items and services furnished to beneficiaries by investing in increased staffing, health care infrastructure, and the provision of accountable care for underserved beneficiaries, which may include addressing social determinants of health. Expenditures of advance investment payments must comply with the beneficiary incentive provision at § 425.304, paragraph (e)(2) of this section, and all other applicable laws and regulations.

(2) *Prohibited uses.* Advance investment payments may not be used for any expense other than allowable uses under paragraph (e)(1) of this section. In the case of an ACO participating in

Level E of the BASIC track, the repayment of any shared losses incurred as specified in a written notice in accordance with § 425.605(e)(2).

(3) *Duration for spending payments.* An ACO may spend an advance investment payment over its entire agreement period. An ACO must repay to CMS any unspent funds remaining at the end of the ACO's agreement period, except if the ACO terminated its current participation agreement under § 425.220 at the end of performance year 2 or later and immediately enters a new agreement period to continue its participation in the Shared Savings Program, the ACO must spend its advance investment payments within 5 performance years of when it first received advance investment payments and repay to CMS any unspent funds remaining at the end of that fifth performance year.

(4) *Segregation of advance investment payments.* An ACO must segregate advance investment payments from all other revenues by establishing and maintaining a separate account into which all advance investment payments will be deposited immediately and from which all disbursements of such funds are made only for allowable uses in accordance with this paragraph.

(f) *Payment methodology.* An ACO receives two types of advance investment payments: a one-time payment of $250,000 and quarterly payments calculated pursuant to the methodology defined in paragraph (f)(2) of this section. CMS notifies in writing each ACO of its determination of the amount of advance investment payment and the notice will inform the ACO of its right to request reconsideration review in accordance with the procedures specified in subpart I of this part. If CMS does not make any advance investment payment, the notice will specify the reason(s) why and inform the ACO of its right to request reconsideration review in accordance with the procedures specified in subpart I of this part.

(1) *Frequency of payments.* An ACO will receive the one-time payment at the beginning of Performance Year 1 of the ACO's agreement period. An ACO will receive quarterly payments each quarter for the first two performance years of the ACO's agreement period. An ACO may receive no more than eight quarterly payments.

(2) *Quarterly payment amount calculation methodology.* CMS does all of the following in determining the quarterly payment amount prior to the start of the quarter.

(i) Determines the ACO's assigned beneficiary population. The assigned beneficiaries used in determining the quarterly payment amount are the beneficiaries most recently assigned to the ACO under § 425.400(a)(2) (for an ACO under preliminary prospective assignment with retrospective reconciliation) or § 425.400(a)(3) (for an ACO under prospective assignment), based on the certified ACO participant list for the relevant performance year.

(ii) Assigns each beneficiary a risk factors-based score. For each beneficiary in the assigned population identified in paragraph (f)(2)(i) of this section, CMS applies the following requirements in assigning a risk factors-based score:

(A) The risk factors-based score will be set to 100 if the beneficiary is enrolled in the Medicare Part D LIS or is dually eligible for Medicare and Medicaid.

(B) The risk factors-based score will be set to the Area Deprivation Index national percentile rank matched to the beneficiary's mailing address if the beneficiary is not enrolled in the LIS or is not dually eligible for Medicare and Medicaid and sufficient data is available to match the beneficiary to an Area Deprivation Index national percentile rank.

(C) The risk factors-based score will be set to 50 if the beneficiary is not enrolled in the LIS or is not dually eligible for Medicare and Medicaid and sufficient data is not available to match the beneficiary to an Area Deprivation Index national percentile rank.

(iii) Determines a beneficiary's payment amount. For each beneficiary in the assigned population identified in paragraph (f)(2)(i) of this section, CMS determines the payment amount that corresponds to the beneficiary's risk factors-based score determined in paragraph (f)(2)(ii) of this section. The beneficiary payment amount is as follows:

TABLE 1 TO PARAGRAPH (f)(2)(iii)

Risk factors-based score	1–24	25–34	35–44	45–54	55–64	65–74	75–84	85–100
Payment amount	$0	$20	$24	$28	$32	$36	$40	$45

(iv) Calculates the ACO's quarterly payment amount. The ACO's quarterly payment amount is the sum of the beneficiary payment amounts corresponding to each assigned beneficiary's risk factors-based score, specified in paragraph (f)(2)(iii) of this section, capped at 10,000 beneficiaries. If the ACO has more than 10,000 assigned beneficiaries according to paragraph (f)(2)(i) of this section, CMS will calculate the quarterly payment amount based on the 10,000 assigned beneficiaries with the highest risk factors-based scores determined according to paragraph (f)(2)(ii) of this section.

(g) *Recoupment and recovery of advance investment payments, and notice of bankruptcy.* (1) CMS will recoup advance investment payments made to an ACO from any shared savings the ACO earns until CMS has recouped in full the amount of advance investment payments made to the ACO. For both renewing and re-entering ACOs, CMS will carry forward any remaining balance owed to subsequent performance year(s) in which the ACO achieves shared savings, including in any performance year(s) in a subsequent agreement period.

(2) If the amount of shared savings earned by the ACO is revised upward by CMS for any reason, CMS will reduce the redetermined amount of shared savings by the amount of advance investment payments made to the ACO as of the date of the redetermination. If the amount of shared savings earned by the ACO is revised downward by CMS for any reason, the ACO will not receive a refund of any portion of the advance investment payments previously recouped or otherwise repaid.

(3) Except as provided for in paragraphs (g)(4) through (6) of this section and § 425.316(e)(3), for each performance year, CMS will not recover an amount of advance investment payments greater than the shared savings earned by an ACO in that performance year.

(4) If an ACO terminates its participation agreement during the agreement period in which it received an advance investment payment, the ACO must repay all advance investment payments it received, unless the ACO terminated its current participation agreement under § 425.220 at the end of performance year 2 or later during the agreement period in which it received advance investment payments and immediately enters a new agreement period to continue its participation in the program. CMS will provide written notification to the ACO of the amount due and the ACO must pay such amount no later than 90 days after the receipt of such notification.

(5) If an ACO notifies CMS that it no longer wants to participate in the advance investment payment option but does want to continue its participation in the Shared Savings Program, the ACO must repay all outstanding advance investment payments it received. CMS will provide written notice to the ACO of the amount due and the ACO must pay such amount no later than 90 days after the receipt of such notification.

(6) If CMS terminates the participation agreement of an ACO that has an outstanding balance of advance investment payments owed to CMS, the ACO must repay any outstanding advance investment payments it received. CMS will provide written notification to the ACO of the amount due and the ACO must pay such amount no later than 90 days after the receipt of such notification.

(7) In the event of bankruptcy—

(i) If an ACO has filed a bankruptcy petition, whether voluntary or involuntary, the ACO must provide written notice of the bankruptcy to CMS and to the U.S. Attorney's Office in the district where the bankruptcy was filed,

unless final payment for the agreement period has been made by either CMS or the ACO and all administrative or judicial review proceedings relating to any payments under the Shared Savings Program have been fully and finally resolved.

(ii) The notice of bankruptcy must be sent by certified mail no later than 5 days after the petition has been filed and must contain a copy of the filed bankruptcy petition (including its docket number). The notice to CMS must be addressed to the CMS Office of Financial Management at 7500 Security Boulevard, Mailstop C3–01–24, Baltimore, MD 21244 or such other address as may be specified on the CMS website for purposes of receiving such notices.

(h) *Termination of advance investment payments*—(1) *General.* Except as provided in paragraph (h)(2) of this section, CMS may terminate an ACO's advance investment payments if the ACO—

(i) Fails to comply with the requirements of this section;

(ii) Meets any of the grounds for ACO termination set forth in § 425.218(b);

(iii) Voluntarily terminates its participation agreement in accordance with § 425.220(a); or

(iv) Voluntarily terminates payments of advance investment payments but continues its participation in the Shared Savings Program.

(2) *Eligibility sanction.* CMS will terminate an ACO's advance investment payments in accordance with § 425.316(e) if the ACO no longer meets the eligibility requirements specified in paragraphs (b)(3) and (b)(4) of this section.

(3) *No pre-termination actions.* CMS may immediately terminate an ACO's advance investment payments without taking any of the pre-termination actions set forth in § 425.216.

(i) *Reporting information on advance investment payments.* The ACO must report information on its receipt of and use of advance investment payments, as follows:

(1) The ACO must publicly report information about the ACO's use of advance investment payments for each performance year, in accordance with § 425.308(b)(8).

(2) In a form and manner and by a deadline specified by CMS, the ACO must report to CMS the same information it is required to publicly report under § 425.308(b)(8).

[87 FR 70242, Nov. 18, 2022, as amended at 88 FR 79548, Nov. 16, 2023; 89 FR 98571, Dec. 9, 2024]

§§ 425.631–425.639 [Reserved]

§ 425.640 Option to receive prepaid shared savings.

(a) *Purpose.* Prepaid shared savings provide an additional cash flow option to ACOs with a history of earning shared savings that will encourage their investment in activities that reduce costs for the Medicare program and beneficiaries and improve the quality of care provided to their assigned beneficiaries.

(b) *Eligibility.* An ACO is eligible to receive prepaid shared savings in an agreement period as specified in this section if CMS determines that all of the following criteria are met:

(1) The ACO meets either of the following conditions:

(i) The ACO is a renewing ACO as defined under § 425.20 entering an agreement period beginning on January 1, 2026, or in subsequent years.

(ii) The ACO was a renewing ACO as defined under § 425.20 entering an agreement period beginning on January 1, 2025, and applied to receive prepaid shared savings in accordance with paragraph (c)(2) of this section starting with the performance year beginning on January 1, 2026.

(2) The ACO must have received a shared savings payment for the most recent performance year that:

(i) Occurred prior to the agreement period for which the ACO has applied to receive prepaid shared savings; and

(ii) CMS has conducted financial reconciliation.

(3) The ACO must have a positive prior savings adjustment for the agreement period for which the ACO has applied to receive prepaid shared savings as calculated pursuant to § 425.658.

(4) The ACO does not have any outstanding shared losses or advance investment payments that have not yet been repaid to CMS after reconciliation for the most recent performance year

for which CMS completed financial reconciliation.

(5) If the ACO received prepaid shared savings in the current agreement period or a prior agreement period, the ACO must have fully repaid the amount of prepaid shared savings received through the most recent performance year for which CMS has completed financial reconciliation.

(6) The ACO is participating in Levels C through E of the BASIC track or the ENHANCED track during the agreement period in which it would receive prepaid shared savings.

(7) The ACO has in place an adequate repayment mechanism in accordance with § 425.204(f) that can be used to recoup outstanding prepaid shared savings.

(8) During the agreement period immediately preceding the agreement period in which the ACO would receive prepaid shared savings, the ACO:

(i) Met the quality performance standard as specified under § 425.512; and

(ii) Has not been determined by CMS to have avoided at-risk beneficiaries as specified under § 425.316(b)(2).

(c) *Application procedure.* (1) For an ACO renewing to enter an agreement period beginning on January 1, 2026, or in subsequent years, to obtain a determination regarding whether the ACO may receive prepaid shared savings, the ACO must submit to CMS a complete supplemental application with its application to renew for a new agreement period in the Shared Savings Program (submitted pursuant to § 425.224) in the form and manner and by a deadline specified by CMS.

(2) For an ACO that renewed to enter an agreement period beginning on January 1, 2025, to obtain a determination regarding whether the ACO may receive prepaid shared savings, the ACO must submit to CMS a complete supplemental application for prepaid shared savings prior to the start of the performance year beginning on January 1, 2026, in the form and manner and by a deadline specified by CMS.

(d) *Application contents and review*—(1) *General.* An ACO must submit to CMS supplemental application information sufficient for CMS to determine whether the ACO is eligible to receive prepaid shared savings. In addition, the ACO must submit a proposed spend plan as part of the supplemental application information.

(2) *Spend plan.* The ACO's spend plan must:

(i) Describe how an ACO receiving prepaid shared savings will spend the payments during the first performance year in which it will receive prepaid shared savings. The spend plan must be updated annually for each performance year of the agreement period during which the ACO receives prepaid shared savings.

(ii) Identify the categories of items and services that will be purchased and investments that will be made in the ACO with prepaid shared savings (consistent with the allowable uses under paragraph (e) of this section), the dollar amounts to be spent on such categories, information about which groups of beneficiaries the ACO expects to receive direct beneficiary services that will be purchased with prepaid shared savings, how direct beneficiary services will be distributed to beneficiaries and how such services support the care of beneficiaries, descriptions of the investments that will be made in the ACO with prepaid shared savings, and such other information as may be specified by CMS.

(iii) Include an attestation that the ACO will not discriminate on the basis of race, color, religion, sex, national origin, disability, or age with respect to their use of prepaid shared savings.

(iv) Include the ACO's communication strategy for notifying CMS and any impacted beneficiaries if an ACO will no longer be providing any direct beneficiary services that had previously been provided by the ACO using prepaid shared savings.

(3) *CMS review.* CMS will review the supplemental application information to determine whether an ACO meets the eligibility criteria and other requirements necessary to receive prepaid shared savings and will approve or deny the ACO's prepaid shared savings application accordingly. CMS may review an ACO's spend plan at any time and require the ACO to modify its spend plan to comply with the requirements of this paragraph (d) and paragraph (e) of this section.

(e) *Use and management of prepaid shared savings*—(1) *Allowable uses.* An ACO must use prepaid shared savings to improve the quality and efficiency of items and services furnished to beneficiaries by investing in staffing, healthcare infrastructure, and direct beneficiary services. Expenditures of prepaid shared savings must comply with paragraph (e)(2) of this section, the beneficiary incentive provision at § 425.304(a), (b), and (d), and all other applicable laws and regulations.

(i) An ACO may spend up to 50 percent of its estimated annual prepaid shared savings on staffing and healthcare infrastructure in each performance year.

(ii) An ACO may spend up to 100 percent, but not less than 50 percent, of its estimated annual prepaid shared savings on direct beneficiary services in each performance year.

(2) *Prohibited uses.* An ACO may not use prepaid shared savings for any expense other than those allowed under paragraph (e)(1) of this section. Prohibited uses include the following—

(i) Management company or parent company profit;

(ii) Performance bonuses;

(iii) Provision of medical services covered by Medicare;

(iv) Cash or cash equivalent payments to patients;

(v) Items or activities unrelated to ACO operations or care of beneficiaries; and

(vi) In the case of an ACO participating in Levels C through E of the BASIC track or the ENHANCED track, the repayment of any shared losses incurred as specified in a written notice in accordance with § 425.605(e)(2) or § 425.610(h)(2), respectively.

(3) *Duration for spending payments.* An ACO must spend all prepaid shared savings in the agreement period in which they are received. An ACO must repay to CMS any unspent funds remaining at the end of each agreement period. Any unspent funds received for a performance year must be reallocated in the spend plan for the ACO's next performance year. When reallocated in the spend plan for the next performance year, the total unspent funds in each category must be reallocated within their originally indicated category specified in accordance with paragraph (d)(2) of this section. If an ACO fails to spend a majority of the prepaid shared savings they receive in a performance year, CMS may withhold future quarterly payments until the ACO spends the funding they have already received and reports this spending to CMS through an updated spend plan.

(f) *Payment & payment methodology.* An ACO determined eligible pursuant to paragraph (b) of this section receives quarterly prepaid shared savings payments equal to the maximum quarterly payment amount calculated pursuant to the methodology specified in paragraphs (f)(2) through (4) of this section unless the ACO elects to receive a lesser amount pursuant to paragraph (f)(6) of this section. CMS notifies in writing each ACO of its determination of the amount of prepaid shared savings and the notice will inform the ACO of its right to request reconsideration review in accordance with the procedures specified in subpart I of this part. If CMS does not make any prepaid shared savings payment, the notice will specify the reason(s) why and inform the ACO of its right to request reconsideration review in accordance with the procedures specified in subpart I.

(1) *Frequency of payments.* (i) An eligible ACO entering an agreement period beginning on January 1, 2026, or in subsequent years will receive quarterly prepaid shared savings payments for the entirety of the ACO's agreement period unless the payment is withheld or terminated pursuant to paragraph (h) of this section.

(ii) An eligible ACO participating in an agreement period beginning on January 1, 2025, will receive quarterly prepaid shared savings payments starting with the performance year beginning on January 1, 2026, and for the remainder of its agreement period, unless the payment is withheld or terminated pursuant to paragraph (h) of this section. The ACO will not receive additional or catch-up payments for performance year 2025.

(iii) If an ACO's quarterly payment is withheld or terminated pursuant to paragraph (h) of this section, the ACO will not receive additional or catch-up payments if quarterly prepaid shared savings payments are later resumed.

(2) *Calculating the prepaid shared savings multiplier.* (i) Calculate total per capita savings or losses for each performance year that constitutes BY1 and BY2 of the agreement period in which the ACO receives prepaid shared savings. Per capita savings or losses will be set to zero for a performance year if the ACO was not reconciled for the performance year.

(ii) Take the simple average of the per capita savings or losses calculated in paragraph (f)(2)(i) of this section, including values of zero, if applicable.

(iii) Apply a proration factor to account for any upward growth in the ACO's assigned population in BY1 and BY2 of the agreement period in which the ACO receives prepaid shared savings as compared to the size of the assigned population when the ACO was reconciled for the corresponding performance years in its prior agreement period.

(iv) Adjust the pro-rated average per capita amount computed in paragraph (f)(2)(iii) of this section by multiplying by 50 percent.

(v) The prepaid shared savings multiplier is the lesser of the following:

(A) Two-thirds of the pro-rated, adjusted average per capita amount computed in paragraph (f)(2)(iv) of this section.

(B) 5 percent of national per capita expenditures for Parts A and B services under the original Medicare fee-for-service program in BY2 for assignable beneficiaries identified for the 12-month calendar year corresponding to BY2 using data from the CMS Office of the Actuary and expressed as a single value by taking a person-year weighted average of the Medicare enrollment type-specific values.

(3) *Recalculation of the prepaid shared savings multiplier during an agreement period.* For the first performance year during the term of the agreement period in which the ACO receives prepaid shared savings, the ACO's prepaid shared savings multiplier is recalculated for changes in per capita shared savings or losses for the performance years used in the calculation of the prepaid shared savings multiplier as a result of issuance of a revised initial determination under §425.315. For the second and each subsequent performance year during the term of the agreement period in which the ACO receives prepaid shared savings, the ACO's prepaid shared savings multiplier is recalculated for the following, as applicable: For the addition and removal of ACO participants or ACO providers/suppliers in accordance with §425.118(b), for a change to the ACO's beneficiary assignment methodology selection under §425.226(a)(1), for a change to the beneficiary assignment methodology specified in subpart E of this part, and for changes in per capita shared savings or losses for the performance years used in the calculation of the prepaid shared savings multiplier as a result of issuance of a revised initial determination under §425.315. To recalculate the prepaid shared savings multiplier, CMS does the following:

(i) Takes into account changes to the ACO's savings or losses for a performance year for either of the 2 years that constitute BY1 and BY2 of the agreement period for which the ACO receives prepaid shared savings under paragraph (f)(2)(i) of this section, including values of zero, if applicable, as a result of issuance of a revised initial determination under §425.315, when calculating the simple average of the per capita savings or losses calculated in paragraph (f)(2)(ii) of this section.

(ii) Redetermines the proration factor used in calculating the prepaid shared savings multiplier under paragraph (f)(2)(iii) of this section to account for changes in the ACO's assigned beneficiary population in the benchmark years of the ACO's agreement period in which the ACO receives prepaid shared savings due to the addition and removal of ACO participants or ACO providers/suppliers in accordance with §425.118(b), a change to the ACO's beneficiary assignment methodology selection under §425.226(a)(1), or changes to the beneficiary assignment methodology under subpart E of this part.

(4) *Calculating the maximum quarterly payment amount.* For each quarter for each performance year, the maximum quarterly prepaid shared savings amount is equal to the product of one-fourth of the prepaid shared savings multiplier calculated in paragraph (f)(2)(v) of this section or recalculated

according to paragraph (f)(3) of this section and the ACO's performance year assigned beneficiary person years calculated from the ACO's most recent assignment list.

(5) *Estimated annual payment amount calculation methodology*. For the purposes of determining the amount of prepaid shared savings permitted to be allocated to the uses specified in paragraph (e) of this section during each performance year, the estimated annual prepaid shared savings amount can be calculated by multiplying the first quarterly payment amount the ACO receives in each performance year by four. If an ACO's maximum quarterly payments decrease over the performance year, the ACO will not be subject to compliance action solely because it spent more than 50 percent of the actual annual amount of prepaid shared savings it received during that PY on staffing and healthcare infrastructure, as long as it did not spend more than 50 percent of the originally estimated annual maximum prepaid shared savings amount on staffing and healthcare infrastructure.

(6) *ACO selection of quarterly payment amount*. An ACO may request a smaller quarterly payment amount from CMS in a form and manner and by a deadline specified by CMS.

(g) *Recoupment and recovery of prepaid shared savings; notice of bankruptcy*. (1) CMS will recoup prepaid shared savings made to an ACO from any shared savings the ACO earns until CMS has recouped in full the amount of prepaid shared savings made to the ACO. CMS will carry forward any remaining balance owed to subsequent performance year(s) in which the ACO achieves shared savings.

(2) If the amount of shared savings earned by the ACO is revised upward by CMS for any reason, CMS will reduce the redetermined amount of shared savings by the amount of prepaid shared savings made to the ACO as of the date of the redetermination. If the amount of shared savings earned by the ACO is revised downward by CMS for any reason, the ACO will not receive a refund of any portion of the prepaid shared savings previously recouped or otherwise repaid, and any prepaid shared savings that are now outstanding due to the revision in earned shared savings must be repaid to CMS upon request.

(3) If an ACO has an outstanding balance of prepaid shared savings after the calculation of shared savings or losses for the final performance year of an agreement period in which an ACO receives prepaid shared savings, the ACO must repay any outstanding amount of prepaid shared savings it received in full upon request from CMS. CMS will provide written notification to the ACO of the amount due and the ACO must pay such amount no later than 90 days after the receipt of notification. If the ACO fails to repay any outstanding amount of prepaid shared savings within 90 days of that written notification, CMS will recoup any outstanding balance of prepaid shared savings from the ACO's repayment mechanism established under § 425.204(f). CMS may also recover any outstanding amount of prepaid shared savings owed by recouping from any future shared savings the ACO may be eligible to receive in a subsequent agreement period.

(4) Except as provided in paragraph (g)(4)(ii) of this section, if an ACO or CMS terminates the ACOs participation agreement during the agreement period in which it received prepaid shared savings, the ACO must repay all outstanding prepaid shared savings it received in full upon request from CMS.

(i) CMS will provide written notification to the ACO of the amount due and the ACO must pay such amount no later than 90 days after the receipt of notification. If the ACO fails to repay within 90 days, CMS will recoup any outstanding balance from the ACO's repayment mechanism established under § 425.204(f).

(ii) If the ACO terminates its current participation agreement under § 425.220 and immediately enters a new agreement period to continue its participation in the program, CMS may recover the amount owed by recouping from any future shared savings the ACO may be eligible to receive in subsequent agreement periods.

(5)(i) If an ACO has filed a bankruptcy petition, whether voluntary or involuntary, the ACO must provide written notice of the bankruptcy to

CMS and to the U.S. Attorney's Office in the district where the bankruptcy was filed, unless final payment for the agreement period has been made by either CMS or the ACO and all administrative or judicial review proceedings relating to any payments under the Shared Savings Program have been fully and finally resolved.

(ii) The notice of bankruptcy must be sent by certified mail no later than 5 days after the petition has been filed and must contain a copy of the filed bankruptcy petition (including its docket number). The notice to CMS must be addressed to the CMS Office of Financial Management at 7500 Security Boulevard, Mailstop C3–01–24, Baltimore, MD 21244 or such other address as may be specified on the CMS website for purposes of receiving such notices.

(h) *Withholding or termination of prepaid shared savings*—(1) *General.* Except as provided in paragraph (h)(2) of this section, CMS may withhold or terminate an ACO's prepaid shared savings during an agreement period if—

(i) The ACO fails to comply with the requirements of this section;

(ii) The ACO meets any of the grounds for ACO termination set forth in § 425.218(b);

(iii) The ACO fails to earn sufficient shared savings in a performance year to repay the prepaid shared savings they received during that performance year;

(iv) CMS determines that the ACO is not expected to earn shared savings in a performance year during the agreement period in which the ACO received prepaid shared savings based on a rolling 12-month window of beneficiary claims data or year to date beneficiary claims data;

(v) The ACO falls below 5,000 assigned beneficiaries;

(vi) The ACO fails to spend the majority of prepaid shared savings they receive in a performance year; or

(vii) The ACO requests that CMS withhold a future quarterly prepaid shared savings payment.

(2) *Eligibility sanction.* CMS must terminate an ACO's prepaid shared savings if—

(i) The ACO fails to maintain an adequate repayment mechanism in accordance with § 425.204(f); or

(ii) The ACO fails to meet the quality performance standard as specified under § 425.512 or is subject to a pre-termination action after CMS determined the ACO avoided at-risk beneficiaries as specified under § 425.316(b)(2).

(3) *No additional payments.* If CMS withholds or terminates a quarterly payment pursuant to this paragraph (h), the ACO will not receive additional or catch-up payments if quarterly payments of prepaid shared savings are later resumed.

(4) *No pre-termination actions.* CMS may immediately terminate an ACO's prepaid shared savings under paragraphs (h)(1) and (2) of this section without taking any of the pre-termination actions set forth in § 425.216.

(i) *Reporting information on prepaid shared savings.* The ACO must report information on its receipt of and use of prepaid shared savings, as follows:

(1) The ACO must publicly report information about the ACO's use of prepaid shared savings for each performance year, in accordance with § 425.308(b)(10).

(2) In a form and manner and by a deadline specified by CMS, the ACO must report to CMS the same information it is required to publicly report under § 425.308(b)(10).

[89 FR 98571, Dec. 9, 2024]

§§ 425.641–425.649 [Reserved]

§ 425.650 Benchmarking methodology.

(a) *Scope and purpose.* The methodology by which CMS establishes, adjusts, updates and resets an ACO's historical benchmark is described within this subpart G. The benchmarking methodology for agreement periods beginning before January 1, 2024, is specified in §§ 425.601, 425.602, 425.603, and 425.659. The benchmarking methodology for agreement periods beginning on or after January 1, 2024, is specified in §§ 425.652 through 425.662.

(b) [Reserved]

[87 FR 70243, Nov. 18, 2022, as amended at 88 FR 79548, Nov. 16, 2023; 89 FR 98574, Dec. 9, 2024]

§ 425.652 Establishing, adjusting, and updating the benchmark for agreement periods beginning on January 1, 2024, and in subsequent years.

(a) *Computing per capita Medicare Part A and Part B benchmark expenditures for an ACO's first agreement period.* For agreement periods beginning on January 1, 2024, and in subsequent years, in computing an ACO's historical benchmark for its first agreement period under the Shared Savings Program, CMS determines the per capita Parts A and B fee-for-service expenditures for beneficiaries that would have been assigned to the ACO in any of the 3 most recent years prior to the start of the agreement period using the ACO participant TINs identified before the start of the agreement period as required under § 425.118(a) and the beneficiary assignment methodology selected by the ACO for the first performance year of the agreement period as required under § 425.400(a)(4)(ii). CMS does all of the following:

(1) Calculates the payment amounts included in Parts A and B fee-for-service claims using a 3-month claims run out with a completion factor.

(i) This calculation excludes indirect medical education (IME) and disproportionate share hospital (DSH) payments, and the supplemental payment for IHS/Tribal hospitals and Puerto Rico hospitals.

(ii) This calculation includes individually beneficiary identifiable final payments made under a demonstration, pilot or time limited program.

(2) Makes separate expenditure calculations for each of the following populations of beneficiaries: ESRD, disabled, aged/dual eligible Medicare and Medicaid beneficiaries and aged/non-dual eligible Medicare and Medicaid beneficiaries.

(3) Adjusts expenditures for changes in severity and case mix using prospective HCC risk scores.

(4) Truncates an assigned beneficiary's total annual Parts A and B fee-for-service per capita expenditures at the 99th percentile of national Medicare fee-for-service expenditures for assignable beneficiaries identified for the 12-month calendar year corresponding to each benchmark year in order to minimize variation from catastrophically large claims.

(5) Trends forward expenditures for each benchmark year (BY1 and BY2) to the third benchmark year (BY3) dollars using a blend of national and regional growth rates.

(i) To trend forward the benchmark, CMS makes separate calculations for expenditure categories for each of the following populations of beneficiaries:

(A) ESRD.

(B) Disabled.

(C) Aged/dual eligible Medicare and Medicaid beneficiaries.

(D) Aged/non-dual eligible Medicare and Medicaid beneficiaries.

(ii) National growth rates are computed using CMS Office of the Actuary national Medicare expenditure data for each of the years making up the historical benchmark for assignable beneficiaries identified for the 12-month calendar year corresponding to each benchmark year.

(iii) Regional growth rates are computed using expenditures for the ACO's regional service area for each of the years making up the historical benchmark as follows:

(A) Determine the counties included in the ACO's regional service area based on the ACO's assigned beneficiary population for the relevant benchmark year.

(B) Determine the ACO's regional expenditures as specified under § 425.654 of this section.

(iv) The national and regional growth rates are blended together by taking a weighted average of the two. The weight applied to the—

(A) National growth rate is calculated as the share of assignable beneficiaries in the ACO's regional service area for BY3 that are assigned to the ACO in BY3, as calculated in paragraph (a)(5)(v) of this section; and

(B) Regional growth rate is equal to 1 minus the weight applied to the national growth rate.

(v) CMS calculates the share of assignable beneficiaries in the ACO's regional service area that are assigned to the ACO by doing all of the following:

(A) Calculating the county-level share of assignable beneficiaries that are assigned to the ACO for each county in the ACO's regional service area.

The assignable population of beneficiaries is identified for BY3 using the assignment window or expanded window for assignment that is consistent with the beneficiary assignment methodology selected by the ACO for the performance year according to § 425.400(a)(4)(ii).

(B) Weighting the county-level shares according to the ACO's proportion of assigned beneficiaries in the county, determined by the number of the ACO's assigned beneficiaries residing in the county in relation to the ACO's total number of assigned beneficiaries.

(C) Aggregating the weighted county-level shares for all counties in the ACO's regional service area.

(6) Restates BY1 and BY2 trended and risk adjusted expenditures using BY3 proportions of ESRD, disabled, aged/dual eligible Medicare and Medicaid beneficiaries and aged/non-dual eligible Medicare and Medicaid beneficiaries.

(7) Weights each year of the benchmark for an ACO's initial agreement period using the following percentages:

(i) BY3 at 60 percent.

(ii) BY2 at 30 percent.

(iii) BY1 at 10 percent.

(8) Adjusts the historical benchmark, if applicable:

(i) For agreement periods beginning on January 1, 2024, except as provided in paragraph (a)(8)(i)(C) of this section, CMS adjusts the historical benchmark based on the ACO's regional service area expenditures (as specified under § 425.656), or for savings generated by the ACO, if any, in the 3 most recent years prior to the start of the agreement period (as specified under § 425.658). CMS does all of the following to determine the adjustment, if any, applied to the historical benchmark:

(A) Computes the regional adjustment in accordance with § 425.656 and the prior savings adjustment in accordance with § 425.658.

(B) If an ACO is not eligible to receive a prior savings adjustment under § 425.658(b)(3)(i), and the regional adjustment, expressed as a single value as described in § 425.656(d), is positive, the ACO will receive an adjustment to its benchmark equal to the positive regional adjustment amount. The adjustment will be calculated as described in § 425.656(c) and applied separately to the following populations of beneficiaries: ESRD, disabled, aged/dual eligible Medicare and Medicaid beneficiaries, and aged/non-dual eligible Medicare and Medicaid beneficiaries.

(C) If an ACO is not eligible to receive a prior savings adjustment under § 425.658(b)(3)(i), and the regional adjustment, expressed as a single value as described in § 425.656(d), is negative or zero, the ACO will not receive an adjustment to its benchmark.

(D) If an ACO is eligible to receive a prior savings adjustment and the regional adjustment, expressed as a single value as described in § 425.656(d), is positive, the ACO will receive an adjustment to its benchmark equal to the higher of the following:

(*1*) The positive regional adjustment amount. The adjustment will be calculated as described in § 425.656(c) and applied separately to the following populations of beneficiaries: ESRD, disabled, aged/dual eligible Medicare and Medicaid beneficiaries, and aged/non-dual eligible Medicare and Medicaid beneficiaries.

(*2*) The prior savings adjustment. The adjustment will be calculated as described in § 425.658(c) and applied as a flat dollar amount to the following populations of beneficiaries: ESRD, disabled, aged/dual eligible Medicare and Medicaid beneficiaries, and aged/non-dual eligible Medicare and Medicaid beneficiaries.

(E) If an ACO is eligible to receive a prior savings adjustment and the regional adjustment, expressed as a single value as described in § 425.656(d), is negative or zero, the ACO will receive an adjustment to its benchmark equal to the prior savings adjustment. The adjustment will be calculated as described in § 425.658(c) and applied as a flat dollar amount to the following populations of beneficiaries: ESRD, disabled, aged/dual eligible Medicare and Medicaid beneficiaries, and aged/non-dual eligible Medicare and Medicaid beneficiaries.

(ii) For agreement periods beginning on January 1, 2025, and in subsequent years, except as provided in paragraph (a)(8)(ii)(B)(*2*) of this section, CMS adjusts the historical benchmark based

on the ACO's regional service area expenditures (as specified under § 425.656), for savings generated by the ACO, if any, in the 3 most recent years prior to the start of the agreement period (as specified under § 425.658), or to account for the ACO serving higher proportions of underserved beneficiaries (as specified in § 425.662). CMS does all of the following to determine the adjustment, if any, applied to the historical benchmark:

(A) Computes the regional adjustment in accordance with § 425.656, the prior savings adjustment in accordance with § 425.658, and the health equity benchmark adjustment (HEBA) in accordance with § 425.662.

(B) Compares the regional adjustment, expressed as a single value as described in § 425.656(d), the per capita prior savings adjustment determined in § 425.658(c), if any, and the HEBA determined in § 425.662(b), if any, to determine the adjustment applied to the historical benchmark.

(*1*) The ACO will receive the highest of the positive adjustments for which it is eligible. The adjustment will be calculated as described in § 425.656(c), § 425.658(c), or § 425.662(b), respectively, and applied separately to the following populations of beneficiaries: ESRD, disabled, aged/dual eligible Medicare and Medicaid beneficiaries, and aged/non-dual eligible Medicare and Medicaid beneficiaries.

(*2*) If an ACO is not eligible to receive a prior savings adjustment under § 425.658(b)(3)(i) or the HEBA under § 425.662(b)(3), and the regional adjustment, expressed as a single value as described in § 425.656(d), is negative or zero, the ACO will not receive an adjustment to its benchmark.

(9) For the first performance year during the term of the agreement period, the ACO's benchmark is adjusted for the following, as applicable: For changes in values used in benchmark calculations in accordance with § 425.316(b)(2)(ii)(B) or (C) due to compliance action to address avoidance of at-risk beneficiaries or as a result of issuance of a revised initial determination under § 425.315, and for changes in values used in benchmark calculations as a result of the performance year being affected by significant, anomalous, and highly suspect billing under § 425.672. For the second and each subsequent performance year during the term of the agreement period, the ACO's benchmark is adjusted for the following, as applicable: For the addition and removal of ACO participants or ACO providers/suppliers in accordance with § 425.118(b), for a change to the ACO's beneficiary assignment methodology selection under § 425.226(a)(1), for a change to the beneficiary assignment methodology specified in subpart E of this part, for a change in the CMS–HCC risk adjustment methodology used to calculate prospective HCC risk scores under § 425.659, for changes in values used in benchmark calculations in accordance with § 425.316(b)(2)(ii)(B) or (C) due to compliance action to address avoidance of at-risk beneficiaries or as a result of issuance of a revised initial determination under § 425.315, and for changes in values used in benchmark calculations as a result of the performance year being affected by significant, anomalous, and highly suspect billing under § 425.672. To adjust the benchmark, CMS does the following:

(i) Takes into account the expenditures of beneficiaries who would have been assigned to the ACO in any of the 3 most recent years prior to the start of the agreement period.

(ii) Redetermines the regional adjustment amount under § 425.656 according to the ACO's assigned beneficiaries for BY3, and based on the assignable population of beneficiaries identified for BY3 using the assignment window or expanded window for assignment that is consistent with the beneficiary assignment methodology selected by the ACO for the performance year according to § 425.400(a)(4)(ii).

(iii) Redetermines the offset factor used in determining the negative regional adjustment amount under § 425.656(c)(4) and (5).

(iv) Redetermines the proration factor used in calculating the prior savings adjustment under § 425.658(b)(3)(ii) to account for changes in the ACO's assigned beneficiary population in the benchmark years of the ACO's current agreement period due to the addition and removal of ACO participants or ACO providers/suppliers in accordance

with § 425.118(b), a change to the ACO's beneficiary assignment methodology selection under § 425.226(a)(1), or changes to the beneficiary assignment methodology under subpart E of this part.

(v) Redetermines the HEBA scaler used in calculating the HEBA under § 425.662(b)(2) to account for changes in the ACO's regional adjustment or prior savings adjustment in accordance with paragraphs (a)(9)(ii) through (iv) of this section.

(vi) In accordance with paragraph (a)(8) of this section, CMS redetermines the adjustment to the historical benchmark based on the redetermined regional adjustment (as specified under § 425.656), the prior savings adjustment (as specified under § 425.658), or the HEBA (as specified under § 425.662) if applicable.

(vii) Redetermines factors based on prospective HCC risk scores calculated for benchmark years by calculating the prospective HCC risk scores using the CMS–HCC risk adjustment methodology that applies for the calendar year corresponding to the applicable performance year in accordance with § 425.659(b)(1).

(viii) Recalculates benchmark year expenditures to account for the impact of improper payments, for the benchmark year corresponding to a performance year for which CMS issued a revised initial determination under § 425.315. In recalculating expenditures for the benchmark year, CMS applies the calculation methodology applied in recalculating expenditures for the corresponding performance year in accordance with § 425.674.

(ix) Recalculates expenditures used in Shared Savings Program benchmark calculations under this section, and as applicable under §§ 425.654 through 425.662, to exclude the same HCPCS or CPT codes identified as displaying significant, anomalous, and highly suspect billing patterns in calculation of performance year expenditures, in accordance with § 425.672.

(10) The historical benchmark is further adjusted at the time of reconciliation for a performance year to account for changes in severity and case mix of the ACO's assigned beneficiary population as described under §§ 425.605(a) and 425.610(a).

(b) *Updating the benchmark.* For all agreement periods beginning on January 1, 2024, and in subsequent years, CMS updates the historical benchmark annually for each year of the agreement period using a three-way blend calculated as a weighted average of a two-way blend of national and regional growth rates determined after the end of each performance year and a fixed projected growth rate determined at the beginning of the ACO's agreement period called the Accountable Care Prospective Trend (ACPT).

(1) To update the benchmark, CMS makes separate calculations for expenditure categories for each of the following populations of beneficiaries:

(i) ESRD.

(ii) Disabled.

(iii) Aged/dual eligible Medicare and Medicaid beneficiaries.

(iv) Aged/non-dual eligible Medicare and Medicaid beneficiaries.

(2) CMS computes the two-way blend of national and regional growth rates as follows:

(i) Computes national growth rates using CMS Office of the Actuary national Medicare expenditure data for BY3 and the performance year for assignable beneficiaries identified for the 12-month calendar year corresponding to each year.

(ii) Computes regional growth rates using expenditures for the ACO's regional service area for BY3 and the performance year, computed as follows:

(A) Determine the counties included in the ACO's regional service area based on the ACO's assigned beneficiary population for the year.

(B) Determine the ACO's regional expenditures as specified under § 425.654.

(C) Multiply the growth rate calculated in this paragraph (b)(2)(ii) by a regional risk score growth cap adjustment factor computed as described in § 425.655.

(iii) The national and regional growth rates are blended together by taking a weighted average of the two. The weight applied to the—

(A) National growth rate is calculated as the share of assignable beneficiaries in the ACO's regional service area that are assigned to the ACO for

the applicable performance year as specified in paragraph (b)(2)(iv) of this section; and

(B) Regional growth rate is equal to 1 minus the weight applied to the national growth rate.

(iv) CMS calculates the share of assignable beneficiaries in the ACO's regional service area that are assigned to the ACO by doing all of the following:

(A) Calculating the county-level share of assignable beneficiaries that are assigned to the ACO for each county in the ACO's regional service area. The assignable population of beneficiaries is identified for the performance year using the assignment window or expanded window for assignment that is consistent with the beneficiary assignment methodology selected by the ACO for the performance year according to § 425.400(a)(4)(ii).

(B) Weighting the county-level shares according to the ACO's proportion of assigned beneficiaries in the county, determined by the number of the ACO's assigned beneficiaries residing in the county in relation to the ACO's total number of assigned beneficiaries.

(C) Aggregating the weighted county-level shares for all counties in the ACO's regional service area.

(3) CMS computes the ACPT as described in § 425.660.

(4) The two-way blend computed under paragraph (b)(2) of this section and the ACPT are blended together by taking a weighted average of the two.

(i) Absent unforeseen circumstances, the weight applied to the components of the blend is as follows—

(A) Two-way blend is equal to two-thirds; and

(B) ACPT is equal to one-third.

(ii) CMS has sole discretion to determine whether an unforeseen circumstance exists that warrants a reduction to the weight of the ACPT and the reduced weight that will apply to the ACPT.

(5) If an ACO's average per capita Medicare expenditures for the performance year are above its updated benchmark for the year determined as described in paragraph (b)(4) of this section by at least the MLR or negative MSR established for the ACO, CMS will compute a recalculated updated benchmark using the two-way blend described in paragraph (b)(2) of this section.

(i) If the ACO's average per capita Medicare expenditures for the performance year are above the recalculated updated benchmark by a smaller amount than the amount by which they are above the updated benchmark determined as described in paragraph (b)(4) of this section, CMS will use the recalculated updated benchmark to determine the following:

(A) The ACO's responsibility for sharing losses with the Medicare program for ACOs in two-sided models as described under §§ 425.605 and 425.610.

(B) The ACO's financial performance for purposes of monitoring ACO financial performance as described under § 425.316(d).

(ii) If the ACO's average per capita Medicare expenditures for the performance year are below the recalculated updated benchmark, the ACO will neither be responsible for sharing losses with the Medicare program nor eligible for sharing in savings.

(c) *Resetting the benchmark.* (1) An ACO's benchmark is reset at the start of each subsequent agreement period.

(2) For second or subsequent agreements periods beginning on January 1, 2024, and in subsequent years, CMS establishes, adjusts, and updates the rebased historical benchmark in accordance with paragraphs (a) and (b) of this section except that rather than weighting each year of the benchmark using the percentages provided in paragraph (a)(7) of this section, each benchmark year is weighted equally.

[87 FR 70244, Nov. 18, 2022, as amended at 88 FR 79548, Nov. 16, 2023; 89 FR 98574, Dec. 9, 2024]

§ 425.654 Calculating county expenditures and regional expenditures.

(a) *Calculating county expenditures.* For agreement periods beginning on January 1, 2024, and in subsequent years, CMS does all of the following to determine risk adjusted county fee-for-service expenditures for use in calculating the ACO's regional fee-for-service expenditures:

(1)(i) Determines average county fee-for-service expenditures based on expenditures for the assignable population of beneficiaries in each county in the ACO's regional service area. The assignable population of beneficiaries is identified for the relevant benchmark or performance year using the assignment window or expanded window for assignment that is consistent with the beneficiary assignment methodology selected by the ACO for the performance year according to § 425.400(a)(4)(ii).

(ii) Makes separate expenditure calculations for each of the following populations of beneficiaries:

(A) ESRD.

(B) Disabled.

(C) Aged/dual eligible Medicare and Medicaid beneficiaries.

(D) Aged/non-dual eligible Medicare and Medicaid beneficiaries.

(2) Calculates assignable beneficiary expenditures using the payment amounts included in Parts A and B fee-for-service claims with dates of service in the 12-month calendar year for the relevant benchmark or performance year, using a 3-month claims run out with a completion factor. The calculation—

(i) Excludes IME and DSH payments, and the supplemental payment for IHS/Tribal hospitals and Puerto Rico hospitals; and

(ii) Considers individually beneficiary identifiable final payments made under a demonstration, pilot or time limited program.

(3) Truncates a beneficiary's total annual Parts A and B fee-for-service per capita expenditures at the 99th percentile of national Medicare fee-for-service expenditures for assignable beneficiaries identified for the 12-month calendar year that corresponds to the relevant benchmark or performance year, in order to minimize variation from catastrophically large claims.

(4) Adjusts fee-for-service expenditures for severity and case mix of assignable beneficiaries in the county using prospective HCC risk scores. The calculation is made according to the following populations of beneficiaries:

(i) ESRD.

(ii) Disabled.

(iii) Aged/dual eligible Medicare and Medicaid beneficiaries.

(iv) Aged/non-dual eligible Medicare and Medicaid beneficiaries.

(b) *Calculating regional expenditures.* For all agreement periods beginning on January 1, 2024, and in subsequent years, CMS calculates an ACO's risk adjusted regional expenditures by:

(1) Weighting the risk adjusted county-level fee-for-service expenditures determined under paragraph (a) of this section according to the ACO's proportion of assigned beneficiaries in the county, determined by the number of the ACO's assigned beneficiaries in the applicable population (according to Medicare enrollment type) residing in the county in relation to the ACO's total number of assigned beneficiaries in the applicable population (according to Medicare enrollment type) for the relevant benchmark or performance year for each of the following populations of beneficiaries:

(i) ESRD.

(ii) Disabled.

(iii) Aged/dual eligible Medicare and Medicaid beneficiaries.

(iv) Aged/non-dual eligible Medicare and Medicaid beneficiaries.

(2) Aggregating the values determined under paragraph (b)(1) of this section for each population of beneficiaries (according to Medicare enrollment type) across all counties within the ACO's regional service area.

[87 FR 70246, Nov. 18, 2022, as amended at 88 FR 79549, Nov. 16, 2023]

§ 425.655 Calculating the regional risk score growth cap adjustment factor.

(a) *General.* This section describes the methodology for calculating the regional risk score growth cap adjustment factor that will be applied to the regional growth rate component of the three-way blend used to update the historical benchmark as described in § 425.652(b) for agreement periods beginning on January 1, 2024, and in subsequent years.

(b) *Calculating county risk scores.* CMS does all of the following to determine county prospective HCC and demographic risk scores for use in calculating the ACO's regional risk scores:

(1) Determines average county prospective HCC and demographic risk

scores for the assignable population of beneficiaries in each county in the ACO's regional service area. The assignable population of beneficiaries is identified for the relevant benchmark or performance year using the assignment window or expanded window for assignment that is consistent with the beneficiary assignment methodology selected by the ACO for the performance year according to § 425.400(a)(4)(ii).

(2) Makes separate risk score calculations for each of the following populations of beneficiaries:

(i) ESRD.

(ii) Disabled.

(iii) Aged/dual eligible Medicare and Medicaid beneficiaries.

(iv) Aged/non-dual eligible Medicare and Medicaid beneficiaries.

(c) *Calculating regional risk scores.* CMS calculates an ACO's regional prospective HCC and demographic risk scores by:

(1) Weighting the county-level risk scores determined under paragraph (b) of this section according to the ACO's proportion of assigned beneficiaries in the county, determined by the number of the ACO's assigned beneficiaries in the applicable population (according to Medicare enrollment type) residing in the county in relation to the ACO's total number of assigned beneficiaries in the applicable population (according to Medicare enrollment type) for the relevant benchmark or performance year for each of the following populations of beneficiaries:

(i) ESRD.

(ii) Disabled.

(iii) Aged/dual eligible Medicare and Medicaid beneficiaries.

(iv) Aged/non-dual eligible Medicare and Medicaid beneficiaries.

(2) Aggregating the values determined under paragraph (c)(1) of this section for each population of beneficiaries (according to Medicare enrollment type) across all counties within the ACO's regional service area.

(d) *Determining aggregate growth in regional risk scores.* CMS determines aggregate growth in regional prospective HCC and demographic risk scores by:

(1) Determining growth in regional prospective HCC and demographic risk scores determined in paragraph (c) of this section (expressed as a ratio of the performance year regional risk score to the BY3 regional risk score) for each of the following populations of beneficiaries:

(i) ESRD.

(ii) Disabled.

(iii) Aged/dual eligible Medicare and Medicaid beneficiaries.

(iv) Aged/non-dual eligible Medicare and Medicaid beneficiaries.

(2) Determines the aggregate growth in regional risk scores by calculating a weighted average of the growth in regional prospective HCC risk scores or demographic risk scores, as applicable, across the populations described in paragraph (d)(1) of this section. When calculating the weighted average growth in prospective HCC risk scores or demographic risk scores, as applicable, the weight applied to the growth in risk scores for each Medicare enrollment type is equal to the product of the ACO's historical benchmark expenditures, adjusted in accordance with § 425.652(a)(8), for that enrollment type and the ACO's performance year assigned beneficiary person years for that enrollment type.

(e) *Determining the cap on regional risk score growth.* CMS determines the cap on regional prospective HCC risk score growth by:

(1) Computing the sum of the aggregate growth in regional demographic risk scores as determined in paragraph (d)(2) of this section and 3 percentage points.

(2) Calculating the ACO's aggregate market share by calculating the weighted average of the share of assignable beneficiaries in the ACO's regional service area that are assigned to the ACO for the performance year as determined in § 425.652(b)(2)(iv) across the populations described in § 425.652(b)(1). In calculating this weighted average, the weight applied to the share for each Medicare enrollment type is equal to the ACO's performance year assigned beneficiary person years for that enrollment type.

(3) Adding to the sum computed in paragraph (e)(1) of this section an amount equal to the product of:

(i) The ACO's aggregate market share as determined in paragraph (e)(2) of this section.

(ii) The difference between the aggregate growth in regional prospective HCC risk scores as determined in paragraph (d)(2) of this section and the sum determined in paragraph (e)(1) of this section. This difference is subject to a floor of zero.

(f) *Determining the regional risk score growth cap adjustment factor.* CMS determines the regional risk score growth cap adjustment factor for each Medicare enrollment type to be applied in calculating the regional growth rate described in § 425.652(b) by comparing the aggregate growth in regional prospective HCC risk scores determined in paragraph (d)(2) of this section and, if applicable, the growth in regional prospective HCC risk scores for individual Medicare enrollment types as determined in paragraph (d)(1) of this section with the cap determined in paragraph (e) of this section.

(1) If the aggregate growth in regional prospective HCC risk scores determined in paragraph (d)(2) of this section does not exceed the cap on regional risk score growth determined in paragraph (e) of this section, CMS will set the regional risk score growth cap adjustment factor equal to 1 for each of the following populations of beneficiaries:

(i) ESRD.

(ii) Disabled.

(iii) Aged/dual eligible Medicare and Medicaid beneficiaries.

(iv) Aged/non-dual eligible Medicare and Medicaid beneficiaries.

(2) If the aggregate growth in regional prospective HCC risk scores determined in paragraph (d)(2) of this section exceeds the cap determined in paragraph (e) of this section, CMS will compare the growth in regional prospective HCC risk scores for each Medicare enrollment type as determined in paragraph (d)(1) of this section with the cap on regional risk score growth determined in paragraph (e) of this section.

(i) If the growth in regional prospective HCC risk scores for the enrollment type determined in paragraph (d)(1) of this section does not exceed the cap on regional risk score growth determined in paragraph (e) of this section, CMS will set the regional risk score growth cap adjustment factor for that enrollment type equal to 1.

(ii) If the growth in regional prospective HCC risk scores determined in paragraph (d)(1) for the enrollment type exceeds the cap on regional risk score growth determined in paragraph (e) of this section, CMS will set the regional risk score growth cap adjustment factor for that enrollment type equal to the growth in regional prospective HCC risk scores for the enrollment type determined in paragraph (d)(1) of this section divided by the cap on regional risk score growth determined in paragraph (e) of this section.

[88 FR 79549, Nov. 16, 2023, as amended at 89 FR 98576, Dec. 9, 2024]

§ 425.656 Calculating the regional adjustment to the historical benchmark.

(a) *General.* This section describes the methodology for calculating the regional adjustment to the historical benchmark based on the ACO's regional service area expenditures, making separate calculations for the following populations of beneficiaries: ESRD, disabled, aged/dual eligible Medicare and Medicaid beneficiaries, and aged/non-dual eligible Medicare and Medicaid beneficiaries. This section applies to regional adjustment calculations for agreement periods beginning on January 1, 2024, and in subsequent years.

(b) *Calculation of an average per capita expenditure amount for the ACO's regional service area.* To compute an average per capita expenditure amount for the ACO's regional service area, CMS does all of the following:

(1) Determines the counties included in the ACO's regional service area based on the ACO's BY3 assigned beneficiary population.

(2) Determines the ACO's regional expenditures as specified under § 425.654 for BY3.

(3) Adjusts for differences in severity and case mix between the ACO's assigned beneficiary population for BY3 and the assignable population of beneficiaries for the ACO's regional service area for BY3. The assignable population of beneficiaries is identified for BY3 using the assignment window or expanded window for assignment that

is consistent with the beneficiary assignment methodology selected by the ACO for the performance year according to § 425.400(a)(4)(ii).

(c) *Calculation of the adjustment.* To calculate the adjustment, CMS does all of the following:

(1) Determines the difference between the average per capita amount of expenditures for the ACO's regional service area as specified under paragraph (b)(1) of this section and the average per capita amount of the ACO's historical benchmark determined under § 425.652(a)(1) through (7) and (c)(2), for each of the following populations of beneficiaries:

(i) ESRD.

(ii) Disabled.

(iii) Aged/dual eligible Medicare and Medicaid beneficiaries.

(iv) Aged/non-dual eligible Medicare and Medicaid beneficiaries.

(2) Applies a percentage, as determined in paragraph (e) of this section.

(3) Caps the per capita dollar amount for each Medicare enrollment type (ESRD, disabled, aged/dual eligible Medicare and Medicaid beneficiaries, aged/non-dual eligible Medicare and Medicaid beneficiaries) calculated under paragraph (c)(2) of this section at a dollar amount equal to a percentage of national per capita expenditures for Parts A and B services under the original Medicare fee-for-service program in BY3 for assignable beneficiaries in that enrollment type identified for the 12-month calendar year corresponding to BY3 using data from the CMS Office of the Actuary. The cap is applied as follows:

(i) For positive adjustments, the per capita dollar amount for a Medicare enrollment type is capped at 5 percent of the national per capita expenditure amount for the enrollment type for BY3.

(ii) For negative adjustments, the per capita dollar amount for a Medicare enrollment type is capped at negative 1.5 percent of the national per capita expenditure amount for the enrollment type for BY3.

(4) For negative adjustments, CMS will multiply the regional adjustments calculated in paragraphs (c)(2) or (3) of this section by 1 minus an offset factor equal to the sum of the following—

(i) Proportion of the ACO's BY3 assigned beneficiaries that are dually eligible for Medicare and Medicaid; and

(ii) The difference between the ACO's weighted average prospective HCC risk score for BY3 taken across the four Medicare enrollment types and 1. When calculating the weighted average prospective HCC risk score, the weight applied to the prospective HCC risk score for BY3 for each Medicare enrollment type is equal to the product of the BY3 per capita expenditures for that enrollment type and the BY3 person years for that enrollment type.

(5) The offset factor described in paragraph (c)(4) of this section is subject to a minimum value of zero (representing no offset to the negative regional adjustment) and a maximum value of 1 (representing a full offset to the negative regional adjustment).

(d) *Expression of the regional adjustment as a single value.* (1) CMS expresses the regional adjustment as a single value by taking a person-year weighted average of the Medicare enrollment type-specific regional adjustment values determined in paragraph (c) of this section.

(2) CMS uses the regional adjustment expressed as a single value for purposes of determining the adjustment, if any, that will be applied to the benchmark in accordance with § 425.652(a)(8).

(e) *Phase-in of weights used in regional adjustment calculation.* (1) The first time that an ACO's benchmark is adjusted based on the ACO's regional service area expenditures, CMS calculates the regional adjustment as follows:

(i) Using 35 percent of the difference between the average per capita amount of expenditures for the ACO's regional service area and the average per capita amount of the ACO's initial or rebased historical benchmark, if the ACO is determined to have lower spending than the ACO's regional service area.

(ii) Using 15 percent of the difference between the average per capita amount of expenditures for the ACO's regional service area and the average per capita amount of the ACO's initial or rebased historical benchmark, if the ACO is determined to have higher spending than the ACO's regional service area.

(2) The second time that an ACO's benchmark is adjusted based on the ACO's regional service area expenditures, CMS calculates the regional adjustment as follows:

(i) Using 50 percent of the difference between the average per capita amount of expenditures for the ACO's regional service area and the average per capita amount of the ACO's rebased historical benchmark if the ACO is determined to have lower spending than the ACO's regional service area.

(ii) Using 25 percent of the difference between the average per capita amount of expenditures for the ACO's regional service area and the average per capita amount of the ACO's rebased historical benchmark if the ACO is determined to have higher spending than the ACO's regional service area.

(3) The third time that an ACO's benchmark is adjusted based on the ACO's regional service area expenditures, CMS calculates the regional adjustment as follows:

(i) Using 50 percent of the difference between the average per capita amount of expenditures for the ACO's regional service area and the average per capita amount of the ACO's rebased historical benchmark if the ACO is determined to have lower spending than the ACO's regional service area.

(ii) Using 35 percent of the difference between the average per capita amount of expenditures for the ACO's regional service area and the average per capita amount of the ACO's rebased historical benchmark if the ACO is determined to have higher spending than the ACO's regional service area.

(4) The fourth or subsequent time that an ACO's benchmark is adjusted based on the ACO's regional service area expenditures, CMS calculates the regional adjustment to the historical benchmark using 50 percent of the difference between the average per capita amount of expenditures for the ACO's regional service area and the average per capita amount of the ACO's rebased historical benchmark.

(5) To determine if an ACO has lower or higher spending compared to the ACO's regional service area, CMS does the following:

(i) Multiplies the difference between the average per capita amount of expenditures for the ACO's regional service area and the average per capita amount of the ACO's historical benchmark for each population of beneficiaries (ESRD, disabled, aged/dual eligible Medicare and Medicaid beneficiaries, aged/non-dual eligible Medicare and Medicaid beneficiaries) as calculated under paragraph (c)(1) of this section by the applicable proportion of the ACO's assigned beneficiary population (ESRD, disabled, aged/dual eligible Medicare and Medicaid beneficiaries, aged/non-dual eligible Medicare and Medicaid beneficiaries) for BY3 of the historical benchmark.

(ii) Sums the amounts determined in paragraph (e)(5)(i) of this section across the populations of beneficiaries (ESRD, disabled, aged/dual eligible Medicare and Medicaid beneficiaries, aged/non-dual eligible Medicare and Medicaid beneficiaries).

(iii) If the resulting sum is a net positive value, the ACO is considered to have lower spending compared to the ACO's regional service area. If the resulting sum is a net negative value, the ACO is considered to have higher spending compared to the ACO's regional service area.

(iv) If during the term of the agreement period CMS adjusts the ACO's benchmark, as specified in § 425.652(a)(9), CMS redetermines whether the ACO is considered to have lower spending or higher spending compared to the ACO's regional service area for purposes of determining the percentage in paragraphs (e)(1) through (3) of this section used in calculating the regional adjustment.

(f) *Special rules for determining the weights used in the regional adjustment calculation for a re-entering ACO.* For a re-entering ACO whose prior agreement period benchmark was calculated according to § 425.603(c), CMS determines the weight used in the regional adjustment calculation described in paragraphs (b) through (e) of this section by considering the agreement period the ACO is entering into according to § 425.600(f) in combination with either of the following—

(1) The weight previously applied to calculate the regional adjustment to the ACO's benchmark under

§ 425.603(c)(9) in its most recent prior agreement period; or

(2) For a new ACO identified as a reentering ACO, CMS considers the weight previously applied to calculate the regional adjustment to the benchmark under § 425.603(c)(9) in its most recent prior agreement period of the ACO in which the majority of the new ACO's participants were participating previously.

[87 FR 70246, Nov. 18, 2022, as amended at 88 FR 79550, Nov. 16, 2023]

§ 425.658 Calculating the prior savings adjustment to the historical benchmark.

(a) *General.* For agreement periods beginning on January 1, 2024, and in subsequent years, CMS calculates an adjustment to the historical benchmark to account for savings generated in the 3 years prior to the start of the ACO's current agreement period for renewing or re-entering ACOs that were reconciled for one or more performance years in the Shared Savings Program during this period.

(b) *Calculate average per capita savings amount.* (1) Calculate total per capita savings or losses for each performance year during the 3 years prior to the start of the ACO's current agreement period. CMS applies the following requirements in determining the amount of per capita savings or losses for each performance year:

(i) Per capita savings or losses will be set to zero for a performance year if the ACO was not reconciled for the performance year.

(ii) If an ACO generated savings for a performance year but was not eligible to receive a shared savings payment for that year due to noncompliance with the requirements of this part, per capita savings for that year will be set to zero.

(iii) For a new ACO identified as reentering ACO, per capita savings or losses will be determined based on the per capita savings or losses of the ACO in which the majority of the ACO's ACO participants were participating.

(2) Take the simple average of the per capita savings or losses calculated in paragraph (b)(1) of this section, including values of zero, if applicable.

(3) Determine the ACO's eligibility for the prior savings adjustment as follows:

(i) If the average per capita amount computed in paragraph (b)(2) of this section is less than or equal to zero, the ACO is not eligible to receive an adjustment for prior savings.

(ii) If the average per capita amount computed in paragraph (b)(2) of this section is positive, apply a proration factor to account for any upward growth in the ACO's assigned population in the benchmark years of the ACO's current agreement period as compared to the size of the assigned population when the ACO was reconciled for the corresponding performance years in its prior agreement period.

(c) *Calculate the per capita prior savings adjustment.* (1) If an ACO is eligible for the prior savings adjustment as determined in paragraph (b)(3) of this section, the prior savings adjustment will equal the lesser of the following:

(i) 50 percent of the pro-rated average per capita amount computed in paragraph (b)(3)(ii) of this section.

(ii) 5 percent of national per capita expenditures for Parts A and B services under the original Medicare fee-for-service program in BY3 for assignable beneficiaries identified for the 12-month calendar year corresponding to BY3 using data from the CMS Office of the Actuary and expressed as a single value by taking a person-year weighted average of the Medicare enrollment type-specific values.

(2) [Reserved]

(d) *Applicability of the prior savings adjustment.* CMS compares the per capita prior savings adjustment determined in paragraph (c)(1) of this section with the regional adjustment, expressed as a single value as described in § 425.656(d), and the HEBA as determined in § 425.662(b), if any, to determine the adjustment, if any, that will be applied to the ACO's benchmark in accordance with § 425.652(a)(8).

(e) *Recalculation of the prior savings adjustment during an agreement period.* (1) The ACO's prior savings adjustment is recalculated for changes to the ACO's savings or losses for a performance year used in the prior savings adjustment calculation in accordance

with § 425.316(b)(2)(ii)(B) or (C) due to compliance action to address avoidance of at-risk beneficiaries or as a result of issuance of a revised initial determination under § 425.315.

(2) For a new ACO identified as a reentering ACO, the prior savings adjustment is recalculated for changes to savings or losses for a performance year used in the prior savings adjustment calculation, if the savings or losses of the ACO in which the majority of the new ACO's participants were participating change in accordance with § 425.316(b)(2)(ii)(B) or (C) due to compliance action to address avoidance of at-risk beneficiaries or as a result of issuance of a revised initial determination under § 425.315.

[87 FR 70248, Nov. 18, 2022, as amended at 88 FR 79551, Nov. 16, 2023; 89 FR 98576, Dec. 9, 2024]

§ 425.659 Calculating risk scores used in Shared Savings Program benchmark calculations.

(a) *General.* CMS accounts for differences in severity and case mix of the ACO's assigned beneficiaries and assignable beneficiaries (as defined under § 425.20) in calculations used in establishing, adjusting, and updating the ACO's historical benchmark.

(b) *Prospective Hierarchical Condition Category (HCC) risk score calculation.* In determining Medicare FFS beneficiary prospective HCC risk scores for a performance year and each benchmark year of the ACO's agreement period, CMS does the following:

(1) CMS specifies the CMS–HCC risk adjustment methodology used to calculate prospective HCC risk scores for Medicare FFS beneficiaries (as defined under § 425.20) for use in Shared Savings Program calculations as follows:

(i) In calculating risk scores for Medicare FFS beneficiaries for a performance year, CMS applies the CMS–HCC risk adjustment methodology applicable for the corresponding calendar year.

(ii) For agreement periods beginning before January 1, 2024, CMS applies the CMS–HCC risk adjustment methodology for the calendar year corresponding to the benchmark year in calculating risk scores for Medicare FFS beneficiaries for each benchmark year of the agreement period.

(iii) For agreement periods beginning on January 1, 2024, and in subsequent years, CMS applies the CMS–HCC risk adjustment methodology for the calendar year corresponding to the performance year, as specified under paragraph (b)(1)(i) of this section, in calculating risk scores for Medicare FFS beneficiaries for each benchmark year of the agreement period.

(2) CMS does the following to calculate the prospective HCC risk scores identified in paragraph (b)(1) of this section for a benchmark or performance year:

(i) Removes the Medicare Advantage coding intensity adjustment, if applicable.

(ii) Renormalizes prospective HCC risk scores by Medicare enrollment type (ESRD, disabled, aged/dual eligible Medicare and Medicaid beneficiaries, and aged/non-dual eligible Medicare and Medicaid beneficiaries) based on the national assignable FFS population for the relevant benchmark or performance year.

(iii) Calculates the average prospective HCC risk score by Medicare enrollment type (ESRD, disabled, aged/dual eligible Medicare and Medicaid beneficiaries, and aged/non-dual eligible Medicare and Medicaid beneficiaries).

[88 FR 79551, Nov. 16, 2023]

§ 425.660 Accountable Care Prospective Trend (ACPT).

(a) *General.* For agreement periods beginning on January 1, 2024, and in subsequent years, CMS incorporates a fixed projected growth rate determined at the beginning of the ACO's agreement period called the Accountable Care Prospective Trend (ACPT) into the blended update factor described in § 425.652(b) when updating an ACO's benchmark for each performance year of the agreement period.

(b) *Determination of ACPT.* An ACPT is a flat dollar amount calculated using one or more annualized growth rates based on national fee-for-service Medicare expenditures projected by the CMS Office of the Actuary. In determining the ACPT for an enrollment type for each performance year, CMS does all of the following:

(1) Projects per capita growth in Parts A and B fee-for-service expenditures for benchmark year 3 (BY3) and each performance year of the ACO's agreement period. The calculation—

(i) Excludes IME and DSH payments, and the supplemental payment for IHS/Tribal hospitals and Puerto Rico hospitals; and

(ii) Makes separate expenditure calculations for each of the following populations of beneficiaries:

(A) ESRD.

(B) Aged/Disabled.

(2) Calculates one or more annualized growth rates for the population of beneficiaries described in paragraph (b)(1)(ii)(A) of this section (the ESRD ACPT) and one or more annualized growth rates for the population of beneficiaries described in paragraph (b)(1)(ii)(B) of this section (the Aged/Disabled ACPT). These annualized growth rates will remain fixed over the ACO's agreement period. The annualized growth rate is an annual rate of growth in projected expenditures during the ACO's 5-year agreement period relative to BY3, calculated as follows—

(i) Using a uniform annualized projected rate of growth over each of the 5 performance years of the 5-year agreement period; or

(ii) If annualization as specified in paragraph (b)(2)(i) of this section is determined not to reasonably fit the anticipated growth curve, CMS will apply an alternative annualization technique using two or more annualized growth rates reflecting the projected rates of growth during the 5 performance years comprising the 5-year agreement period.

(3) For each performance year, multiplies the applicable annualized growth rate described in paragraph (b)(2) of this section by BY3 truncated national per capita fee-for-service Medicare expenditures for assignable beneficiaries for each Medicare enrollment type (ESRD, disabled, aged/dual eligible Medicare and Medicaid beneficiaries, and aged/non-dual eligible Medicare and Medicaid beneficiaries) identified for the 12-month calendar year corresponding to BY3 to express the annualized growth rate as a flat dollar amount as follows:

(i) The ESRD ACPT is used for the ESRD population.

(ii) The Aged/Disabled ACPT is used for the following populations: disabled, aged/dual eligible Medicare and Medicaid beneficiaries, and aged/non-dual eligible Medicare and Medicaid beneficiaries.

(4) Adjusts the flat dollar amounts described in paragraph (b)(3) of this section for each performance year for differences in severity and case mix between the ACO's BY3 assigned beneficiary population and the national assignable FFS population for each Medicare enrollment type identified for the 12-month calendar year corresponding to BY3.

(5) Divides the risk adjusted flat dollar amounts described in paragraph (b)(4) of this section by the ACO's historical benchmark expenditures described in § 425.652(a) for each Medicare enrollment type to calculate the percent increase to be included in the blended update factor described in § 425.652(b)(4).

[87 FR 70248, Nov. 18, 2022]

§ 425.661 [Reserved]

§ 425.662 Calculating the health equity adjustment to the historical benchmark.

(a) *General.* For agreement periods beginning on January 1, 2025, and in subsequent years, CMS calculates a health equity adjustment to the historical benchmark (HEBA) to account for ACOs serving higher proportions of underserved beneficiaries.

(b) *Calculation of the health equity benchmark adjustment.* To calculate the adjustment described in paragraph (a) of this section, CMS does all of the following:

(1) Calculates the weighted average of the ACO's third benchmark year (BY3) national per capita expenditure amounts across the following populations of beneficiaries, where the weights are the ACO's BY3 proportion of assigned beneficiaries for that enrollment type:

(i) ESRD.

(ii) Disabled.

(iii) Aged/dual eligible Medicare and Medicaid beneficiaries.

(iv) Aged/non-dual eligible Medicare and Medicaid beneficiaries.

(2) Calculates the HEBA scaler as the difference between 5 percent of the national per capita expenditure amount, expressed as single value as calculated in paragraph (b)(1) of this section, and the higher of: the regional adjustment, expressed as a single value as described in § 425.656(d); the per capita prior savings adjustment determined in § 425.658(c); or no adjustment, in the case where the regional adjustment is negative and the ACO is not eligible for the prior savings adjustment under § 425.658(b)(3)(i).

(3) Determines the ACO's eligibility for the HEBA based on the proportion of the ACO's assigned beneficiaries for the performance year who are enrolled in the Medicare Part D low-income subsidy (LIS) or dually eligible for Medicare and Medicaid. An ACO is only eligible for the HEBA if this proportion is greater than or equal to 15 percent. An ACO with a proportion less than 15 percent is ineligible to receive a HEBA.

(4) Calculates the HEBA. If the ACO is eligible for the HEBA as determined in paragraph (b)(3) of this section, the HEBA is equal to the product of the HEBA scaler calculated in paragraph (b)(2) of this section and the proportion of the ACO's assigned beneficiaries for the performance year who are enrolled in the Medicare Part D LIS or dually eligible for Medicare and Medicaid.

(c) *Applicability of the HEBA.* CMS compares the HEBA determined in paragraph (b)(4) of this section with the regional adjustment, expressed as a single value as described in § 425.656(d), and the per capita prior savings adjustment determined in § 425.658(c), if any, to determine the adjustment, if any, that will be applied to the ACO's benchmark in accordance with § 425.652(a)(8)(ii).

[89 FR 98576, Dec. 9, 2024]

§ 425.663–425.669 [Reserved]

§ 425.670 Adjustments to mitigate the impact of significant, anomalous, and highly suspect billing activity on Shared Savings Program financial calculations involving calendar year 2023.

(a) *General.* This section describes adjustments CMS makes to Shared Savings Program calculations to mitigate the impact of significant, anomalous, and highly suspect billing activity occurring in calendar year 2023.

(b) *Significant, anomalous, and highly suspect billing activity for a HCPCS or CPT code impacting Shared Savings Program calculations.* CMS has determined that the billing of the following HCPCS codes represents significant, anomalous, and highly suspect billing activity for calendar year 2023 that warrants adjustment—

(1) A4352 (Intermittent urinary catheter; Coude (curved) tip, with or without coating (Teflon, silicone, silicone elastomeric, or hydrophilic, etc.), each); and

(2) A4353 (Intermittent urinary catheter, with insertion supplies).

(c) *Applicability of adjustments to performance year and benchmark year calculations.* Notwithstanding any other provision in this part, CMS adjusts the following Shared Savings Program calculations, as applicable, to exclude all Medicare Parts A and B fee-for-service payment amounts on DMEPOS claims (claim types 72 and 82) associated with a HCPCS code specified in paragraph (b) of this section for the period specified in paragraph (d) of this section:

(1) Calculation of Medicare Parts A and B fee-for-service expenditures for an ACO's assigned beneficiaries for all purposes including the following: Establishing, adjusting, updating, and resetting the ACO's historical benchmark and determining performance year expenditures.

(2) Calculation of fee-for-service expenditures for assignable beneficiaries as used in determining county-level fee-for-service expenditures and national Medicare fee-for-service expenditures, including the following calculations:

(i) Determining average county fee-for-service expenditures based on expenditures for the assignable population of beneficiaries in each county in the ACO's regional service area according to §§ 425.601(c) and 425.654(a) for purposes of calculating the ACO's regional fee-for-service expenditures.

(ii) Determining the 99th percentile of national Medicare fee-for-service expenditures for assignable beneficiaries for purposes of the following:

(A) Truncating assigned beneficiary expenditures used in calculating benchmark expenditures under § 425.652(a)(4), and performance year expenditures under §§ 425.605(a)(3) and 425.610(a)(4).

(B) Truncating expenditures for assignable beneficiaries in each county for purposes of determining county fee-for-service expenditures according to §§ 425.601(c)(3) and 425.654(a)(3).

(C) Truncating expenditures for assignable beneficiaries for purposes of determining truncated national per capita fee-for service expenditures for purposes of calculating the ACPT according to § 425.660(b)(3).

(iii) Determining truncated national per capita fee-for-service Medicare expenditures for assignable beneficiaries for purposes of calculating the ACPT according to § 425.660(b)(3).

(iv) Determining national per capita expenditures for Parts A and B services under the original Medicare fee-for-service program for assignable beneficiaries for purposes of capping the regional adjustment to the ACO's historical benchmark according to § 425.656(c)(3) and capping the prior savings adjustment according to § 425.658(c)(1)(ii).

(v) Determining national growth rates that are used as part of the blended growth rates used to trend forward BY1 and BY2 expenditures to BY3 according to § 425.652(a)(5)(ii) and as part of the blended growth rates used to update the benchmark according to §§ 425.601(b)(2) and 425.652(b)(2)(i).

(3) Calculation of Medicare Parts A and B fee-for-service revenue of ACO participants for purposes of calculating the ACO's loss recoupment limit under the BASIC track as specified in § 425.605(d).

(4) Calculation of total Medicare Parts A and B fee-for-service revenue of ACO participants and total Medicare Parts A and B fee-for-service expenditures for the ACO's assigned beneficiaries for purposes of identifying whether an ACO is a high revenue ACO or low revenue ACO, as defined under § 425.20, and determining an ACO's eligibility to receive advance investment payments according to § 425.630.

(5) Calculation or recalculation of the amount of the ACO's repayment mechanism arrangement according to § 425.204(f)(4).

(d) *Period of adjustment.* CMS adjusts the Shared Savings Program calculations specified in paragraph (c) of this section for significant, anomalous, and highly suspect billing activity identified pursuant to paragraph (b) of this section for calendar year 2023, when calendar year 2023 is either a performance year or a benchmark year.

(e) *Adjustments for growth rates used in calculating the ACPT.* In addition to adjustments described in paragraph (c) of this section, CMS makes adjustments for payments associated with a HCPCS code specified in paragraph (b) of this section for BY3 in projecting per capita growth in Parts A and B fee-for-service expenditures, according to § 425.660(b)(1), for purposes of calculating the ACPT for agreement periods beginning on January 1, 2024.

[89 FR 79171, Sept. 27, 2024]

§ 425.672 Adjustments to mitigate the impact of significant, anomalous, and highly suspect billing activity on Shared Savings Program financial calculations involving calendar year 2024 or subsequent calendar years.

(a) *General.* This section describes adjustments CMS may make to Shared Savings Program calculations to mitigate the impact of significant, anomalous, and highly suspect billing activity occurring in calendar year 2024 or subsequent calendar years.

(b) *Significant, anomalous, and highly suspect billing activity for a HCPCS or CPT code impacting Shared Savings Program calculations.* CMS, at its sole discretion, may determine that the billing of one or more specified HCPCS or CPT codes represents significant, anomalous, and highly suspect billing activity for a calendar year that warrants

adjustment to calculations made under this part.

(c) *Applicability of adjustments to performance year and benchmark year calculations.* Notwithstanding any other provision in this part, CMS adjusts the following Shared Savings Program calculations, as applicable, to exclude all Medicare Parts A and B fee-for-service payment amounts on claims for the specified claim types associated with a HCPCS or CPT code identified pursuant to paragraph (b) of this section for the periods identified in paragraph (d) of this section:

(1) Calculation of Medicare Parts A and B fee-for-service expenditures for an ACO's assigned beneficiaries for all purposes including the following: Establishing, adjusting, updating, and resetting the ACO's historical benchmark and determining performance year expenditures.

(2) Calculation of fee-for-service expenditures for assignable beneficiaries as used in determining county-level fee-for-service expenditures and national Medicare fee-for-service expenditures, including the following calculations:

(i) Determining average county fee-for-service expenditures based on expenditures for the assignable population of beneficiaries in each county in the ACO's regional service area according to §§ 425.601(c) and 425.654(a) for purposes of calculating the ACO's regional fee-for-service expenditures.

(ii) Determining the 99th percentile of national Medicare fee-for-service expenditures for assignable beneficiaries for purposes of the following:

(A) Truncating assigned beneficiary expenditures used in calculating benchmark expenditures under §§ 425.601(a)(4) and 425.652(a)(4), and performance year expenditures under §§ 425.605(a)(3) and 425.610(a)(4).

(B) Truncating expenditures for assignable beneficiaries in each county for purposes of determining county fee-for-service expenditures according to §§ 425.601(c)(3) and 425.654(a)(3).

(C) Truncating expenditures for assignable beneficiaries for purposes of determining truncated national per capita fee-for service expenditures for purposes of calculating the ACPT according to § 425.660(b)(3).

(iii) Determining truncated national per capita fee-for-service Medicare expenditures for assignable beneficiaries for purposes of calculating the ACPT according to § 425.660(b)(3).

(iv) Determining national per capita expenditures for Parts A and B services under the original Medicare fee-for-service program for assignable beneficiaries for purposes of capping the regional adjustment to the ACO's historical benchmark according to §§ 425.601(a)(8)(ii)(C) and 425.656(c)(3), capping the prior savings adjustment according to § 425.658(c)(1)(ii), capping the prepaid shared savings multiplier according to § 425.640(f)(2)(v), and calculating the HEBA scaler according to § 425.662(b)(2).

(v) Determining national growth rates that are used as part of the blended growth rates used to trend forward BY1 and BY2 expenditures to BY3 according to §§ 425.601(a)(5)(ii) and 425.652(a)(5)(ii) and as part of the blended growth rates used to update the benchmark according to §§ 425.601(b)(2) and 425.652(b)(2)(i).

(3) Calculation of Medicare Parts A and B fee-for-service revenue of ACO participants for purposes of calculating the ACO's loss recoupment limit under the BASIC track as specified in § 425.605(d).

(4) Calculation of total Medicare Parts A and B fee-for-service revenue of ACO participants and total Medicare Parts A and B fee-for-service expenditures for the ACO's assigned beneficiaries for purposes of identifying whether an ACO is a high revenue ACO or low revenue ACO, as defined under § 425.20, determining an ACO's eligibility to receive advance investment payments according to § 425.630, and determining whether an ACO qualifies for a shared savings payment under § 425.605(h).

(5) Calculation or recalculation of the amount of the ACO's repayment mechanism arrangement according to § 425.204(f)(4).

(d) *Periods of adjustment.* CMS adjusts the Shared Savings Program calculations identified in paragraph (c) of this section for significant, anomalous, and highly suspect billing activity identified for calendar year 2024 or subsequent calendar years as follows:

(1) The calendar year for which the significant, anomalous, and highly suspect billing activity was identified pursuant to paragraph (b) of this section, when it is either a performance year or a benchmark year.

(2) The 3 most recent years prior to the start of the ACO's agreement period used in establishing the historical benchmark, when such a benchmark is used to reconcile the ACO for a performance year adjusted in accordance with paragraph (d)(1) of this section.

(e) *Adjustments for growth rates used in calculating the ACPT.* In addition to adjustments described in paragraph (c) of this section, CMS makes adjustments for payments associated with a HCPCS or CPT code identified pursuant to paragraph (b) of this section for any calendar year corresponding to BY3 in projecting per capita growth in Parts A and B fee-for-service expenditures, according to § 425.660(b)(1), for purposes of calculating the ACPT for agreement periods beginning on January 1, 2024, and in subsequent years.

[89 FR 98576, Dec. 9, 2024]

§ 425.674 Accounting for the impact of improper payments on Shared Savings Program financial calculations.

(a) *General rule.* Upon the reopening of an initial determination pursuant to § 425.315(a)(4), CMS will use the methodology specified in this section to account for the impact of improper payments when:

(1) Determining savings or losses for the relevant performance year in accordance with § 425.315 in order to issue a revised initial determination.

(2) Adjusting the benchmark by recalculating benchmark year expenditures under §§ 425.601(a)(9)(iii) and 425.652(a)(9)(viii) in the event that CMS recalculates a payment determination and issues a revised initial determination for the corresponding performance year in a prior agreement period, in accordance with paragraph (a)(1) of this section.

(b) *Improper payment.* For the purpose of this section, improper payment includes:

(1) An amount associated with a demanded overpayment determination.

(2) An amount identified in a settlement agreement or judgment, pursuant to conduct by individuals or entities performing functions or services related to an ACO's activities, less any penalties or damages.

(c) *Accounting for improper payments.* To adjust Medicare Parts A and B fee-for-service expenditures for improper payments CMS does the following:

(1) Identify each Shared Savings Program expenditure calculation for a performance year or benchmark year, as calculated according to the standard methodology described in this subpart and expressed as a per capita dollar amount, that will be adjusted for the impact of improper payments.

(2) Determine each specific population of Medicare fee-for-service beneficiaries used to calculate the expenditure amount identified in paragraph (c)(1) of this section. The populations relevant for a specific expenditure calculation may include:

(i) The population of beneficiaries assigned to the ACO for calculating the ACO's performance year or benchmark year expenditures.

(ii) The population of assignable beneficiaries in each county in the ACO's regional service area for calculating county-level expenditures.

(iii) The national population of assignable beneficiaries for calculating national assignable expenditures.

(iv) The national population of Medicare fee-for-service beneficiaries for calculating national expenditures.

(3) Determine the per capita amount of improper payments for the performance year or benchmark year included in the per capita Medicare Parts A and B fee-for-service expenditure amount for a population identified in paragraph (c)(2) of this section in accordance with paragraph (d) of this section for all providers or suppliers with identified improper payments.

(4) Subtract the per capita amount determined in paragraph (c)(3) of this section from the expenditure calculation identified in paragraph (c)(1) of this section for the population identified in paragraph (c)(2) of this section for each of the following populations of beneficiaries:

(i) ESRD.

(ii) Disabled.

(iii) Aged/dual eligible Medicare and Medicaid beneficiaries.

(iv) Aged/non-dual eligible Medicare and Medicaid beneficiaries.

(5) If applicable, CMS will do the following to adjust regional expenditures for improper payments:

(i) Adjust county-level fee-for-service expenditures determined under paragraph (c)(4) of this section, for each county in the ACO's regional service area, for severity and case mix of assignable beneficiaries in the county using prospective HCC risk scores. This calculation is made for each of the populations of beneficiaries identified in paragraphs (c)(4)(i) through (iv) of this section.

(ii) Weight the risk adjusted county-level fee-for-service expenditures determined under paragraph (c)(5)(i) of this section according to the ACO's proportion of assigned beneficiaries in the county, determined in accordance with § 425.601(d)(1), § 425.603(f)(1), or § 425.654(b)(1), as applicable, for each of the populations of beneficiaries identified in paragraphs (c)(4)(i) through (iv) of this section.

(iii) Aggregate the values determined in paragraph (c)(5)(ii) of this section for each of the populations of beneficiaries identified in paragraphs (c)(4)(i) through (iv) of this section across all counties within the ACO's regional service area.

(d) *Determining the per capita amount of improper payments.* CMS may use one or more of the following approaches to determine the per capita amount that will be used to adjust expenditure calculations identified in paragraph (c)(1) of this section:

(1) Calculate aggregate improper payments attributable to a population identified in paragraph (c)(2) of this section for each provider or supplier that had improper payments.

(i) For improper payments associated with specific claims, CMS will do the following:

(A) For improper payments to a provider or supplier that correspond to payment amounts on claims or line items that were used in a Shared Savings Program calculation identified in paragraph (c)(1) of this section, and subsequently adjusted after the 3-month claims run out period, CMS will sum the improper payment amounts across all such claims or line items with dates of service during the period used to calculate performance year or benchmark year expenditures for the population identified in paragraph (c)(2) of this section.

(B) In the event CMS determines it is necessary to account for the impact of improper payments on Shared Savings Program financial calculations by adjusting the payment amounts for a specific HCPCS or CPT code billed by the provider or supplier for the population identified in paragraph (c)(2) of this section, CMS will do the following—

(*1*) Identify the applicable claims or line items with dates of service during the period used to calculate performance year or benchmark year expenditures processed before the end of the applicable 3-month claims run out period;

(*2*) Sum the claim or line item payment amounts, on the claims or line items identified in paragraph (d)(1)(i)(B)(*1*) of this section; and

(*3*) If applicable, multiply the sum calculated in paragraph (d)(1)(i)(B)(*2*) of this section by a scaling factor to compute the payment differential between the HCPCS or CPT code that was improperly billed and a CMS-identified alternate code.

(ii) For aggregate improper payment amounts that are not linked to specific claims or line items, CMS will calculate the amount attributable to the population identified in paragraph (c)(2) of this section by applying a proration factor to the aggregate improper payment amount identified for that provider or supplier. CMS calculates the proration factor as follows:

(A) The denominator of the proration factor is total Medicare Parts A and B claim or line item payment amounts to the provider or supplier for all fee-for-service beneficiaries on claims of specified claim types for the time period associated with the aggregate improper payment amount identified for the provider or supplier that were made before the end of the applicable 3-month claims run out period.

(B) The numerator of the proration factor is the portion of the total from the denominator, in paragraph (d)(1)(ii)(A) of this section, that CMS determines is attributable to the population identified in paragraph (c)(2) of

this section with dates of service during the period used to calculate expenditures for the applicable performance year or benchmark year.

(2) Sum the amounts calculated pursuant to paragraph (d)(1) of this section attributable to a population identified in paragraph (c)(2) of this section across all providers or suppliers that had identified improper payments.

(3) Take the lesser of the following two values—

(i) The sum from paragraph (d)(2) of this section; or

(ii) Total Medicare Parts A and B claim or line item payment amounts to all providers or suppliers that had improper payments for the population identified in paragraph (c)(2) of this section on claims of specified claim types with dates of service within the performance year or benchmark year made before the end of the applicable 3-month claims run out period.

(4) Express the lesser-of amount from paragraph (d)(3) of this section as a per capita value by dividing by the total beneficiary person years in the population identified in paragraph (c)(2) of this section for the applicable performance year or the benchmark year.

[89 FR 98577, Dec. 9, 2024]

Subpart H—Data Sharing With ACOs

§ 425.700 General rules.

(a) CMS shares aggregate reports with the ACO.

(b) CMS shares beneficiary identifiable data with ACOs on the condition that the ACO, its ACO participants, ACO providers/suppliers, and other individuals or entities performing functions or services related to the ACO's activities observe all relevant statutory and regulatory provisions regarding the appropriate use of data and the confidentiality and privacy of individually identifiable health information and comply with the terms of the data use agreement described in this subpart.

(c) The ACO must not limit or restrict appropriate sharing of medical record data with providers and suppliers both within and outside the ACO in accordance with applicable law.

§ 425.702 Aggregate reports.

CMS shares aggregate reports with ACOs as follows:

(a) Aggregate reports are shared at the start of the agreement period based on beneficiary claims data used to calculate the benchmark, and each quarter thereafter during the agreement period.

(b) These aggregate reports include, when available, the following information, deidentified in accordance with 45 CFR 164.514(b):

(1) Aggregated metrics on the assigned beneficiary population.

(2) Utilization and expenditure data at the start of the agreement period based on historical beneficiaries used to calculate the benchmark.

(c)(1)(i) For performance years 2012 through 2015, at the beginning of the agreement period, during each quarter (and in conjunction with the annual reconciliation), and at the beginning of each performance year, CMS, upon the ACO's request for the data for purposes of population-based activities relating to improving health or reducing growth in health care costs, process development, case management, and care coordination, will provide the ACO with information regarding preliminarily prospectively assigned beneficiaries whose data was used to generate the aggregate data reports under paragraphs (a) and (b) of this section. The information includes the following:

(A) Beneficiary name.

(B) Date of birth.

(C) HICN.

(D) Sex.

(ii) For performance year 2016 and subsequent performance years, at the beginning of the agreement period, during each quarter (and in conjunction with the annual reconciliation), and at the beginning of each performance year, CMS, upon the ACO's request for the data for purposes of population-based activities relating to improving health or reducing growth in health care costs, protocol development, case management, and care coordination, provides the ACO with information about its fee-for-service population.

(A) For an ACO participating under preliminary prospective assignment with retrospective reconciliation as

specified under § 425.400(a)(2), the following information is made available regarding preliminarily prospectively assigned beneficiaries and beneficiaries that received a primary care service during the previous 12 months from one of the ACO participants that submits claims for primary care services used to determine the ACO's assigned population under subpart E of this part:

(*1*) Beneficiary name.

(*2*) Date of birth.

(*3*) Beneficiary identifier.

(*4*) Sex.

(B) For an ACO participating under preliminary prospective assignment with retrospective reconciliation as specified under § 425.400(a)(2), information in the following categories, which represents the minimum data necessary for ACOs to conduct health care operations work, is made available regarding preliminarily prospectively assigned beneficiaries:

(*1*) Demographic data such as enrollment status.

(*2*) Health status information such as risk profile and chronic condition subgroup.

(*3*) Utilization rates of Medicare services such as the use of evaluation and management, hospital, emergency, and post-acute services, including the dates and place of service.

(*4*) Expenditure information related to utilization of services.

(C) The information under paragraphs (c)(1)(ii)(A) and (B) of this section is made available to ACOs participating under prospective assignment as specified under § 425.400(a)(3), but is limited to the ACO's prospectively assigned beneficiaries.

(iii) For performance year 2024 and subsequent performance years, CMS, upon the ACO's request for the data for purposes of population-based activities relating to improving health or reducing growth in health care costs, protocol development, case management, and care coordination, provides the ACO with information about its fee-for-service population.

(A) The following information is made available to ACOs regarding beneficiaries eligible for Medicare CQMs as defined at § 425.20:

(*1*) Beneficiary name.

(*2*) Date of birth.

(*3*) Beneficiary identifier.

(*4*) Sex.

(B) Information in the following categories, which represents the minimum data necessary for ACOs to conduct health care operations work, is made available to ACOs regarding beneficiaries eligible for Medicare CQMs as defined at § 425.20:

(*1*) Demographic data such as enrollment status.

(*2*) Health status information such as risk profile and chronic condition subgroup.

(*3*) Utilization rates of Medicare services such as the use of evaluation and management, hospital, emergency, and post-acute services, including the dates and place of service.

(2) In its request for these data, the ACO must certify that it is seeking the following information:

(i) As a HIPAA-covered entity, and the request reflects the minimum data necessary for the ACO to conduct its own health care operations work that falls within the first or second paragraph of the definition of health care operations at 45 CFR 164.501.

(ii) As the business associate of its ACO participants and ACO providers/suppliers, who are HIPAA-covered entities, and the request reflects the minimum data necessary for the ACO to conduct health care operations work that falls within the first or second paragraph of the definition of health care operations at 45 CFR 164.501 on behalf of those participants.

(iii) As an organized health care arrangement (as defined at 45 CFR 160.103), and the request reflects the minimum data necessary for the ACO to conduct health care operations work that falls within the first or second paragraph of the definition of health care operations at 45 CFR 164.501 on behalf of the organized health care arrangement.

(d) For an ACO eligible to be reconciled under § 425.609(b), CMS shares with the ACO quarterly aggregate reports as provided in paragraphs (b) and (c)(1)(ii) of this section for CY 2019.

[76 FR 67973, Nov. 2, 2011, as amended at 80 FR 32844, June 9, 2015; 83 FR 60096, Nov. 23, 2018; 83 FR 68081, Dec. 31, 2018; 87 FR 70249, Nov. 18, 2022; 88 FR 79551, Nov. 16, 2023]

§ 425.704 Beneficiary-identifiable claims data.

Subject to providing the beneficiary with the opportunity to decline data sharing as described in this § 425.708, and subject to having a valid DUA in place, CMS, upon the ACO's request for the data for purposes of evaluating the performance of its ACO participants or its ACO providers/suppliers, conducting quality assessment and improvement activities, and conducting population-based activities relating to improved health, will provide the ACO with beneficiary identifiable claims data for preliminarily prospectively and prospectively assigned beneficiaries and other beneficiaries who receive primary care services from an ACO participant that submits claims for primary care services used to determine the ACO's assigned population under subpart E of this part during the performance year.

(a) If an ACO wishes to receive beneficiary identifiable claims data, it must sign a DUA and it must submit a formal request for data. ACOs may access requested data as often as once per month.

(b) The ACO must certify that it is requesting claims data about any of the following:

(1) Its own patients, as a HIPAA-covered entity, and the request reflects the minimum data necessary for the ACO to conduct its own health care operations work that falls within the first or second paragraph of the definition of health care operations at 45 CFR 164.501.

(2) The patients of its HIPAA-covered entity ACO participants or its ACO providers/suppliers as the business associate of these HIPAA covered entities, and the request reflects the minimum data necessary for the ACO to conduct health care operations work that falls within the first or second paragraph of the definition of health care operations at 45 CFR 164.501 on behalf of those participants.

(3) The patients of the organized health care arrangement (as defined at 45 CFR 160.103) in which the ACO is participating with its ACO participants and ACO providers/suppliers, and the request reflects the minimum data necessary for the ACO to conduct health care operations work that falls within the first or second paragraph of the definition of health care operations at 45 CFR 164.501 on behalf of the organized health care arrangement.

(c) The use of identifiers and claims data will be limited to developing processes and engaging in appropriate activities related to coordinating care and improving the quality and efficiency of care that are applied uniformly to all Medicare beneficiaries with primary care services at the ACO, and that these data will not be used to reduce, limit or restrict care for specific beneficiaries.

(d) To ensure that beneficiaries have a meaningful opportunity to decline having their claims data shared with the ACO, the ACO may only request claims data about a beneficiary if—

(1) For an ACO participating under—

(i) Preliminary prospective assignment with retrospective reconciliation as specified under § 425.400(a)(2), the beneficiary's name appears on the preliminary prospective assignment list provided to the ACO at the beginning of the performance year, during each quarter (and in conjunction with the annual reconciliation) or the beneficiary has received a primary care service from an ACO participant upon whom assignment is based (under subpart E of this part) during the most recent 12-month period; or

(ii) Prospective assignment as specified under § 425.400(a)(3), the beneficiary's name appears on the prospective assignment list provided to the ACO at the beginning of the performance year.

(2) The beneficiary has been notified in compliance with § 425.708 that the ACO has requested access to beneficiary identifiable claims data in order to improve the quality of care that is furnished to the beneficiary and, where applicable, coordinate care offered to the beneficiary; and

(3) The beneficiary did not exercise the opportunity to decline having his/her claims data shared with the ACO as provided in § 425.708.

(e) At the ACO's request, CMS continues to provide ACOs with updates to the requested beneficiary identifiable claims data, subject to beneficiary's opportunity to decline data sharing under § 425.708.

(f) If an ACO requests beneficiary identifiable information, compliance with the terms of the data use agreement described in § 425.710 is a condition of an ACO's participation in the Shared Savings Program.

[76 FR 67973, Nov. 2, 2011, as amended at 80 FR 32844, June 9, 2015; 83 FR 68082, Dec. 31, 2018; 87 FR 70249, Nov. 18, 2022]

§ 425.706 Minimum necessary data.

(a) ACOs must limit their identifiable data requests to the minimum necessary to accomplish a permitted use of the data. The minimum necessary Parts A and B data elements may include but are not limited to the following data elements:

(1) Beneficiary ID.
(2) Procedure code.
(3) Gender.
(4) Diagnosis code.
(5) Claim ID.
(6) The from and through dates of service.
(7) The provider or supplier ID.
(8) The claim payment type.
(9) Date of birth and death, if applicable.
(10) TIN.
(11) NPI.

(b) The minimum necessary Part D data elements may include but are not limited to the following data elements:

(1) Beneficiary ID.
(2) Prescriber ID.
(3) Drug service date.
(4) Drug product service ID.
(5) Quantity dispensed.
(6) Days supplied.
(7) Brand name.
(8) Generic name.
(9) Drug strength.
(10) TIN.
(11) NPI.
(12) Indication if on formulary.
(13) Gross drug cost.

§ 425.708 Beneficiaries may decline claims data sharing.

(a) Beneficiaries must receive notification about the Shared Savings Program and the opportunity to decline claims data sharing and instructions on how to inform CMS directly of their preference.

(1) FFS beneficiaries are notified about the opportunity to decline claims data sharing through CMS materials such as the Medicare & You Handbook and through the notifications required under § 425.312.

(2) The notifications provided under § 425.312 must state that the ACO may have requested beneficiary identifiable claims data about the beneficiary for purposes of its care coordination and quality improvement work, and inform the beneficiary how to decline having his or her claims information shared with the ACO in the form and manner specified by CMS.

(3) Beneficiary requests to decline claims data sharing will remain in effect unless and until a beneficiary subsequently contacts CMS to amend that request to permit claims data sharing with ACOs.

(b) The opportunity to decline having claims data shared with an ACO under paragraph (a) of this section does not apply to the information that CMS provides to ACOs under § 425.702(c).

(c) In accordance with 42 U.S.C. 290dd–2 and the implementing regulations at 42 CFR part 2, CMS does not share beneficiary identifiable claims data relating to the diagnosis and treatment of alcohol and substance abuse without the explicit written consent of the beneficiary.

(d) The provisions of this section relate only to the sharing of Medicare claims data between the Medicare program and the ACO under the Shared Savings Program and are in no way intended to impede existing or future data sharing under other authorities.

[76 FR 67973, Nov. 2, 2011, as amended at 80 FR 32840, June 9, 2015]

§ 425.710 Data use agreement.

(a)(1) Before receiving any beneficiary identifiable data, ACOs must enter into a DUA with CMS. Under the DUA, the ACO must comply with the limitations on use and disclosure that are imposed by HIPAA, the applicable DUA, and the statutory and regulatory requirements of the Shared Savings Program.

(2) If the ACO misuses or discloses data in a manner that violates any applicable statutory or regulatory requirements or that is otherwise noncompliant with the provisions of the DUA, it will no longer be eligible to receive data under subpart H of this part,

may be terminated from the Shared Savings Program under § 425.218, and may be subject to additional sanctions and penalties available under the law.

(b) [Reserved]

Subpart I—Reconsideration Review Process

§ 425.800 Preclusion of administrative and judicial review.

(a) There is no reconsideration, appeal, or other administrative or judicial review of the following determinations under this part:

(1) The specification of quality and performance standards under §§ 425.500, 425.502, 425.510, and 425.512.

(2) The assessment of the quality of care furnished by an ACO under the performance standards established in § 425.502 or § 425.512, as applicable.

(3) The assignment of Medicare fee-for-service beneficiaries under Subpart E of this part.

(4) The initial determination or revised initial determination of whether an ACO is eligible for shared savings, and the amount of such shared savings, including the initial determination or revised initial determination of the estimated average per capita Medicare expenditures under the ACO for Medicare fee-for-service beneficiaries assigned to the ACO and the average benchmark for the ACO in accordance with section 1899(d) of the Act, as implemented under §§ 425.601, 425.602, 425.603, 425.604, 425.605, 425.606, 425.610, and 425.652.

(5) The percent of shared savings specified by the Secretary and the limit on the total amount of shared savings established under §§ 425.604, 425.605, 425.606, and 425.610.

(6) The termination of an ACO for failure to meet the quality performance standards established under § 425.502 or § 425.512, as applicable.

(7) The termination of a beneficiary incentive program established under § 425.304(c).

(b) [Reserved]

[76 FR 67973, Nov. 2, 2011, as amended at 81 FR 38017, June 10, 2016; 83 FR 68082, Dec. 31, 2018; 85 FR 85044, Dec. 28, 2020; 87 FR 70249, Nov. 18, 2022]

§ 425.802 Request for review.

(a) An ACO may appeal an initial determination that is not prohibited from administrative or judicial review under § 425.800 by requesting a reconsideration review by a CMS reconsideration official.

(1) An ACO that wants to request reconsideration review by a CMS reconsideration official must submit a written request by an authorized official for receipt by CMS within 15 days of the notice of the initial determination.

(i) If the 15th day is a weekend or a Federal holiday, then the timeframe is extended until the end of the next business day.

(ii) Failure to submit a request for reconsideration within 15 days will result in denial of the request for reconsideration.

(2) The reconsideration review must be held on the record (review of submitted documentation).

(b) An ACO that requests a reconsideration review for termination will remain operational throughout the review process.

[76 FR 67973, Nov. 2, 2011, as amended at 80 FR 32845, June 9, 2015]

§ 425.804 Reconsideration review process.

(a) *Acknowledgement of reconsideration review request.* The reconsideration official sends an acknowledgement of the reconsideration review request to the ACO and CMS that includes the following:

(1) Review procedures.

(2) Procedures for submission of evidence including format and timelines.

(3) A briefing schedule that permits each party to submit only one written brief, including any evidence, for consideration by the reconsideration official in support of the party's position. The submission of any additional briefs or supplemental evidence will be at the sole discretion of the reconsideration official.

(b) *Burden of proof, standard of proof, and standards of review.* The burden of proof is on the ACO to demonstrate to the reconsideration official with convincing evidence that the initial determination is not consistent with the requirements of this part or applicable statutory authority.

(c) *Reconsideration official.* The reconsideration official is an independent CMS official who did not participate in the initial determination that is being reviewed.

(d) *Evidence.* (1) The reconsideration official's review will be based only on evidence submitted by the reconsideration official's requested deadline, unless otherwise requested by the reconsideration official.

(2) Documentation submitted for the record as evidence cannot be documentation that was not previously submitted to CMS by the applicable deadline and in the requested format.

(3) All evidence submitted by the ACO and CMS, in preparation for the reconsideration review will be shared with the other party to the hearing.

(e) The reconsideration official will notify CMS and the ACO of his or her recommendation.

[76 FR 67973, Nov. 2, 2011, as amended at 80 FR 32845, June 9, 2015]

§ 425.806 On-the-record review of reconsideration official's recommendation by independent CMS official.

(a)(1) If CMS or the ACO disagrees with the recommendation of the reconsideration official, it may request an on the record review of the initial determination and recommendation by an independent CMS official who was not involved in the initial determination or the reconsideration review process.

(2) In order to request an on-the-record review, CMS or the ACO must submit an explanation of why it disagrees with the recommendation by the timeframe and in the format indicated in the reconsideration official's recommendation letter.

(b) The on-the-record review process is based only on evidence presented during the reconsideration review.

(c) The independent CMS official considers the recommendation of the reconsideration official and makes a final agency determination.

§ 425.808 Effect of independent CMS official's decision.

(a) The decision of the independent CMS official is final and binding.

(b) The reconsideration review process under this subpart must not be construed to negate, diminish, or otherwise alter the applicability of existing laws, rules, and regulations or determinations made by other government agencies.

§ 425.810 Effective date of decision.

(a) If the initial determination denying an ACO's application to participate in the Shared Savings Program is upheld, the application will remain denied based on the effective date of the original notice of denial.

(b) If the initial determination to terminate an agreement with an ACO is upheld, the decision to terminate the agreement is effective as of the date indicated in the initial notice of termination.

(c) If the initial determination to terminate an ACO is reversed, the ACO is reinstated into the Shared Savings Program, retroactively back to the original date of termination.

PART 426—REVIEW OF NATIONAL COVERAGE DETERMINATIONS AND LOCAL COVERAGE DETERMINATIONS

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AUTHORITY: Secs. 1102 and 1871 of the Social Security Act (42 U.S.C. 1302 and 1395hh)

SOURCE: 68 FR 63716, Nov. 7, 2003, unless otherwise noted.

Subpart A—General Provisions

§ 426.100 Basis and scope.

(a) *Basis.* This part implements sections 1869(f)(1) and (f)(2) of the Act, which provide for the review of LCDs, NCDs, and certain determinations that are deemed to be NCDs by statute.

(b) *Scope.* This subpart establishes the requirements and procedures for the review of LCDs and NCDs.

§ 426.110 Definitions.

For the purposes of this part, the following definitions apply:

Aggrieved party means a Medicare beneficiary, or the estate of a Medicare beneficiary, who—

(1) Is entitled to benefits under Part A, enrolled under Part B, or both (including an individual enrolled in fee-for-service Medicare, in a Medicare + Choice plan, or in another Medicare managed care plan);

(2) Is in need of coverage for a service that is denied based on an applicable LCD (in the relevant jurisdiction) or an NCD, regardless of whether the service was received; and

(3) Has obtained documentation of the need by the beneficiary's treating physician.

Board means the Departmental Appeals Board.

Clinical and scientific experts mean experts that are consulted by the ALJ or Board as independent and impartial individuals, with significant experience and/or published work, pertaining to the subject of the review.

Contractor means a carrier (including a Durable Medical Equipment Regional Carrier), or a fiscal intermediary (including a Regional Home Health Intermediary) that has jurisdiction for the LCD at issue.

Deemed NCD means a determination that the Secretary makes, in response to a request for an NCD under section 1869(f)(4)(B) and (C) of the Act, that no national coverage or noncoverage determination is appropriate, or the Secretary's failure to meet the deadline under section 1869(f)(4)(A)(iv) of the Act.

New evidence means clinical or scientific evidence that was not previously considered by the contractor or CMS before the LCD or NCD was issued.

Party means an aggrieved party, which is an individual, or estate who has a right to participate in the LCD or NCD review process, and, as appropriate, a contractor or CMS.

Proprietary data and *Privileged information* means information from a source external to CMS or a contractor, or protected health information, that meets the following criteria:

(1) It is ordinarily protected from disclosure in accordance with 45 CFR part 164, under the Trade Secrets Act (18 U.S.C. 1905) or under Exemptions 4 or 5 of the Freedom of Information Act (5 U.S.C. 552) as specified in 45 CFR 5.31(d) and (e).

(2) The party who possesses the right to protection of the information from public release or disclosure has not provided its consent to the public release or disclosure of the information. Any information submitted by the public that is not marked proprietary is not considered proprietary.

Reasonableness standard means the standard that an ALJ or the Board must apply when conducting an LCD or an NCD review. In determining whether LCDs or NCDs are valid, the adjudicator must uphold a challenged policy (or a provision or provisions of a challenged policy) if the findings of fact, interpretations of law, and applications of fact to law by the contractor or CMS are reasonable based on the LCD or NCD record and the relevant record developed before the ALJ or the Board.

Supplemental LCD/NCD record is a record that the contractor/CMS provides to the ALJ/Board and any aggrieved party and consists of all materials received and considered during a reconsideration. Materials that are already in the record before the ALJ/Board (for example, new evidence presented in the taking of evidence or hearing) need not be provided but may be incorporated by reference in the supplement to the LCD/NCD record. The contractor/CMS may provide statements, evidence, or other submissions to the ALJ/Board during the proceedings, as provided elsewhere in these regulations, but these submissions are not considered as supplementing the LCD/NCD record.

Treating physician means the physician who is the beneficiary's primary clinician with responsibility for overseeing the beneficiary's care and either approving or providing the service at issue in the challenge.

[68 FR 63716, Nov. 7, 2003, as amended at 85 FR 72909, Nov. 16, 2020]

§ 426.120 Calculation of deadlines.

In counting days, Saturdays, Sundays, and Federal holidays are included. If a due date falls on a Saturday, Sunday, or Federal holiday, the due date is the next Federal working day.

§ 426.130 Party submissions.

Any party submitting material, except for material for which a privilege is asserted, or proprietary data, to the ALJ or the Board after that party's initial challenge must serve the material on all other parties at the same time.

Subpart B [Reserved]

Subpart C—General Provisions for the Review of LCDs and NCDs

§ 426.300 Review of LCDs, NCDs, and deemed NCDs.

(a) Upon the receipt of an acceptable LCD complaint as described in § 426.400, an ALJ conducts a review of a challenged provision (or provisions) of an LCD using the reasonableness standard.

(b) Upon the receipt of an acceptable NCD complaint as described in § 426.500, the Board conducts an NCD review of a challenged provision (or provisions) of an NCD using the reasonableness standard.

(c) The procedures established in this part governing the review of NCDs also apply in cases in which a deemed NCD is challenged.

§ 426.310 LCD and NCD reviews and individual claim appeals.

(a) LCD and NCD reviews are distinct from the claims appeal processes set forth in part 405, subparts G and H; part 417, subpart Q; and part 422, subpart M of this chapter.

(b) An aggrieved party must notify the ALJ or the Board, as appropriate, regarding the submission and disposition of any pending claim or appeal relating to the subject of the aggrieved party's LCD or NCD complaint. This reporting obligation continues through the entire LCD or NCD review process.

§ 426.320 Who may challenge an LCD or NCD.

(a) Only an aggrieved party may initiate a review of an LCD or NCD (including a deemed NCD), or provisions of an LCD or NCD by filing an acceptable complaint.

(b) Neither an ALJ nor the Board recognizes as valid any attempt to assign rights to request review under section 1869(f) of the Act.

§ 426.325 What may be challenged.

(a) Only LCDs or NCDs (including deemed NCDs) that are currently effective may be challenged.

(b) Some items are not reviewable under this part, including the following:

(1) Pre-decisional materials, including—

(i) Draft LCDs;

(ii) Template LCDs or suggested LCDs; and

(iii) Draft NCDs, including national coverage decision memoranda.

(2) Retired LCDs or withdrawn NCDs.

(3) LCD or NCD provisions that are no longer in effect due to revisions or reconsiderations.

(4) Interpretive policies that are not an LCD or NCD.

(5) Contractor decisions that are not based on section 1862(a)(1)(A) of the Act.

(6) Contractor claims processing edits.

(7) Payment amounts or methodologies.

(8) Procedure coding issues, including determinations, methodologies, definitions, or provisions.

(9) Contractor bulletin articles, educational materials, or Web site frequently asked questions.

(10) Any M + C organization or managed care plan policy, rule, or procedure.

(11) An individual claim determination.

(12) Any other policy that is not an LCD or an NCD as set forth in § 400.202 of this chapter.

§ 426.330 Burden of proof.

During an LCD or NCD review, an aggrieved party bears the burden of proof and the burden of persuasion for the

issue(s) raised in a complaint. The burden of persuasion is judged by a preponderance of the evidence.

§ 426.340 Procedures for review of new evidence.

(a) The process for review of new evidence is initiated once the ALJ/Board completes the taking of evidence.

(b) If an aggrieved party has submitted new evidence pertaining to the LCD/NCD provision(s) in question, and the ALJ or the Board finds that evidence admissible, the ALJ or the Board reviews the record as a whole and decide whether the new evidence has the potential to significantly affect the ALJ's or the Board's evaluation of the LCD/NCD provision(s) in question under the reasonableness standard.

(c) If the ALJ or the Board determines that the new evidence does not have the potential to significantly affect the ALJ's or the Board's evaluation of the LCD/NCD provision(s) in question under the reasonableness standard, this evidence is included in the review record, and the review goes forward to a decision on the merits.

(d) If the ALJ or the Board determines that the new evidence has the potential to significantly affect the ALJ's or the Board's evaluation of the LCD or NCD provision(s) in question under the reasonableness standard, then the ALJ or the Board—

(1) Stays the proceedings and ensures that the contractor or CMS, whichever is appropriate, has a copy of the new evidence for its examination; and

(2) Allows the contractor/CMS 10 days, generally, to examine the new evidence, and to decide whether the contractor or CMS initiates a reconsideration.

(e) If the contractor or CMS informs the ALJ or the Board by the end of the 10 days that a reconsideration is initiated, and then the ALJ or the Board—

(1) Continues the stay in proceedings; and

(2) Sets a reasonable timeframe—

(i) For LCDs, of not more than 90 days, by which the contractor completes the reconsideration; or

(ii) For NCDs, in compliance with the timeframes specified in section 1862(1) of the Act, by which CMS completes the reconsideration.

(f) The ALJ or Board lifts the stay in proceedings and continues the review on the challenged provision(s) of the original LCD or NCD, including the new evidence in the review record, if the contractor or CMS—

(1) Informs the ALJ or Board that a reconsideration is not initiated; or

(2) Does not meet—

(i) For LCDs, the 90-day reconsideration timeframe; or

(ii) For NCDs, the reconsideration timeframe specified by the Board, in compliance with section 1862(l) of the Act.

(g) If an LCD or NCD is reconsidered and revised within the timeframe allotted by the ALJ or Board, then the revised LCD or NCD and any supplement to the LCD or NCD record is forwarded to the ALJ or the Board and all parties and the review proceeds on the LCD or NCD.

[68 FR 63716, Nov. 7, 2003, as amended at 70 FR 70335, Nov. 21, 2005; 71 FR 9461, Feb. 24, 2006]

Subpart D—Review of an LCD

§ 426.400 Procedure for filing an acceptable complaint concerning a provision (or provisions) of an LCD.

(a) *The complaint.* An aggrieved party may initiate a review of an LCD by filing a written complaint with the office designated by CMS on the Medicare Web site, *http://www.medicare.gov/coverage/static/appeals.asp.*

(b) *Timeliness of a complaint.* An LCD complaint is not considered timely unless it is filed with the office designated by CMS within—

(1) 6 months of the issuance of a written statement from each aggrieved party's treating practitioner, in the case of aggrieved parties who choose to file an LCD challenge before receiving the service; or

(2) 120 days of the initial denial notice, in the case of aggrieved parties who choose to file an LCD challenge after receiving the service.

(c) *Components of a valid complaint.* A complaint must include the following:

(1) *Beneficiary-identifying information:*

(i) Name.

(ii) Mailing address.

(iii) State of residence, if different from mailing address.

(iv) Telephone number, if any.

(v) Health Insurance Claim number, if applicable.

(vi) E-mail address, if applicable.

(2) *If the beneficiary has a representative,* the representative-identifying information must include the following:

(i) Name.

(ii) Mailing address.

(iii) Telephone number.

(iv) E-mail address, if any.

(v) Copy of the written authorization to represent the beneficiary.

(3) *Treating physician written statement.* A copy of a written statement from the treating physician that the beneficiary needs the service that is the subject of the LCD. This statement may be in the form of a written order for the service or other documentation from the beneficiary's medical record (such as progress notes or discharge summary) indicating that the beneficiary needs the service.

(4) *LCD-identifying information:*

(i) Name of the contractor using the LCD.

(ii) Title of LCD being challenged.

(iii) The specific provision (or provisions) of the LCD adversely affecting the aggrieved party.

(5) *Aggrieved party statement.* A statement from the aggrieved party explaining what service is needed and why the aggrieved party thinks that the provision(s) of the LCD is (are) not valid under the reasonableness standard.

(6) *Clinical or scientific evidence.* (i) Copies of clinical or scientific evidence that support the complaint and an explanation for why the aggrieved party thinks that this evidence shows that the LCD is not reasonable.

(ii) Any documents or portions of documents that include proprietary data must be marked ''proprietary data,'' and include a legal basis for that assertion.

(iii) Proprietary data submitted by a manufacturer concerning a drug or device for which the manufacturer has submitted information to the Food and Drug Administration, must be considered and given substantive weight only when supported by an affidavit certifying that the submission contains true and correct copies of all data submitted by the manufacturer to the Food and Drug Administration in relation to that drug or device.

(d) *Joint complaints*—(1) *Conditions for a joint complaint.* Two or more aggrieved parties may initiate the review of an LCD by filing a single written complaint with the ALJ if all of the following conditions are met:

(i) Each aggrieved party named in the joint complaint has a similar medical condition or there are other bases for combining the complaints.

(ii) Each aggrieved party named in the joint complaint is filing the complaint in regard to the same provision(s) of the same LCD.

(2) *Components of a valid joint complaint.* A joint complaint must contain the following information:

(i) The beneficiary-identifying information described in paragraph (c)(1) of this section for each aggrieved party named in the joint complaint.

(ii) The LCD-identifying information described in paragraph (c)(2) of this section.

(iii) The documentation described in paragraphs (c)(3) and (c)(4) of this section.

(3) *Timeliness of a joint complaint.* Aggrieved parties, who choose to seek review of an LCD—

(i) Before receiving the service, must file with the ALJ a joint complaint within 6 months of the written statement from each aggrieved party's treating physician.

(ii) After receiving the service, must file with the ALJ a complaint within 120 days of each aggrieved party's initial denial notice.

§ 426.403 Submitting new evidence once an acceptable complaint is filed.

Once an acceptable complaint is filed, the aggrieved party may submit additional new evidence without withdrawing the complaint until the ALJ closes the record.

§ 426.405 Authority of the ALJ.

(a) An ALJ conducts a fair and impartial hearing, avoids unnecessary delay, maintains order, and ensures that all proceedings are recorded.

(b) An ALJ defers only to reasonable findings of fact, reasonable interpretations of law, and reasonable applications of fact to law by the Secretary.

(c) The ALJ has the authority to do any of the following:

(1) Review complaints by an aggrieved party (or aggrieved parties).

(2) Dismiss complaints that fail to comply with § 426.400.

(3) Set and change the date, time, and place of a hearing upon reasonable notice to the parties.

(4) Continue or recess a hearing for a reasonable period of time.

(5) Hold conferences to identify or simplify the issues, or to consider other matters that may aid in the expeditious disposition of the proceeding.

(6) Consult with scientific and clinical experts on his or her own motion concerning clinical or scientific evidence.

(7) Set schedules for submission of exhibits and written reports of experts.

(8) Administer oaths and affirmations.

(9) Examine witnesses.

(10) Issue subpoenas requiring the attendance of witnesses at hearings as permitted by this part.

(11) Issue subpoenas requiring the production of existing documents before, and relating to, the hearing as permitted by this part.

(12) Rule on motions and other procedural matters.

(13) Stay the proceedings in accordance with § 426.340.

(14) Regulate the scope and timing of documentary discovery as permitted by this part.

(15) Regulate the course of a hearing and the conduct of representatives, parties, and witnesses.

(16) Receive, rule on, exclude, or limit evidence, as provided in § 426.340.

(17) Take official notice of facts, upon motion of a party.

(18) Decide cases, upon the motion of a party, by summary judgment when there is no disputed issue of material fact.

(19) Conduct any conference, argument, or hearing in person or, upon agreement of the parties, by telephone, picture-tel, or any other means.

(20) Issue decisions.

(21) Exclude a party from an LCD review for failure to comply with an ALJ order or procedural request without good cause shown.

(22) Stay the proceedings for a reasonable time when all parties voluntarily agree to mediation or negotiation, and provide mediation services upon request.

(d) The ALJ does not have authority to do any of the following under this part:

(1) Conduct an LCD review or conduct LCD hearings on his or her own motion or on the motion of a non-aggrieved party.

(2) Issue a decision based on any new evidence without following § 426.340, regarding procedures for review of new evidence.

(3) Review any decisions by contractors to develop a new or revised LCD.

(4) Conduct a review of any draft, retired, archived, template, or suggested LCDs.

(5) Conduct a review of any policy that is not an LCD, as defined in § 400.202 of this chapter.

(6) Conduct a review of any NCD according to section 1869(f)(1)(A)(i) of the Act.

(7) Conduct a review of the merits of an unacceptable LCD complaint as discussed in § 426.410.

(8) Allow participation by individuals or entities other than—

(i) The aggrieved party and/or his/her representative;

(ii) CMS and/or the contractor; and

(iii) Experts called by the parties or the ALJ.

(9) Compel the parties to participate in a mediation process or to engage in settlement negotiations.

(10) Deny a request for withdrawal of a complaint by an aggrieved party.

(11) Compel the contractor to conduct studies, surveys, or develop new information to support an LCD record.

(12) Deny a contractor the right to reconsider, revise or retire an LCD.

(13) Find invalid applicable Federal statutes, regulations, rulings, or NCDs.

(14) Enter a decision specifying terms to be included in an LCD.

§ 426.406 *Ex parte* contacts.

No party or person (except employees of the ALJ's office) communicates in

any way with the ALJ on any substantive matter at issue in a case, unless on notice and opportunity for all parties to participate. This provision does not prohibit a person or party from inquiring about the status of a case or asking routine questions concerning administrative functions or procedures.

§ 426.410 Docketing and evaluating the acceptability of LCD complaints.

(a) *Docketing the complaint.* The office designated by CMS does the following upon receiving a complaint regarding an LCD:

(1) Dockets the complaint.

(2) Determines whether the complaint is—

(i) The first challenge to a particular LCD; or

(ii) Related to a pending LCD review.

(3) Forwards the complaint to the ALJ that conducts the review. In cases related to pending reviews, the complaint generally is forwarded to the ALJ who is conducting the review.

(b) *Evaluating the acceptability of the complaint.* The ALJ assigned to the LCD review determines if the complaint is acceptable by confirming all of the following:

(1) The complaint is being submitted by an aggrieved party or, in the case of a joint complaint, that each individual named in the joint complaint is an aggrieved party. (In determining if a complaint is acceptable, the ALJ assumes that the facts alleged by the treating physician's documentation regarding the aggrieved party's (or parties') clinical condition are true.)

(2) The complaint meets the requirements for a valid complaint in § 426.400 and does not challenge one of the documents in § 426.325(b).

(c) *Unacceptable complaint.* (1) If the ALJ determines that the complaint is unacceptable, the ALJ must provide the aggrieved party (or parties) one opportunity to amend the unacceptable complaint.

(2) If the aggrieved party (or parties) fail(s) to submit an acceptable amended complaint within a reasonable timeframe as determined by the ALJ, the ALJ must issue a decision dismissing the unacceptable complaint.

(3) If a complaint is determined unacceptable after one amendment, the beneficiary is precluded from filing again for 6 months after being informed that it is unacceptable.

(d) *Acceptable complaint.* If the ALJ determines that the complaint (or amended complaint) is acceptable, the ALJ does the following:

(1) Sends a letter to the aggrieved party (or parties) acknowledging the complaint and informing the aggrieved party (or parties) of the docket number and the deadline for the contractor to produce the LCD record.

(2) Forwards a copy of the complaint, any evidence submitted in the complaint, and the letter described in paragraph (d)(1) of this section to the applicable contractor and CMS.

(3) Requires CMS or the contractor to send a copy of the LCD record to the ALJ and all parties to the LCD review within 30 days of receiving the ALJ's letter, the copy of the complaint, and any associated evidence, subject to extension for good cause shown.

(e) *Consolidation of complaints regarding an LCD*—(1) *Criteria for consolidation.* If a review is pending regarding a particular LCD provision(s) and no decision has been issued ending the review, and a new acceptable complaint is filed, the ALJ consolidates the complaints and conducts a consolidated LCD review if all of the following criteria are met:

(i) The complaints are in regard to the same provision(s) of the same LCD or there are other bases for consolidating the complaints.

(ii) The complaints contain common questions of law, common questions of fact, or both.

(iii) Consolidating the complaints does not unduly delay the ALJ's decision.

(2) *Decision to consolidate complaints.* If an ALJ decides to consolidate complaints, the ALJ does the following:

(i) Provides notification that the LCD review is consolidated and informs all parties of the docket number of the consolidated review.

(ii) Makes a single record of the proceeding.

(iii) Considers the relevant evidence introduced in each LCD complaint as introduced in the consolidated review.

(3) *Decision not to consolidate complaints.* If an ALJ decides not to consolidate complaints, the ALJ conducts separate LCD reviews for each complaint.

[68 FR 63716, Nov. 7, 2003; 68 FR 65346, Nov. 19, 2003]

§ 426.415 CMS' role in the LCD review.

CMS may provide to the ALJ, and all parties to the LCD review, information identifying the person who represents the contractor or CMS, if necessary, in the LCD review process.

§ 426.416 Role of Medicare Managed Care Organizations (MCOs) and State agencies in the LCD review.

Medicare MCOs and Medicaid State agencies have no role in the LCD review process. However, once the ALJ has issued its decision, the decision is made available to all Medicare MCOs and State agencies.

§ 426.417 Contractor's statement regarding new evidence.

(a) The contractor may review any new evidence that is submitted, regardless of whether the ALJ has stayed the proceedings, including but not limited to—

(1) New evidence submitted with the initial complaint;

(2) New evidence submitted with an amended complaint;

(3) New evidence produced during discovery;

(4) New evidence produced when the ALJ consults with scientific and clinical experts; and

(5) New evidence presented during any hearing.

(b) The contractor may submit a statement regarding whether the new evidence is significant under § 426.340, within such deadline as the ALJ may set.

§ 426.418 LCD record furnished to aggrieved party.

(a) *Elements of a contractor's LCD record furnished to the aggrieved party.* Except as provided in paragraph (b) of this section, the contractor's LCD record consists of any document or material that the contractor considered during the development of the LCD, including, but not limited to, the following:

(1) The LCD being challenged.

(2) Any medical evidence considered on or before the date the LCD was issued, including, but not limited to, the following:

(i) Scientific articles.

(ii) Technology assessments.

(iii) Clinical guidelines.

(iv) Statements from clinical experts, medical textbooks, claims data, or other indication of medical standard of practice.

(3) Comment and Response Document (a summary of comments received by the contractor concerning the draft LCD).

(4) An index of documents considered that are excluded under paragraph (b) of this section.

(b) *Elements of the LCD record not furnished to the aggrieved party.* The LCD record furnished to the aggrieved party does not include the following:

(1) Proprietary data or privileged information.

(2) Any new evidence.

§ 426.419 LCD record furnished to the ALJ.

The LCD record furnished to the ALJ includes the following:

(a) Documents included in § 426.418(a).

(b) Privileged information and proprietary data considered that must be filed with the ALJ under seal.

§ 426.420 Retiring or revising an LCD under review.

(a) A contractor may retire an LCD or LCD provision under review before the date the ALJ issues a decision regarding that LCD. Retiring an LCD or LCD provision under review has the same effect as a decision under § 426.460(b).

(b) A contractor may revise an LCD under review to remove or amend the LCD provision listed in the complaint through the reconsideration process before the date the ALJ issues a decision regarding that LCD. Revising an LCD under review to remove the LCD provision in question has the same effect as a decision under § 426.460(b).

(c) A contractor must notify the ALJ within 48 hours of—

(1) Retiring an LCD or LCD provision that is under review; or

(2) Issuing a revised version of the LCD that is under review.

(d) If the contractor issues a revised LCD, the contractor forwards a copy of the revised LCD to the ALJ.

(e) The ALJ must take the following actions upon receiving a notice that the contractor has retired or revised an LCD under review:

(1) If, before the ALJ issues a decision, the ALJ receives notice that the contractor has retired the LCD or revised the LCD to completely remove the provision in question, the ALJ must dismiss the complaint and inform the aggrieved party(ies) who sought the review that he or she or they receive individual claim review without the retired/withdrawn provision(s).

(2) If, before the ALJ issues a decision, the ALJ receives notice that the contractor has revised the LCD provision in question but has not removed it altogether, the ALJ must continue the review based on the revised LCD. In this case, the contractor must send a copy of the supplemental record to the ALJ and all parties. In that circumstance, the ALJ permits the aggrieved party to respond to the revised LCD and supplemental record.

§ 426.423 Withdrawing a complaint regarding an LCD under review.

(a) *Circumstance under which an aggrieved party may withdraw a complaint regarding an LCD.* An aggrieved party who filed a complaint regarding an LCD may withdraw the complaint before the ALJ issues a decision regarding that LCD. The aggrieved party may not file another complaint concerning the same coverage determination for 6 months.

(b) *Process for an aggrieved party withdrawing a complaint regarding an LCD.* To withdraw a complaint regarding an LCD, the aggrieved party who filed the complaint must send a written withdrawal notice to the ALJ (see § 426.400), CMS (if applicable), and the applicable contractor. Supplementing an acceptable complaint with new evidence does not constitute a withdrawal of a complaint, as described in § 426.403.

(c) *Actions the ALJ must take upon receiving a notice announcing the intent to withdraw a complaint regarding an LCD*—(1) *LCD reviews involving one aggrieved party.* If the ALJ receives a withdrawal notice regarding an LCD before the date the ALJ issued a decision regarding that LCD, the ALJ issues a decision dismissing the complaint under § 426.444 and informs the aggrieved party that he or she may not file another complaint to the same coverage determination for 6 months.

(2) *LCD reviews involving joint complaints.* If the ALJ receives a notice from an aggrieved party who is named in a joint complaint withdrawing a complaint regarding an LCD before the date the ALJ issued a decision regarding that LCD, the ALJ issues a decision dismissing only that aggrieved party from the complaint under § 426.444. The ALJ continues the LCD review if there is one or more aggrieved party who does not withdraw from the joint complaint.

(3) *Consolidated LCD reviews.* If the ALJ receives a notice from an aggrieved party who is part of a consolidated LCD review withdrawing a complaint regarding an LCD before the date the ALJ issued a decision regarding that LCD, the ALJ removes that aggrieved party from the consolidated LCD review and issues a decision dismissing that aggrieved party's complaint under § 426.444. The ALJ continues the LCD review if there are one or more aggrieved parties who does not withdraw from the joint complaint.

§ 426.425 LCD review.

(a) *Opportunity for the aggrieved party, after his or her review of the LCD record, to state why the LCD is not valid.* Upon receipt of the contractor's LCD record, the aggrieved party files a statement explaining why the contractor's LCD record is not complete, or not adequate to support the validity of the LCD under the reasonableness standard. This statement must be submitted to the ALJ and to the contractor, or CMS, as appropriate, within 30 days (or within the additional time as allowed by the ALJ for good cause shown) of the date the aggrieved party receives the contractor's LCD record.

(b) *Contractor response.* The contractor has 30 days after receiving the aggrieved party's statement to submit

a response to the ALJ in order to defend the LCD.

(c) *ALJ evaluation.* (1) After the aggrieved party files a statement and the contractor responds, as described in § 426.425(a) and § 426.425(b), or the time for filing has expired, the ALJ applies the reasonableness standard to determine whether the LCD record is complete and adequate to support the validity of the LCD.

(2) Issuance of a decision finding the record complete and adequate to support the validity of the LCD ends the review process.

(3) If the ALJ determines that the LCD record is not complete and adequate to support the validity of the LCD, the ALJ permits discovery and the taking of evidence in accordance with §§ 426.432 and 426.440 and evaluates the LCD in accordance with § 426.431.

(d) The process described in paragraphs (a), (b), and (c) of this section applies when an LCD record has been supplemented, except that discovery and the taking of evidence are not repeated. The period for the aggrieved party to file a statement begins when the aggrieved party receives the supplement.

§ 426.431 ALJ's review of the LCD to apply the reasonableness standard.

(a) *Required steps.* To review the provision(s) listed in the aggrieved party's complaint based on the reasonableness standard, an ALJ must:

(1) Confine the LCD review to the provision(s) of the LCD raised in the aggrieved party's complaint.

(2) Conduct a hearing, unless the matter can be decided on the written record.

(3) Close the LCD review record to the taking of evidence.

(4) Treat as precedential any previous Board decision under § 426.482 that involves the same LCD provison(s), same specific issue and facts in question, and the same clinical conditions.

(5) Issue a decision as described in § 426.447.

(b) *Optional steps.* The ALJ may do the following to apply the reasonableness standard to the provision(s) listed in the aggrieved party's complaint:

(1) Consult with appropriate scientific or clinical experts concerning evidence.

(2) Consider any previous ALJ decision made under § 426.447 regarding the same provision(s) of the LCD under review and for the same clinical conditions.

(c) *Authority for ALJs in LCD reviews when applying the reasonableness standard.* In applying the reasonableness standard to a provision (or provisions) of an LCD, the ALJ must follow all applicable laws, regulations, rulings, and NCDs.

§ 426.432 Discovery.

(a) *General rule.* If the ALJ orders discovery, the ALJ must establish a reasonable timeframe for discovery.

(b) *Protective order*—(1) *Request for a protective order.* Any party receiving a discovery request may file a motion for a protective order before the date of production of the discovery.

(2) *The ALJ granting of a protective order.* The ALJ may grant a motion for a protective order if (s)he finds that the discovery sought—

(i) Is irrelevant or unduly repetitive;

(ii) Is unduly costly or burdensome; or

(iii) Unduly delays the proceeding.

(c) *Types of discovery available.* A party may obtain discovery via a request for the production of documents, and/or via the submission of up to 10 written interrogatory questions, relating to a specific LCD.

(d) *Types of documents.* For the purpose of this section, the term ''documents'' includes relevant information, reports, answers, records, accounts, papers, and other data and documentary evidence. Nothing contained in this section is interpreted to require the creation of a document.

(e) *Types of discovery not available.* Requests for admissions, depositions, or any other forms of discovery, other than those permitted under paragraph (c) of this section, are not authorized.

(f) *Privileged information and proprietary data.* The ALJ must not, under any circumstance, order the disclosure of privileged information or proprietary data filed under seal without the consent of the party who possesses the right to protection of the information.

(g) *Notification.* The ALJ notifies all parties in writing when the discovery period closes.

§ 426.435 Subpoenas.

(a) *Purpose of a subpoena.* A subpoena requires the attendance of an individual at a hearing and may also require a party to produce evidence authorized under § 426.440 at or before the hearing.

(b) *Filing a motion for a subpoena.* A party seeking a subpoena must file a written motion with the ALJ not less than 30 days before the date fixed for the hearing. The motion must do all of the following:

(1) Designate the witnesses.

(2) Specify any evidence to be produced.

(3) Describe the address and location with sufficient particularity to permit the witnesses to be found.

(4) State the pertinent facts that the party expects to establish by the witnesses or documents and whether other evidence may establish without the use of a subpoena.

(c) *Response to a motion for a subpoena.* Within 15 days after the written motion requesting issuance of a subpoena is served on all parties, any party may file an opposition to the motion or other response.

(d) *Extension for good cause shown.* The ALJ may modify the deadlines specified in paragraphs (b) and (c) of this section for good cause shown.

(e) *Motion for a subpoena granted.* If the ALJ grants a motion requesting issuance of a subpoena, the subpoena must do the following:

(1) Be issued in the name of the ALJ.

(2) Include the docket number and title of the LCD under review.

(3) Provide notice that the subpoena is issued according to sections 1872 and 205(d) and (e) of the Act.

(4) Specify the time and place at which the witness is to appear and any evidence the witness is to produce.

(f) *Delivery of the subpoena.* The party seeking the subpoena serves it by personal delivery to the individual named, or by certified mail return receipt requested, addressed to the individual at his or her last dwelling place or principal place of business.

(g) *Motion to quash a subpoena.* The individual to whom the subpoena is directed may file with the ALJ a motion to quash the subpoena within 10 days after service.

(h) *Refusal to obey a subpoena.* The exclusive remedy for contumacy by, or refusal to obey, a subpoena duly served upon any person is specified in section 205(e) of the Act (42 U.S.C. 405(e)) except that any reference to the ''Commissioner of Social Security'' shall be considered a reference to the ''Secretary.''

§ 426.440 Evidence.

(a) Except as provided in this part, the ALJ is not bound by the Federal Rules of Evidence. However, the ALJ may apply the Federal Rules of Evidence when appropriate, for example, to exclude unreliable evidence.

(b) The ALJ must exclude evidence that (s)he determines is clearly irrelevant, immaterial, or unduly repetitive.

(c) The ALJ may accept privileged information or proprietary data, but must maintain it under seal.

(d) The ALJ may permit the parties to introduce the testimony of expert witnesses on scientific and clinical issues, rebuttal witnesses, and other relevant evidence. The ALJ may require that the testimony of expert witnesses be submitted in the form of a written report, accompanied by the curriculum vitae of the expert preparing the report.

(e) Experts submitting reports must be available for cross-examination at an evidentiary hearing upon request of the ALJ or a party to the proceeding, or the reports will be excluded from the record.

(f) Except as set forth in paragraph (c) of this section or unless otherwise ordered by the ALJ for good cause shown, all documents and other evidence offered or taken for the record are open to examination by all parties.

§ 426.444 Dismissals for cause.

(a) The ALJ may, at the request of any party, or on his or her own motion, dismiss a complaint if the aggrieved party fails to do either of the following:

(1) Attend or participate in a pre-hearing conference (the pre-hearing

may be conducted by telephone) or hearing without good cause shown.

(2) Comply with a lawful order of the ALJ without good cause shown.

(b) The ALJ must dismiss any complaint concerning LCD provision(s) if the following conditions exist:

(1) The ALJ does not have the authority to rule on that provision under § 426.405(d).

(2) The complaint is not timely. (See § 426.400(b).)

(3) The complaint is not filed by an aggrieved party.

(4) The complaint is filed by an individual who fails to provide an adequate statement of need for the service from the treating physician.

(5) The complaint challenges a provision or provisions of an NCD. (See § 426.405, regarding the authority of the ALJ.)

(6) The contractor notifies the ALJ that the LCD provision(s) is (are) no longer in effect.

(7) The aggrieved party withdraws the complaint. (See § 426.423 for requirements related to withdrawing a complaint regarding an LCD under review.)

§ 426.445 Witness fees.

(a) A witness testifying at a hearing before an ALJ receives the same fees and mileage as witnesses in Federal district courts of the United States. If the witness qualifies as an expert, he or she is entitled to an expert witness fee. Witness fees are paid by the party seeking to present the witness.

(b) If an ALJ requests expert testimony, the appropriate office overseeing the ALJ is responsible for paying all applicable fees and mileage, unless the expert waives payment.

§ 426.446 Record of hearing.

The ALJ must ensure that all hearings are open to the public and are electronically, mechanically or stenographically reported. Except for privileged information and proprietary data that are filed under seal, all evidence upon which the ALJ relies for decision must be admitted into the public record. All medical reports, exhibits, and any other pertinent document, either in whole or in material part, must be offered, marked for identification, and retained in the case record.

§ 426.447 Issuance and notification of an ALJ's decision.

An ALJ must issue to all parties to the LCD review, within 90 days of closing the LCD review record to the taking of evidence, one of the following:

(a) A written decision, including a description of appeal rights.

(b) A written notification stating that a decision is pending, and an approximate date of issuance for the decision.

§ 426.450 Mandatory provisions of an ALJ's decision.

(a) *Findings.* An ALJ's decision must include one of the following:

(1) A determination that the provision of the LCD is valid under the reasonableness standard.

(2) A determination that the provision of the LCD is not valid under the reasonableness standard.

(3) A statement dismissing the complaint regarding the LCD and a rationale for the dismissal.

(4) A determination that the LCD record is complete and adequate to support the validity of the LCD provisions under the reasonableness standard.

(b) *Other information.* An ALJ's decision must include all of the following:

(1) The date of issuance.

(2) The docket number of the LCD review.

(3) A statement as to whether the aggrieved party has filed a claim for the service(s) named in the complaint, the date(s)-of-service, and the disposition, if known.

(4) A basis for concluding that the LCD was or was not valid based on the application of the reasonableness standard to the record before the ALJ, including the contractor's:

(i) Findings of fact.

(ii) Interpretations of law.

(iii) Applications of fact to law.

(5) A summary of the evidence reviewed. If proprietary or privileged data were submitted under seal, the decision must state whether the data were material and what role they played in the determination, but without disclosing the substance or contents of the evidence under seal. A separate statement of the rationale for the ALJ's treatment of the sealed evidence must be prepared and kept under

seal itself. If the ALJ decision is appealed to the Board, this statement must be provided to the Board under seal.

(6) A statement regarding appeal rights.

§ 426.455 Prohibited provisions of an ALJ's decision.

An ALJ's decision may not do any of the following:

(a) Order CMS or its contractors to add any language to a provision or provisions of an LCD.

(b) Order CMS or its contractors to pay a specific claim.

(c) Set a time limit for CMS or its contractors to establish a new or revised LCD.

(d) Review or evaluate an LCD other than the LCD under review.

(e) Include a requirement for CMS or its contractors that specifies payment, coding, or systems changes for an LCD, or deadlines for implementing these types of changes.

(f) Order or address how a contractor(s) must implement an LCD.

§ 426.457 Optional provisions of an ALJ's decision.

When appropriate, the ALJ may limit a decision holding invalid a specific provision(s) of an LCD to specific clinical indications and for similar conditions.

§ 426.458 ALJ's LCD review record.

(a) *Elements of the ALJ's LCD review record furnished to the public.* Except as provided in paragraph (b) of this section, the ALJ's LCD review record consists of any document or material that the ALJ compiled or considered during the LCD review, including, but not limited to, the following:

(1) The LCD complaint.

(2) The LCD and LCD record.

(3) The supplemental LCD record, if applicable.

(4) Transcripts of record.

(5) Any other relevant evidence gathered under § 426.440.

(6) The ALJ's decision.

(b) *Elements of the ALJ's LCD review record furnished to the Board under seal.* The ALJ's review record must include, under seal, any proprietary data or privileged information maintained under seal, and such data or information must not be included in the review record furnished to the public.

§ 426.460 Effect of an ALJ's decision.

(a) *Valid under the reasonableness standard.* If the ALJ finds that the provision or provisions of the LCD named in the complaint is (are) valid under the reasonableness standard, the aggrieved party or parties may appeal that (those) part(s) of the ALJ decision to the Board under § 426.465.

(b) *Not valid under the reasonableness standard.* If the ALJ finds that the provision or provisions of the LCD named in the complaint is (are) invalid under the reasonableness standard, and no appeal is filed by the contractor or CMS under § 426.465(b), the contractor, the M + C organization, or other Medicare managed care organization must provide the following—

(1) *Individual claim review.* (i) If neither the contractor nor CMS appeals the ALJ decision under § 426.425(b), and if the party's claim or appeal(s) was previously denied, the contractor, an M + C organization or another Medicare managed care organization must reopen the claim of the party who challenged the LCD and adjudicate the claim without using the provision(s) of the LCD that the ALJ found invalid.

(ii) If a revised LCD is issued, the contractor, the M + C organization, and any other Medicare managed care organization within the contractor's jurisdiction uses the revised LCD in reviewing claim or appeal submissions or request for services delivered or services performed on or after the effective date of the revised LCD.

(iii) If the aggrieved party who sought the review has not yet submitted a claim, the contractor adjudicates the claim without using the provision(s) of the LCD that the ALJ found invalid.

(iv) In either case, the claim and any subsequent claims for the service provided under the same circumstances is adjudicated without using the LCD provision(s) found invalid.

(2) *Coverage determination relief.* If neither the contractor nor CMS appeals the ALJ decision under § 426.425(b), the

contractor implements the ALJ decision within 30 days. Any change in policy applies prospectively to requests for service or claims filed with dates of service after the implementation of the ALJ decision.

§ 426.462 Notice of an ALJ's decision.

After the ALJ has made a decision regarding an LCD complaint, the ALJ sends a written notice of the decision to each party. The notice must—

(a) State the outcome of the review; and

(b) Inform each party to the determination of his or her rights to seek further review if he or she is dissatisfied with the determination, and the time limit under which an appeal must be requested.

§ 426.463 Future new or revised LCDs.

The contractor may not reinstate an LCD provision(s) found to be unreasonable unless the contractor has a different basis (such as additional evidence) than what the ALJ evaluated.

§ 426.465 Appealing part or all of an ALJ's decision.

(a) *Circumstances under which an aggrieved party may appeal part or all of an ALJ's decision.* An aggrieved party (including one or more aggrieved parties named in a joint complaint and an aggrieved party who is part of a consolidated LCD review) may appeal to the Board any part of an ALJ's decision that does the following:

(1) States that a provision of an LCD is valid under the reasonableness standard; or

(2) Dismisses a complaint regarding an LCD (except as prohibited in paragraph (b) of this section).

(b) *Circumstance under which a contractor or CMS may appeal part or all of an ALJ's decision.* A contractor or CMS may appeal to the Board any part of an ALJ's decision that states that a provision (or provisions) of an LCD is (are) unreasonable.

(c) *Stay of an implementation pending appeal.* (1) If an ALJ's decision finds a provision or provisions of an LCD unreasonable, an appeal by a contractor or CMS stays implementation as described under § 426.460(b) until the Board issues a final decision.

(2) The appeal request must be submitted to the Board in accordance with paragraph (e) of this section.

(d) *Circumstances under which an ALJ's decision may not be appealed.* An ALJ's decision dismissing a complaint is not subject to appeal in either of the following circumstances:

(1) The contractor has retired the LCD provision(s) under review.

(2) The aggrieved party who filed the complaint has withdrawn the complaint.

(e) *Receipt of the appeal by the Board.* Unless there is good cause shown, an appeal described in paragraphs (a) or (b) of this section must be filed with the Board within 30 days of the date the ALJ's decision was issued.

(f) *Filing an appeal.* (1) To file an appeal described in paragraph (a) of this section, an aggrieved party, who sought LCD review, a contractor, or CMS must send the following to the Board:

(i) The full names and addresses of the parties, including the name of the LCD.

(ii) The date of issuance of the ALJ's decision.

(iii) The docket number that appears on the ALJ's decision.

(iv) A statement identifying the part(s) of the ALJ's decision that are being appealed.

(2) If an appeal described in paragraph (a) of this section is filed with the Board later than the date described in paragraph (c) of this section, it must include a rationale stating why the Board must accept the late appeal.

(3) An appeal described in paragraph (a) of this section must include a statement explaining why the ALJ's decision should be reversed.

§ 426.468 Decision to not appeal an ALJ's decision.

(a) Failure to timely appeal without good cause shown waives the right to challenge any part(s) of the ALJ's decision under § 426.465.

(b) Unless the Board finds good cause shown for late filing, an untimely appeal is dismissed.

(c) If a party does not timely appeal any part(s) of the ALJ's decision on an LCD review to the Board, as provided

in this subpart, then the ALJ's decision is final and not subject to further review.

§ 426.470 Board's role in docketing and evaluating the acceptability of appeals of ALJ decisions.

(a) *Docketing the appeal.* The Board does the following upon receiving an appeal of part or all of an ALJ's decision:

(1) Dockets the appeal either separately or with similar appeals.

(2) Assigns a docket number.

(b) *Evaluating the acceptability of the appeal.* The Board determines if the appeal is acceptable by confirming that the appeal meets all of the criteria in § 426.465.

(c) *Unacceptable appeal.* If the Board determines that an appeal is unacceptable, the Board must dismiss the appeal.

(d) *Acceptable appeal.* If the Board determines that an appeal is acceptable, the Board does the following:

(1) Sends a letter to the appellant to acknowledge that the appeal is acceptable, and informs them of the docket number.

(2) Forwards a copy of the appeal and the letter described in paragraph (d)(1) of this section to all parties involved in the appeal.

(3) Requires the ALJ to send a copy of the ALJ's LCD review record (maintaining any sealed documents) to the Board and a copy of the public record to all parties involved in the appeal.

(e) *No participation as amicus curiae.* The Board may not allow participation by amicus participants in the review of an LCD.

§ 426.476 Board review of an ALJ's decision.

(a) *Review steps.* If the Board determines that an appeal is acceptable, the Board—

(1) Permits the party that did not file the appeal an opportunity to respond to the appeal;

(2) Hears oral argument (which may be held by telephone) if the Board determines that oral argument would be helpful to the Board's review of the ALJ decision;

(3) Reviews the LCD review record and the parties' arguments; and

(4) Issues a written decision either upholding, modifying, or reversing the ALJ decision, or remanding the case to the ALJ for further proceedings.

(b) *Standard of review*—(1) *In general.* The Board determines whether the ALJ decision contains any material error, including any failure to properly apply the reasonableness standard.

(2) If the ALJ erred in determining that the contractor's record was complete and adequate to support the validity of the LCD, the Board remands the case to the ALJ for discovery and the taking of evidence.

(3) If a party alleges a prejudicial error of procedure, and the Board determines that such an error was made, the Board may remand the case to the ALJ for further proceedings consistent with the Board decision or may take other appropriate steps to correct the procedural error.

(4) Harmless error is not a basis for reversing an ALJ decision.

(c) *Scope of review.* In reaching its conclusions, the Board is bound by applicable laws, regulations, and NCDs.

(d) *Dismissal as moot.* The Board dismisses an appeal by an aggrieved party of an ALJ decision finding that an LCD was valid if the contractor notifies the Board that it has retired the LCD or revised the LCD to remove the LCD provision in question.

§ 426.478 Retiring or revising an LCD during the Board's review of an ALJ's decision.

A contractor may retire or revise an LCD during the Board's review of an ALJ's decision using the same process described in § 426.420. If an LCD is retired or revised to remove completely the challenged provision(s), the aggrieved party who sought the review is entitled to individual claim review provided at § 426.488(b).

§ 426.480 Withdrawing an appeal of an ALJ's decision.

(a) *Withdrawal of an appeal of an ALJ's decision.* A party who filed an appeal of an ALJ's decision may withdraw the appeal before the Board issues a decision regarding the ALJ's decision.

(b) *Process of withdrawing an appeal of an ALJ's decision.* To withdraw an appeal of an ALJ's decision, the party who filed the appeal must send a written notice announcing the intent to withdraw to the Board and to any other party.

(c) *Actions the Board must take upon receiving a notice announcing the intent to withdraw an appeal of an ALJ's decision*—(1) *Appeals involving one aggrieved party, or initiated by CMS or a contractor.* If the Board receives a notice withdrawing an appeal of an ALJ's decision before the Board has issued its decision, the Board must issue a decision dismissing the appeal.

(2) *Appeals involving joint complaints.* If the Board receives a notice withdrawing an appeal from an aggrieved party who is named in a joint appeal before the Board issues its decision, the Board must issue a decision dismissing only that aggrieved party from the appeal. The Board must continue its review of the ALJ's decision for the remaining aggrieved party or parties.

§ 426.482 Issuance and notification of a Board decision.

The Board must issue a written decision, including a description of appeal rights, to all parties to the review of the ALJ decision.

§ 426.484 Mandatory provisions of a Board decision.

(a) *Findings.* A Board decision must include at least one of the following:

(1) A statement upholding the part(s) of the ALJ decision named in the appeal.

(2) A statement reversing the part(s) of the ALJ decision named in the appeal.

(3) A statement modifying the part(s) of the ALJ decision named in the appeal.

(4) A statement dismissing the appeal of an ALJ decision and a rationale for the dismissal.

(b) *Other information.* A Board decision must include all of the following:

(1) The date of issuance.

(2) The docket number of the review of the ALJ decision.

(3) A summary of the ALJ's decision.

(4) A rationale for the basis of the Board's decision.

§ 426.486 Prohibited provisions of a Board decision.

A Board decision must not do any of the following:

(a) Order CMS or its contractors to add any language to a provision or provisions of an LCD.

(b) Order CMS or its contractors to pay a specific claim.

(c) Set a time limit to establish a new or revised LCD.

(d) Review or evaluate an LCD other than the LCD named in the ALJ's decision.

(e) Include a requirement for CMS or its contractors that specifies payment, coding, or system changes for an LCD or deadlines for implementing these changes.

(f) Order CMS or its contractors to implement an LCD in a particular manner.

§ 426.487 Board's record on appeal of an ALJ's decision.

(a) *Elements of the Board's LCD review record furnished to the public.* Except as provided in paragraph (b) of this section, the Board's LCD review record consists of any document or material that the Board compiled or considered during an LCD review, including, but not limited to, the following:

(1) The LCD complaint.

(2) The LCD and LCD record.

(3) The supplemental LCD record, if applicable.

(4) Transcripts of record.

(5) Any other relevant evidence gathered under § 426.440.

(6) The ALJ's decision.

(7) The Board's decision.

(b) *Elements of the Board's LCD appeal record furnished to the court under seal.* The Board's LCD review record must include, under seal, any proprietary data or privileged information submitted and reviewed in the LCD review process, and that data or information must not be included in the review record furnished to the public, but the information must be maintained, under seal, by the Board.

(c) *Protective order.* In any instance where proprietary data or privileged information is used in the LCD process and a court seeks to obtain or require disclosure of any proprietary data or privileged information contained in the

LCD record, CMS or the Department will seek to have a protective order issued for that information, as appropriate.

§ 426.488 Effect of a Board decision.

(a) *The Board's decision upholds an ALJ decision that an LCD is valid or reverses an ALJ decision that an LCD is invalid.* If the Board's decision upholds the ALJ decision that an LCD is valid under the reasonableness standard or reverses an ALJ decision that an LCD is invalid, the contractor or CMS is not required to take any action.

(b) *The Board's decision upholds an ALJ determination that the LCD is invalid.* If the Board's decision upholds an ALJ determination that the LCD is invalid, then the contractor, the M + C organization, or other Medicare managed care organization implements the decision as described in § 426.460(b).

(c) *The Board's decision reverses a dismissal or an ALJ decision that the LCD is valid.* If the Board reverses an ALJ decision dismissing a complaint or holding that an LCD is valid without requiring discovery or the taking of evidence, the Board remands to the ALJ and the LCD review continues. If the Board reverses an ALJ decision holding that an LCD is valid that is reached after the ALJ has completed discovery and the taking of evidence, the Board may remand the case to the ALJ for further proceedings, or the Board may find that the provision(s) of the LCD named in the complaint is (are) invalid under the reasonableness standard, and the contractor, the M + C organization, or other Medicare managed care organization provides the relief in § 426.460(b).

§ 426.489 Board remands.

(a) *Notice when case is remanded to the ALJ.* If the Board remands a case to the ALJ, the Board—

(1) Notifies each aggrieved party who sought the LCD review, through his or her representative or at his or her last known address, the contractor, and CMS of the Board's remand decision; and

(2) Explains why the case is being remanded and the specific actions ordered by the Board.

(b) *Action by an ALJ on remand.* An ALJ takes any action that is ordered by the Board and may take any additional action that is not inconsistent with the Board's remand order.

§ 426.490 Board decision.

A decision by the Board (other than a remand) constitutes a final agency action and is subject to judicial review. Neither the contractor nor CMS may appeal a Board decision.

Subpart E—Review of an NCD

§ 426.500 Procedure for filing an acceptable complaint concerning a provision (or provisions) of an NCD.

(a) *The complaint.* An aggrieved party may initiate a review of an NCD by filing a written complaint with the Department of Health and Human Services Departmental Appeals Board.

(b) *Timeliness of a complaint.* An NCD complaint is not considered timely unless it is filed with the Board within—

(1) 6 months of the written statement from each aggrieved party's treating physician, in the case of aggrieved parties who choose to file an NCD challenge before receiving the service; or

(2) 120 days of the initial denial notice, in the case of aggrieved parties who choose to file an NCD challenge after receiving the service.

(c) *Components of a valid complaint.* A complaint must include the following:

(1) *Beneficiary-identifying information:*

(i) Name.

(ii) Mailing address.

(iii) State of residence, if different from mailing address.

(iv) Telephone number, if any.

(v) Health Insurance Claim number, if applicable.

(vi) Email address, if applicable.

(2) *If the beneficiary has a representative,* the representative's indetifying information must include the following:

(i) Name.

(ii) Address.

(iii) Telephone number.

(iv) E-mail address (if any)

(v) Copy of the written authorization to represent the beneficiary.

(3) *Treating physician written statement.* A copy of a written statement from the treating physician that the

beneficiary needs the service that is the subject of the NCD. This statement may be in the form of a written order for the service or other documentation from the beneficiary's medical record (such as progress notes or discharge summary) indicating that the beneficiary needs the service.

(4) *NCD-identifying information:*

(i) Title of NCD being challenged.

(ii) The specific provision or provisions of the NCD adversely affecting the aggrieved party.

(5) *Aggrieved party statement.* A statement from the aggrieved party explaining what service is needed and why the aggrieved party thinks that the provision(s) of the NCD is (are) not valid under the reasonableness standard.

(6) *Clinical or scientific evidence.* (i) Copies of clinical or scientific evidence that supports the complaint and an explanation for why the aggrieved party thinks that this evidence shows that the NCD is not reasonable.

(ii) Any documents or portions of documents that include proprietary data must be marked ''proprietary data,'' and include a legal basis for that assertion.

(iii) Proprietary data submitted by a manufacturer concerning a drug or device for which the manufacturer has submitted information to the Food and Drug Administration, must be considered and given substantive weight only when supported by an affidavit certifying that the submission contains true and correct copies of all data submitted by the manufacturer to the Food and Drug Administration in relation to that drug or device.

(d) *Joint complaints*—(1) *Conditions for a joint complaint.* Two or more aggrieved parties may initiate the review of an NCD by filing a single written complaint with the Board if all of the following conditions are met:

(i) Each aggrieved party named in the joint complaint has a similar medical condition or there are other bases for combining the complaints.

(ii) Each aggrieved party named in the joint complaint is filing the complaint in regard to the same provision(s) of the same NCD.

(2) *Components of a valid joint complaint.* A joint complaint must contain the following information:

(i) The beneficiary-identifying information described in paragraph (c)(1) of this section for each aggrieved party named in the joint complaint.

(ii) The NCD-identifying information described in paragraph (c)(2) of this section.

(iii) The documentation described in paragraphs (c)(3) and (c)(4) of this section.

(3) *Timeliness of a joint complaint.* Aggrieved parties, who choose to seek review of an NCD—

(i) Before receiving the service, must file with the Board a joint complaint within 6 months of the written statement from each aggrieved party's treating physician; or

(ii) After receiving the service, must file with the Board a complaint within 120 days of each aggrieved party's initial denial notice.

§ 426.503 Submitting new evidence once an acceptable complaint has been filed.

Once an acceptable complaint has been filed, the aggrieved party may submit additional new evidence without withdrawing the complaint until the Board closes the record.

§ 426.505 Authority of the Board.

(a) The Board conducts a fair and impartial hearing, avoids unnecessary delay, maintains order, and ensures that all proceedings are recorded.

(b) The Board defers only to reasonable findings of fact, reasonable interpretations of law, and reasonable applications of fact to law by the Secretary.

(c) The Board has the authority to do any of the following:

(1) Review complaints by an aggrieved party (or aggrieved parties).

(2) Dismiss complaints that fail to comply with § 426.500.

(3) Set and change the date, time, and place of a hearing upon reasonable notice to the parties.

(4) Continue or recess a hearing for a reasonable period of time.

(5) Hold conferences to identify or simplify the issues, or to consider other matters that may aid in the expeditious disposition of the proceeding.

(6) Consult with scientific and clinical experts on its own motion, concerning clinical or scientific evidence.

(7) Set schedules for submission of exhibits and written reports of experts.

(8) Administer oaths and affirmations.

(9) Examine witnesses.

(10) Issue subpoenas requiring the attendance of witnesses at hearings as permitted by this part.

(11) Issue subpoenas requiring the production of existing documents before, and relating to, the hearing as permitted by this part.

(12) Rule on motions and other procedural matters.

(13) Stay the proceeding in accordance with § 426.340.

(14) Regulate the scope and timing of documentary discovery as permitted by this part.

(15) Regulate the course of a hearing and the conduct of representatives, parties, and witnesses.

(16) Receive, rule on, exclude, or limit evidence, as provided in this regulation.

(17) Take official notice of facts, upon motion of a party.

(18) Decide cases, upon the motion of a party, by summary judgment when there is no disputed issue of material fact.

(19) Conduct any conference, argument, or hearing in person or, upon agreement of the parties, by telephone, picture-tel, or any other means.

(20) Issue decisions.

(21) Exclude a party from an NCD review for failure to comply with a Board order or procedural request without good cause.

(22) Stay the proceedings for a reasonable time when all parties voluntarily agree to mediation or negotiation, and provide mediation services upon request.

(d) The Board does not have authority to do any of the following under this part:

(1) Conduct an LCD review or conduct LCD hearings, except as provided by § 426.465.

(2) Conduct an NCD review or conduct NCD hearings on its own motion or on the motion of a nonaggrieved party.

(3) Issue a decision based on any new evidence without following § 426.340, regarding procedures for review of new evidence.

(4) Review any decisions by CMS to develop a new or revised NCD.

(5) Conduct a review of any draft NCDs, coverage decision memoranda, or withdrawn NCDs.

(6) Conduct a review of the merits of an unacceptable NCD complaint as discussed in § 426.510.

(7) Conduct an NCD review of any policy that is not an NCD, as defined in § 400.202 of this chapter.

(8) Allow participation by individuals or entities other than—

(i) The aggrieved party and/or his or her representative;

(ii) CMS and/or the contractor;

(iii) Experts called by the parties or Board; or

(iv) Third parties with a clearly identifiable and substantial interest in the outcome of the dispute who have petitioned for and been granted permission by the Board to participate in the proceedings as *amicus curiae*.

(9) Compel the parties to participate in a mediation process or to engage in settlement negotiations.

(10) Deny a request for withdrawal of a complaint by an aggrieved party.

(11) Compel CMS to conduct studies, surveys, or develop new information to support an NCD record.

(12) Deny CMS the right to reconsider, revise, or withdraw an NCD.

(13) Subject to the timely filing requirements, deny an aggrieved party, CMS, or its contractor the right to appeal an ALJ decision.

(14) Find invalid applicable Federal statutes, regulations, or rulings.

(15) Enter a decision specifying terms to be included in an NCD.

§ 426.506 *Ex parte* contacts.

No party or person (except Board staff) communicates in any way with the Board on any substantive matter at issue in a case, unless on notice and opportunity for all parties to participate. This provision does not prohibit a person or party from inquiring about the status of a case or asking routine questions concerning administrative functions or procedures.

§ 426.510 Docketing and evaluating the acceptability of NCD complaints.

(a) *Docketing the complaint.* The Board does the following upon receiving a complaint regarding an NCD:

(1) Dockets the complaint.

(2) Determines whether the complaint is—

(i) The first challenge to a particular NCD; or

(ii) Related to a pending NCD review.

(3) Forwards the complaint to the Board member who conducts the review.

(b) *Evaluating the acceptability of the complaint.* The Board determines if the complaint is acceptable by confirming all of the following:

(1) The complaint is being submitted by an aggrieved party or, in the case of a joint complaint, that each individual named in the joint complaint is an aggrieved party. (In determining if a complaint is acceptable, the Board assumes that the facts alleged by the treating physician's documentation regarding the aggrieved party's (or parties') clinical condition are true.)

(2) The complaint meets the requirements for a valid complaint in § 426.500 and is not one of the documents in § 426.325(b).

(c) *Unacceptable complaint.* (1) If the Board determines that the complaint is unacceptable, the Board must provide the aggrieved party (or parties) one opportunity to amend the unacceptable complaint.

(2) If the aggrieved party (or parties) fail(s) to submit an acceptable amended complaint within a reasonable timeframe as determined by the Board, the Board must issue a decision dismissing the unacceptable complaint.

(3) If a complaint is determined to be unacceptable after one amendment, the beneficiary is precluded from filing again for 6 months after being informed that it is unacceptable.

(d) *Acceptable complaint.* If the Board determines that the complaint (or amended complaint) is acceptable, the Board does the following:

(1) Sends a letter to the aggrieved party (or parties) acknowledging the complaint and informing the aggrieved party (or parties) of the docket number and the deadline for CMS to produce the NCD record.

(2) Forwards a copy of the complaint, any evidence submitted in the complaint, and the letter described in paragraph (d)(1) of this section to CMS.

(3) Requires CMS to send a copy of the NCD record to the Board and all parties to the NCD review within 30 days of receiving the Board's letter, a copy of the complaint, and any associated evidence, subject to extension for good cause shown.

(e) *Consolidation of complaints regarding an NCD*—(1) *Criteria for condideration.* If a review is pending regarding a particular NCD provision(s) and no decision has been issued ending the review, and a new acceptable complaint is filed, the Board consolidates the complaints and conducts a consolidated NCD review if all of the following criteria are met:

(i) The complaints are in regard to the same provision(s) of the same NCD, or there are other bases for consolidating the complaints.

(ii) The complaints contain common questions of law, common questions of fact, or both.

(iii) Consolidating the complaints does not unduly delay the Board's decision.

(2) *Decision to consolidate complaint.* If the Board decides to consolidate complaints, the Board does the following:

(i) Provides notification that the NCD review is consolidated and informs all parties of the docket number of the consolidated review.

(ii) Makes a single record of the proceeding.

(iii) Considers the relevant evidence introduced in each NCD complaint as introduced in the consolidated review.

(3) *Decision not to consolidate complaints.* If the Board decides not to consolidate complaints, the Board conducts separate NCD reviews for each complaint.

(f) *Public notice of complaint and opportunity for interested parties to participate.* (1) If an acceptable complaint is the first complaint the Board has received challenging the particular NCD or provision, then the Board posts notice on its Web site that it has received the complaint, specifying a time period for requests to participate in the review process.

(2) If an acceptable complaint challenges an NCD provision when review is pending and no decision has been issued ending the review, the Board may supplement the public notice on its Web site and extend the time for participation requests if indicated.

(3) The Board may allow participation, in the manner and by the deadlines established by the Board, when an NCD is being challenged and the Board decides that—

(i) The *amicus* participant has a clearly identifiable and substantial interest in the outcome of the dispute;

(ii) Participation would clarify the issues or otherwise be helpful in resolution of the dispute;

(iii) Participation does not result in substantial delay; and

(iv) The petition for participation meets the criteria in § 426.513.

§ 426.513 Participation as *amicus curiae*.

(a) *Petition for participation*. Any person or organization that wishes to participate as *amicus curiae* must timely file with the Board a petition that concisely states—

(1) The petitioner's interest in the hearing;

(2) Who will represent the petitioner; and

(3) The issues on which the petitioner intends to present argument.

(b) *The nature of the proposed amicus participation*. An *amicus curiae* is not a party to the hearing but may participate by—

(1) Submitting a written statement of position to the Board before the beginning of the hearing;

(2) Presenting a brief oral statement or other evidence at the hearing, at the point in the proceedings specified by the Board; and

(3) Submitting a brief or a written statement when the parties submit briefs.

(c) *Service by amicus curiae*. Serving copies of any briefs or written statements on all parties.

§ 426.515 CMS' role in making the NCD record available.

CMS will provide a copy of the NCD record (as described in § 426.518) to the Board and all parties to the NCD review within 30 days of the receipt of the Board's order.

§ 426.516 Role of Medicare Managed Care Organizations (MCOs) and State agencies in the NCD review process.

Medicare MCOs and Medicaid State agencies may participate in the NCD review process only if they meet the *amicus* participant criteria listed in §§ 426.510(f)(3) and 426.513.

§ 426.517 CMS' statement regarding new evidence.

(a) CMS may review any new evidence that is submitted, regardless of whether the Board has stayed the proceedings, including but not limited to new evidence:

(1) Submitted with the initial complaint;

(2) Submitted with an amended complaint;

(3) Produced during discovery;

(4) Produced when the Board consults with scientific and clinical experts; and

(5) Presented during any hearing.

(b) CMS may submit a statement regarding whether the new evidence is significant under § 426.340, by a deadline set by the Board.

§ 426.518 NCD record furnished to the aggrieved party.

(a) *Elements of the NCD record furnished to the aggrieved party*. Except as provided in paragraph (b) of this section, the NCD record consists of any document or material that CMS considered during the development of the NCD, including, but not limited to, the following:

(1) The NCD being challenged.

(2) Any medical evidence considered on or before the date the NCD was issued, including, but not limited to, the following:

(i) Scientific articles.

(ii) Technology assessments.

(iii) Clinical guidelines.

(iv) Statements from clinical experts, medical textbooks, claims data, or other indication of medical standard of practice.

(v) MCAC transcripts.

(3) Public comments received during the notice and comment period.

(4) Coverage decision memoranda.

(5) An index of documents considered that are excluded under paragraph (b) of this section.

(b) *Elements of the NCD record not furnished to the aggrieved party.* The NCD record furnished to the aggrieved party does not include the following:

(1) Proprietary data or privileged information.

(2) Any new evidence.

§ 426.519 NCD record furnished to the Board.

The NCD record furnished to the Board includes—

(a) Documents included in § 426.518(a); and

(b) Privileged information and proprietary data considered that must be filed with the Board under seal.

§ 426.520 Withdrawing an NCD under review or issuing a revised or reconsidered NCD.

(a) CMS may withdraw an NCD or NCD provision under review before the date the Board issues a decision regarding that NCD. Withdrawing an NCD or NCD provision under review has the same effect as a decision under § 426.560(b).

(b) CMS may revise an NCD under review to remove or amend the NCD provision listed in the complaint through the reconsideration process before the date the Board issues a decision regarding that NCD. Revising an NCD under review to remove the NCD provision in question has the same effect as a decision under § 426.560(b).

(c) CMS must notify the Board within 48 hours of—

(1) Withdrawing an NCD or NCD provision that is under review; or

(2) Issuing a revised or reconsidered version of the NCD that is under review.

(d) If CMS issues a revised or reconsidered NCD, CMS forwards a copy of the revised/reconsidered NCD to the Board.

(e) The Board must take the following actions upon receiving a notice that CMS has withdrawn or revised/reconsidered an NCD under review:

(1) If, before the Board issues a decision, the Board receives notice that CMS has withdrawn the NCD or revised the NCD to completely remove the provision in question, the Board must dismiss the complaint and inform the aggrieved party (ies) who sought the review that he or she or they will receive individual claim review without the retired/withdrawn provisions.

(2) If, before the Board issues a decision, the Board receives notice that CMS has revised the NCD provision in question but has not removed it altogether, the Board must continue the review based on the revised NCD. In this case, CMS must send a copy of the supplemental record to the Board and all parties. In that circumstance, the Board permits the aggrieved party to respond to the revised NCD and the supplemental record.

§ 426.523 Withdrawing a complaint regarding an NCD under review.

(a) *Circumstance under which an aggrieved party withdraws a complaint regarding an NCD.* An aggrieved party who filed a complaint regarding an NCD may withdraw the complaint before the Board issues a decision regarding that NCD. The aggrieved party may not file another complaint concerning the same coverage determination for 6 months.

(b) *Process for an aggrieved party withdrawing a complaint regarding an NCD.* To withdraw a complaint regarding an NCD, the aggrieved party who filed the complaint must send a written withdrawal notice to the Board (see § 426.500) and CMS. Supplementing an acceptable complaint with new evidence does not constitute a withdrawal of a complaint, as described in § 426.503.

(c) *Actions the Board must take upon receiving a notice announcing the intent to withdraw a complaint regarding an NCD*—(1) *NCD reviews involving one aggrieved party.* If the Board receives a withdrawal notice regarding an NCD before the date the Board issued a decision regarding that NCD, the Board issues a decision dismissing the complaint under § 426.544 and informs the aggrieved party that he or she may not file another complaint to the same coverage determination for 6 months.

(2) *NCD reviews involving joint complaints.* If the Board receives a notice from an aggrieved party who is named in a joint complaint withdrawing a complaint regarding an NCD before the

date the Board issued a decision regarding that NCD, the Board issues a decision dismissing only that aggrieved party from the complaint under § 426.544. The Board continues the NCD review if there is one or more aggrieved party who does not withdraw from the joint complaint.

(3) *Consolidated NCD reviews.* If the Board receives a notice from an aggrieved party who is part of a consolidated NCD review withdrawing a complaint regarding an NCD before the date the Board issued a decision regarding that NCD, the Board removes that aggrieved party from the consolidated NCD review and issues a decision dismissing that aggrieved party's complaint under § 426.544. The Board continues the NCD review if there is one or more aggrieved party who does not withdraw from the joint complaint.

§ 426.525 NCD review.

(a) *Opportunity for the aggrieved party after his or her review of the NCD record to state why the NCD is not valid.* Upon receipt of the NCD record, the aggrieved party files a statement explaining why the NCD record is not complete, or not adequate to support the validity of the NCD under the reasonableness standard. This statement must be submitted to the Board and CMS, within 30 days (or within additional time as allowed by the Board for good cause shown) of the date the aggrieved party receives the NCD record.

(b) *CMS response.* CMS has 30 days, after receiving the aggrieved party's statement, to submit a response to the Board in order to defend the NCD.

(c) *Board evaluation.* (1) After the aggrieved party files a statement and CMS responds as described in § 426.525(a) and § 426.525(b), or the time for filing has expired, the Board applies the reasonableness standard to determine whether the NCD record is complete and adequate to support the validity of the NCD.

(2) Issuance of a decision finding the record complete and adequate to support the validity of the NCD ends the review process.

(3) If the Board determines that the NCD record is not complete and adequate to support the validity of the NCD, the Board permits discovery and the taking of evidence in accordance with § 426.532 and § 426.540, and evaluate the NCD in accordance with § 426.531.

(d) The process described in paragraphs (a), (b), and (c) of this section applies when an NCD record has been supplemented, except that discovery and the taking of evidence is not repeated. The period for the aggrieved party to file a statement begins when the aggrieved party receives the supplement.

§ 426.531 Board's review of the NCD to apply the reasonableness standard.

(a) *Required steps.* The Board must do the following to review the provision(s) listed in the aggrieved party's complaint based on the reasonableness standard:

(1) Confine the NCD review to the provision(s) of the NCD raised in the aggrieved party's complaint.

(2) Conduct a hearing unless the matter can be decided on the written record.

(3) Close the NCD review record to the taking of evidence.

(4) Treat as precedential any previous Board decision made under § 426.547 that involves the same NCD provision(s), same specific issue and facts in question, and the same clinical conditions.

(5) Issue a decision as described in § 426.547.

(b) *Optional steps.* The Board may consult with appropriate scientific or clinical experts concerning clinical and scientific evidence to apply the reasonableness standard to the provision(s) listed in the aggrieved party's complaint.

(c) *Authority for the Board in NCD reviews when applying the reasonableness standard.* In applying the reasonableness standard to a provision (or provisions) of an NCD, the Board must follow all applicable laws and regulations, as well as NCDs other than the one under review.

§ 426.532 Discovery.

(a) *General rule.* If the Board orders discovery, the Board must establish a reasonable timeframe for discovery.

(b) *Protective order*—(1) *Request for a protective order.* Any party receiving a discovery request may file a motion for

a protective order before the date of production of the discovery.

(2) *The Board granting of a protective order.* The Board may grant a motion for a protective order if it finds that the discovery sought—

(i) Is irrelevant or unduly repetitive;

(ii) Is unduly costly or burdensome; or

(iii) Will unduly delay the proceeding.

(c) *Types of discovery available.* A party may obtain discovery via a request for the production of documents, and/or via the submission of up to 10 written interrogatory questions, relating to a specific NCD.

(d) *Types of documents.* For the purpose of this section, the term documents includes relevant information, reports, answers, records, accounts, papers, and other data and documentary evidence. Nothing contained in this section will be interpreted to require the creation of a document.

(e) *Types of discovery not available.* Requests for admissions, depositions, or any other forms of discovery, other than those permitted under paragraph (c) of this section, are not authorized.

(f) *Privileged information or proprietary data.* The Board must not under any circumstances order the disclosure of privileged information or proprietary data filed under seal without the consent of the party who possesses the right to protection of the information.

(g) *Notification.* The Board notifies all parties in writing when the discovery period will be closed.

§ 426.535 Subpoenas.

(a) *Purpose of a subpoena.* A subpoena requires the attendance of an individual at a hearing and may also require a party to produce evidence authorized under § 426.540 at or before the hearing.

(b) *Filing a motion for a subpoena.* A party seeking a subpoena must file a written motion with the Board not less than 30 days before the date fixed for the hearing. The motion must do all of the following:

(1) Designate the witnesses.

(2) Specify any evidence to be produced.

(3) Describe the address and location with sufficient particularity to permit the witnesses to be found.

(4) State the pertinent facts that the party expects to establish by witnesses or documents and state whether those facts could be established by evidence other than by the use of a subpoena.

(c) *Response to a motion for a subpoena.* Within 15 days after the written motion requesting issuance of a subpoena is served on all parties, any party may file an opposition to the motion or other response.

(d) *Extension for good cause shown.* The Board may modify the deadlines specified in paragraphs (b) and (c) of this section for good cause shown.

(e) *Motion for a subpoena granted.* If the Board grants a motion requesting issuance of a subpoena, the subpoena must do the following:

(1) Be issued in the name of the presiding Board member.

(2) Include the docket number and title of the NCD under review.

(3) Provide notice that the subpoena is issued according to sections 1872 and 205(d) and (e) of the Act.

(4) Specify the time and place at which the witness is to appear and any evidence the witness is to produce.

(f) *Delivery of the subpoena.* The party seeking the subpoena serves it by personal delivery to the individual named, or by certified mail return receipt requested, addressed to the individual at his or her last dwelling place or principal place of business.

(g) *Motion to quash a subpoena.* The individual to whom the subpoena is directed may file with the Board a motion to quash the subpoena within 10 days after service.

(h) *Refusal to obey a subpoena.* The exclusive remedy for contumacy by, or refusal to obey, a subpoena duly served upon any person is specified in section 205(e) of the Act (42 U.S.C. 405(e)) except that any reference to the ''Commissioner of Social Security'' shall be considered a reference to the ''Secretary.''

§ 426.540 Evidence.

(a) Except as provided in this part, the Board is not bound by the Federal Rules of Evidence. However, the Board

may apply the Federal Rules of Evidence when appropriate, for example, to exclude unreliable evidence.

(b) The Board must exclude evidence that it determines is clearly irrelevant or immaterial, or unduly repetitive.

(c) The Board may accept privileged information or proprietary data, but must maintain it under seal.

(d) The Board may permit the parties to introduce the testimony of expert witnesses on scientific and clinical issues, rebuttal witnesses, and other relevant evidence. The Board may require that the testimony of expert witnesses be submitted in the form of a written report, accompanied by the curriculum vitae of the expert preparing the report.

(e) Experts submitting reports must be available for cross-examination at an evidentiary hearing upon request of the Board or a party to the proceeding, or the report will be excluded from the record.

(f) Except as set forth in paragraph (c) of this section or unless otherwise ordered by the Board for good cause shown, all documents and other evidence offered or taken for the record is open to examination by all parties.

§ 426.544 Dismissals for cause.

(a) The Board may, at the request of any party, or on its own motion, dismiss a complaint if the aggrieved party fails to do either of the following:

(1) Attend or participate in a prehearing conference (the prehearing may be conducted by telephone) or hearing without good cause shown.

(2) Comply with a lawful order of the Board without cause shown.

(b) The Board must dismiss any complaint concerning NCD provision(s) if the following conditions exist:

(1) The Board does not have the authority to rule on that provision under § 426.505(d).

(2) The complaint is not timely. (See § 426.500(b)).

(3) The complaint is not filed by an aggrieved party.

(4) The complaint is filed by an individual who fails to provide an adequate statement of need for the service from the treating physician.

(5) The complaint challenges a provision or provisions of an LCD except as provided in § 426.476, regarding the Board's review of an ALJ decision. (See § 426.505, regarding the authority of the Board.)

(6) CMS notifies the Board that the NCD provision(s) is (are) no longer in effect.

(7) The aggrieved party withdraws the complaint. (See § 426.523, for requirements for withdrawing a complaint regarding an NCD under review.)

§ 426.545 Witness fees.

(a) A witness testifying at a hearing before the Board receives the same fees and mileage as witnesses in Federal district courts of the United States. If the witness qualifies as an expert, he or she is entitled to an expert witness fee. Witness fees are paid by the party seeking to present the witness.

(b) If the Board requests expert testimony, the Board is responsible for paying all applicable fees and mileage, unless the expert waives payment.

§ 426.546 Record of hearing.

The Board must ensure that all hearings are open to the public and are electronically, mechanically, or stenographically reported. Except for privileged information and proprietary data that are filed under seal, all evidence upon which the Board relies for decision must be admitted into the public record. All medical reports, exhibits, and any other pertinent document, either in whole or in material part, must be offered, marked for identification, and retained in the case record.

§ 426.547 Issuance, notification, and posting of a Board's decision.

The Board must do the following:

(a) Issue to all parties to the NCD review, within 90 days of closing the NCD review record to the taking of evidence, one of the following:

(1) A written decision, including a description of appeal rights.

(2) A written notification stating that a decision is pending, and an approximate date of issuance for the decision.

(b) Make the decision available at the HHS Medicare Internet site. The posted decision does not include any information that identifies any individual, provider of service, or supplier.

§ 426.550 Mandatory provisions of the Board's decision.

(a) *Findings.* The Board's decision must include one of the following:

(1) A determination that the provision of the NCD is valid under the reasonableness standard.

(2) A determination that the provision of the NCD is not valid under the reasonableness standard.

(3) A statement dismissing the complaint regarding the NCD, and a rationale for the dismissal.

(4) A determination that the LCD or NCD record is complete and adequate to support the validity of the LCD or NCD provisions under the reasonableness standard.

(b) *Other information.* The Board's decision must include all of the following:

(1) The date of issuance.

(2) The docket number of the NCD review.

(3) A statement as to whether the aggrieved party has filed a claim for the service(s) named in the complaint, the date(s)-of-service, and the disposition, if known.

(4) A basis for concluding that the NCD was or was not valid based on the application of the reasonableness standard to the record before the Board, including CMS':

(i) Findings of fact.

(ii) Interpretations of law.

(iii) Applications of fact to law.

(5) A summary of the evidence reviewed. Where proprietary or privileged data were submitted under seal, the decision must state whether the data were material and what role they played in the determination, but without disclosing the substance or contents of the evidence under seal. A separate statement of the rationale for the Board's treatment of the sealed evidence must be prepared and kept under seal itself. If the Board decision is appealed to the court, this statement must be provided to the court, under seal.

(6) A statement regarding the right to judicial review.

§ 426.555 Prohibited provisions of the Board's decision.

The Board's decision may not do any of the following:

(a) Order CMS to add any language to a provision or provisions of an NCD.

(b) Order CMS or its contractors to pay a specific claim.

(c) Set a time limit for CMS to establish a new or revised NCD.

(d) Review or evaluate an NCD other than the NCD under review.

(e) Include a requirement for CMS or its contractors that specifies payment, coding, or systems changes for an NCD, or deadlines for implementing these types of changes.

(f) Order or address how CMS implements an NCD.

§ 426.557 Optional provisions of the Board's decision.

When appropriate, the Board may limit a decision holding invalid a specific provision(s) of an NCD to specific clinical indications and for similar conditions.

§ 426.560 Effect of the Board's decision.

(a) *Valid under the reasonableness standard.* If the Board finds that the provision (or provisions) of an NCD named in the complaint is (are) valid under the reasonableness standard, the aggrieved party may challenge the final agency action in Federal court.

(b) *Not valid under the reasonableness standard.* If the Board finds that the provision (or provisions) of an NCD named in the complaint is (are) invalid under the reasonableness standard, then CMS instructs its contractor, M + C organization, or other Medicare managed care organization to provide the following—

(1) *Individual claim review.* (i) If the aggrieved party's claim/appeal(s) was previously denied, the contractor, an M + C organization, or another Medicare managed care organization must reopen the claim of the party who challenged the LCD and adjudicate the claim without using the provision(s) of the NCD that the Board found invalid.

(ii) If a revised NCD is issued, contractors, M + C organizations, and other Medicare managed care organizations must use the revised NCD in reviewing claim/appeal submissions or request for services delivered or services performed on or after the effective date of the revised NCD.

(iii) If the aggrieved party who sought review has not yet submitted a claim, the contractor must adjudicate the claim without using the provision(s) of the NCD that the Board found invalid.

(iv) In either case, the claim and any subsequent claims for the service provided under the same circumstances, must be adjudicated without using the NCD provision(s) found invalid.

(2) *Coverage determination relief*. Within 30 days, CMS implements the Board decision. Any change in policy is applied prospectively to requests for service or claims filed with dates of service after the implementation of the Board decision.

§ 426.562 Notice of the Board's decision.

After the Board has made a decision regarding an NCD complaint, the Board sends a written notice of the decision to each party. The notice must—

(a) State the outcome of the review; and

(b) Inform each party to the determination of his or her rights to seek further review if he or she is dissatisfied with the determination, and the time limit under which an appeal must be requested.

§ 426.563 Future new or revised or reconsidered NCDs.

CMS may not reinstate an NCD provision(s) found to be unreasonable unless CMS has a different basis (such as additional evidence) than what the Board evaluated.

§ 426.565 Board's role in making an LCD or NCD review record available.

Upon a request from a Federal Court, the Board must provide to the Federal Court a copy of the Board's LCD or NCD review record (as described in § 426.587).

§ 426.566 Board decision.

A decision by the Board constitutes a final agency action and is subject to judicial review. CMS may not appeal a Board decision.

§ 426.587 Record for appeal of a Board NCD decision.

(a) *Elements of the Board's NCD review record furnished to the public*. Except as provided in paragraph (b) of this section, the Board's NCD review record consists of any document or material that the Board compiled or considered during an NCD review, including, but not limited to, the following:

(1) The NCD complaint.

(2) The NCD and NCD record.

(3) The supplemental NCD record, if applicable.

(4) Transcripts of record.

(5) Any other evidence relevant gathered under § 426.540.

(6) The Board's decision.

(b) *Documents excluded from the NCD review record furnished to the court*. The NCD review record furnished to the court maintains the seal on privileged information or proprietary data that is maintained under seal by the Board. In the event a court seeks to obtain or requires disclosure of any documents excluded from the NCD record as privileged information or proprietary data, CMS or the Department seeks to have a protective order issued for those documents, as appropriate.

PART 427—MEDICARE PART B DRUG INFLATION REBATE PROGRAM

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AUTHORITY: 42 U.S.C. 1395w–3a(i), 1302, and 1395hh.

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Subpart A—General Provisions

§ 427.10 Basis and scope.

(a) *Basis.* This part implements section 1847A(i) of the Social Security Act (''the Act'').

(b) *Scope.* This part sets forth the requirements of the Medicare Part B Drug Inflation Rebate Program, which requires, for each calendar quarter, manufacturers to pay rebates for certain single source drugs and biological products with prices that increase faster than the rate of inflation.

(c) *Severability.* Were any provision of this part to be held invalid or unenforceable by its terms, or as applied to any person or circumstance, such provisions would be severable from this part and the invalidity or unenforceability would not affect the remainder thereof or any other part of this subchapter or the application of such provision to other persons not similarly situated or to other, dissimilar circumstances.

§ 427.20 Definitions.

As used in this part, the following definitions apply:

Allowed charges means the amount that is inclusive of the beneficiary coinsurance and Medicare payment for the covered Part B item or service.

Applicable calendar quarter means a calendar quarter (January 1 to March 31, April 1 to June 30, July 1 to September 30, or October 1 to December 31), starting with January 1, 2023.

Applicable threshold means the amount determined under § 427.101(c)(2).

Average sales price (ASP) means the manufacturer's price for a quarter for a drug represented by a particular 11-digit National Drug Code (NDC–11) determined under § 414.804 of this chapter.

Benchmark period Consumer Price Index for All Urban Consumers (CPI–U) means the CPI–U as set forth in § 427.302(e).

Billing and payment code means the specific code used to classify and report a drug or biological for purposes of Medicare Part B payment. A Healthcare Common Procedure Coding System (HCPCS) code, as established by CMS, is an example of a billing and payment code used to describe a drug or biological and for which CMS may publish a payment amount.

Billing and payment code FDA approval or licensure date means the earliest approval or licensure date for any FDA application number associated with any NDC ever assigned to the billing and payment code.

Billing unit means the identifiable quantity of a drug or biological product associated with a billing and payment code (for example, a HCPCS code), as established by CMS.

Biosimilar biological product has the meaning set forth in section 1847A(c)(6)(H) of the Act.

CPI–U means the monthly Consumer Price Index for All Urban Consumers (United States city average) index level for all items from the Bureau of Labor Statistics.

Food and Drug Administration (FDA) application means, for the purposes of calculating the Part B rebate amount, a New Drug Application (NDA) or Biologics License Application (BLA) approved by the FDA.

Final action claim means a non-rejected claim for which a Medicare payment has been made, and for which all disputes and adjustments have been resolved.

First marketed date means the earliest date of first sale of any NDC–11 within a billing and payment code among all products and package sizes under the same FDA application. The first marketed date will be identified using ASP data reported by NDC–11 to CMS by a manufacturer as required under sections 1927(b)(3)(A)(iii)(I) and 1847A(f)(2) of the Act, if available.

Grouped billing and payment code, for the purposes of Part B rebate calculations, means a billing and payment code, such as a HCPCS code, other than a Not Otherwise Classified (NOC) code, that typically contains multiple drug products approved under multiple NDAs or BLAs and may be inclusive of, but are not limited to, multiple source billing codes.

Inflation-adjusted payment amount means the amount determined under § 427.302(g).

Manufacturer has the meaning set forth in section 1847A(c)(6)(A) of the Act.

National Drug Code (NDC) means the unique identifying prescription drug product number that is listed with FDA identifying the product and package size and type.

Not Otherwise Classified (NOC) code means a billing and payment code, including an unclassified, unspecified, or unlisted code, for drugs and biological products for which no specific billing and payment code is assigned.

Part B rebatable drug means, subject to the exclusions set forth in § 427.101(b), a single source drug or biological product, including a biosimilar biological product but excluding a qualifying biosimilar biological product, for which payment is made under Part B.

Payment amount benchmark quarter means the calendar quarter set forth in § 427.302(c).

Payment amount in the payment amount benchmark quarter means the amount set forth in § 427.302(d).

Rebate period CPI–U means the CPI–U set forth in § 427.302(f).

Single source drug or biological product has the meaning set forth in section 1847A(c)(6)(D) of the Act.

Sold or marketed means, with respect to an NDC, that the NDC has either a date of first sale identified using ASP data reported by NDC–11 to CMS by a manufacturer as required under sections 1927(b)(3)(A)(iii)(I) and 1847A(f)(2) of the Act, or an NDC Directory start marketing date prior to or during the applicable calendar quarter and meets any of the following criteria:

(1) The NDC has units reported for the rebate quarter;

(2) The end marketing date is during the rebate quarter;

(3) The end marketing date is after the rebate quarter; or

(4) The end marketing date is missing.

Specified amount means the amount set forth in § 427.302(b).

Subsequently approved drug means a drug first approved or licensed by the FDA after December 1, 2020.

Unit means, with respect to a Part B rebatable drug, with respect to each National Drug Code (including package size) associated with a drug or biological, the lowest identifiable quantity (such as a capsule or tablet, milligram of molecules, or grams) of the drug or biological that is dispensed, exclusive of any diluent without reference to volume measures pertaining to liquids as reported under section 1847A(b)(2)(B) of the Act.

Subpart B—Determination of Part B Rebatable Drugs

§ 427.100 Definitions.

As used in this subpart, the following definitions apply:

EUA Declaration means the March 27, 2020, Emergency Use Authorization (EUA) Declaration for Drugs and Biological Products under section 564 of the Food, Drug, and Cosmetic (FD&C) Act.

Individual who uses such a drug or biological means a unique Medicare Part B beneficiary who was furnished the Part B drug or biological that was covered under Part B during the applicable calendar quarter, identified using final action claims data with dates of service during the calendar year set forth in § 427.101(b)(6) and with allowed charges greater than zero.

§ 427.101 Identification of Part B rebatable drugs.

(a) *Determination of Part B rebatable drugs.* (1) For each applicable calendar quarter, CMS will:

(i) Identify single source drugs or biological products, including biosimilar biological products, covered under Part B; and

(ii) Identify the applicable billing and payment code for each drug or biological product set forth in paragraph (a)(1)(i) of this section.

(2) For a drug or biological product identified under paragraph (a)(1) of this section, CMS will determine whether the drug or biological product meets the exclusion criteria set forth in paragraph (b) or (c) of this section as of the first day of the applicable calendar quarter.

(3) To determine whether a drug or biological product is a Part B rebatable drug under this section, CMS will use the most recent available data submitted to CMS by manufacturers pursuant to section 1927(b)(3)(A)(iii) of the Act or section 1847A(f)(2), as applicable, and other available data, including but not limited to information available at FDA.gov and information in drug pricing compendia, as applicable.

(b) *Excluded product categories.* The following categories of products are not considered Part B rebatable drugs:

(1) *Qualifying biosimilar biological products.* Biological products as defined under section 1847A(b)(8)(B)(iii) of the Act.

(2) *Products with historically excepted grouped billing and payment codes.* Single source drugs or biological products that were within the same billing and payment code as of October 1, 2003, and which, as required under section 1847A(c)(6)(C)(ii) of the Act, are treated as multiple source drugs.

(3) *Products billed under a NOC code.* A drug or biological product billed under a NOC code.

(4) *Radiopharmaceutical drugs and biological products.* A separately payable radiopharmaceutical drug or biological product not paid under section 1847A of the Act.

(5) *Skin substitutes.* A product included within the suite of cellular- and tissue-based products that aid wound healing.

(6) *Drugs with average total allowed charges under the applicable threshold.* Drugs and biological products for which the Medicare Part B average total allowed charges for a year per individual that uses such drug or biological are below the applicable threshold, as set forth in paragraph (c) of this section.

(7) *Certain vaccines and other products.* The following products:

(i) The vaccines as set forth in section 1861(s)(10) of the Act, which includes the influenza, pneumococcal, hepatitis B, and COVID–19 vaccines.

(ii) Monoclonal antibodies used for treatment or post-exposure prophylaxis of COVID–19 that are covered and paid for under section 1861(s)(10) of the Act. This exclusion will apply to applicable quarters until the end of the calendar year in which the EUA Declaration ends.

(iii) Monoclonal antibodies that are used for pre-exposure prophylaxis of COVID–19 that are covered and paid for under section 1861(s)(10) of the Act. This exclusion will apply to applicable calendar quarters even after the year in which the EUA Declaration ends, as long as after the EUA Declaration is terminated, these products have an FDA-approved application or license.

(8) *Generic drugs.* Part B drugs approved under an Abbreviated New Drug Application (ANDA) submitted under section 505(j) of the Federal Food, Drug, and Cosmetic Act (FD&C Act).

(c) *Drugs and biological products with average total allowed charges below the applicable threshold.* For each applicable calendar quarter, CMS will identify

drugs and biological products with Part B average total allowed charges for a year per individual that uses such a drug or biological product that are below the applicable threshold determined under the calculations set forth in this section. Such drugs and biological products are not considered Part B rebatable drugs and will be excluded from the identification of Part B rebatable drugs in paragraph (a) of this section.

(1) *Average total allowed charges for a year per individual.* For each drug or biological that is identified as set forth in paragraph (a) of this section, CMS will calculate average total allowed charges for a year per individual as follows:

(i) For single source drugs and biological products assigned to only one billing and payment code, CMS will sum the allowed charges from final action claims greater than $0 and divide the summed amount by the number of individuals who use such a drug or biological with allowed charges for this billing and payment code.

(ii) For single source drugs and biological products assigned to more than one billing and payment code, CMS will sum the allowed charges from final action claims greater than $0 for all billing and payment codes and divide the summed amount by the number of individuals who use such a drug or biological with allowed charges for these billing and payment codes.

(iii) For single source drugs and biological products previously crosswalked to a grouped billing and payment code:

(A) If crosswalked to a grouped billing and payment code during the full year, CMS will calculate the average total allowed charges per individual per year for the drug using allowed charges and the number of individuals who used the drug or biological product based on claims for the previously grouped billing and payment code during the year.

(B) If crosswalked to a grouped billing and payment code and later assigned to a unique billing and payment code for part of the year, CMS will calculate average total allowed charges per individual per year by:

(*1*) Summing the total allowed charges billed under the unique billing and payment code for the drug with dates of service on or after the Medicare effective date for this unique billing and payment code and identifying the individuals on those claims.

(*2*) Summing the total allowed charges on claims billed under the previously grouped billing and payment code and identifying individuals with claims prior to the unique billing and payment code's effective date.

(*3*) Summing the total allowed charges as determined in paragraphs (c)(1)(iii)(B)(*1*) and (*2*) of this section and dividing by the total number of individuals, de-duplicated for individuals determined under paragraphs (c)(1)(iii)(B)(*1*) and (*2*).

(2) *Applicable threshold.* CMS will calculate the applicable threshold for an applicable calendar quarter as follows:

(i) For applicable calendar quarters in 2023, the applicable threshold is equal to $100.

(ii) For applicable calendar quarters in 2024, the applicable threshold is equal to $100 increased by the percentage increase in the CPI–U for the 12-month period ending with June of 2023.

(iii) For applicable calendar quarters in each subsequent calendar year, the applicable threshold is equal to the unrounded applicable threshold calculated for the prior calendar year increased by the percentage increase in the CPI–U for the 12-month period ending with June of the previous year.

(iv) If the resulting amount under paragraphs (c)(2)(i) through (iii) of this section is not a multiple of $10, CMS will round that amount to the nearest multiple of $10.

(3) *Application of the* applicable *threshold at the billing and payment code level.* For each applicable calendar quarter, CMS will apply the exclusion of drugs and biological products identified in paragraph (c)(1) of this section, with average total allowed charges for a year per individual less than the applicable threshold set forth in paragraph (c)(2) of this section, to applicable billing and payment codes as follows:

(i) For single source drugs or biological products assigned to a unique billing and payment code, CMS will exclude the assigned billing and payment code for an applicable calendar quarter if the average total allowed charges for a year per individual are less than the applicable threshold.

(ii) For a single source drug or biological product that is assigned to more than one billing and payment code during a year, CMS will exclude all such assigned billing and payment codes for an applicable calendar quarter.

(4) *Definition of year.* For purposes of the calculations set forth in this section, a year is defined as the 4 consecutive calendar quarters beginning 6 calendar quarters before the applicable calendar quarter. CMS will use final action claims from the Medicare fee-for-service claims repository where separate payment was allowed for the applicable billing and payment code for dates of service within a year to calculate Part B average total allowed charges for that year.

Subpart C—Coinsurance Adjustment and Adjusted Medicare Payment for Part B Rebatable Drugs With Price Increases Faster Than Inflation

§ 427.200 Definitions.

As used in this subpart, *inflation-adjusted beneficiary coinsurance* means the coinsurance adjustment as determined under this subpart.

§ 427.201 Computation of beneficiary coinsurance and adjusted Medicare payment for Part B rebatable drugs with price increases faster than inflation.

(a) *Methodology.* CMS must use the methodology set forth in this section to calculate the inflation-adjusted beneficiary coinsurance and associated adjusted Medicare payment percentage for Part B rebatable drugs as set forth in §§ 410.152(m), 419.41(e), and 489.30(b)(6) of this chapter.

(b) *Calculation of inflation-adjusted beneficiary coinsurance.* To calculate the inflation-adjusted beneficiary coinsurance for Part B rebatable drugs with respect to a calendar quarter, CMS compares the payment amount, as set forth in paragraph (b)(3) of this section, to the inflation-adjusted payment amount for the applicable calendar quarter.

(1) If the payment amount exceeds the inflation-adjusted payment amount, the inflation-adjusted beneficiary coinsurance is calculated by multiplying the inflation-adjusted payment amount by 0.20.

(2) If the inflation-adjusted payment amount does not exceed the payment amount, the adjustment to the beneficiary coinsurance set forth in paragraph (b)(1) of this section is not applied.

(3) CMS will use the published payment amount in quarterly pricing files published by CMS as the payment amount in this determination.

(c) *Exclusions.* Any drug that is excluded from Part B rebatable drugs as set forth in § 427.101(b) is not subject to inflation-adjusted beneficiary coinsurance.

Subpart D—Determination of the Rebate Amount for Part B Rebatable Drugs

§ 427.300 Definitions.

As used in this subpart, the following definitions apply:

340B Program is the program under section 340B of the Public Health Service (PHS) Act.

Refundable single-dose container or *single-use package drug* has the meaning set forth in § 414.902 of this chapter.

§ 427.301 Calculation of the total Part B rebate amount to be paid by manufacturers.

(a) *Total rebate.* Subject to paragraph (b) of this section, the total rebate amount to be paid for a Part B rebatable drug, as identified under § 427.101, for an applicable calendar quarter is equal to the product of the per unit Part B rebate amount of such drug, as determined under § 427.302, and the billing units of the Part B rebatable drug furnished during the applicable calendar quarter, as identified as set forth in § 427.303. The rebate amount may be reduced as set forth in subpart E of this part or adjusted as set forth in subpart F of this part.

(b) *Apportionment of the Part B rebate amount.* CMS will identify billing and payment codes for which multiple manufacturers report ASP, as set forth in sections 1927(b)(3) and 1847A(f) of the Act, for NDCs assigned to the billing and payment code. CMS will calculate the rebate amount owed by each manufacturer by:

(1) Determining the total billing units sold for each NDC assigned to the billing and payment code, by multiplying the number of units reported by a manufacturer in ASP data submissions at the NDC–11 package level by the number of billing units per NDC–11 reporting unit.

(2) Summing the individual manufacturer's total billing units sold during the applicable calendar quarter (for all NDCs of the manufacturer assigned to the billing and payment code).

(3) Summing all manufacturers' total billing units sold during the applicable calendar quarter for all NDCs of the Part B rebatable drug assigned to the billing and payment code.

(4) Dividing the resulting amount from paragraph (b)(2) of this section by the resulting amount from paragraph (b)(3) of this section.

(5) Multiplying the resulting amount from paragraph (b)(4) of this section by the total rebate amount as determined under paragraph (a) of this section.

(c) *Apportionment of the Part B rebate amount when reported units for NDCs within a billing and payment code are missing, negative, or equal to zero.*

(1) When there are multiple NDCs in a grouped billing and payment code and the manufacturer-reported ASP units for all NDCs are either missing, negative, or equal to zero but there is a positive rebate amount calculated under § 427.302(a), CMS will:

(i) With respect to NDCs that were sold or marketed during the applicable calendar quarter and for which all NDCs assigned to the grouped billing and payment code lack manufacturer-reported ASP data for the applicable calendar quarter, equally apportion a positive rebate amount to NDCs with missing ASP units that were sold or marketed during the applicable calendar quarter by dividing the total rebate amount for the grouped billing and payment code by the total number of NDCs sold or marketed during the applicable calendar quarter within the billing and payment code; and

(ii) With respect to NDCs that were not sold or marketed during the applicable calendar quarter and lack manufacturer-reported ASP units for the applicable calendar quarter, NDCs with negative manufacturer-reported ASP units for the applicable calendar quarter, and NDCs with manufacturer-reported ASP units equal to zero for the applicable calendar quarter, apportion a $0 rebate amount to each respective NDC. If all NDCs assigned to the grouped billing and payment code are determined under this subparagraph, no rebate will be assessed for that billing and payment code.

(2) When there are multiple NDCs in a grouped billing and payment code and the manufacturer-reported ASP units for some but not all NDCs assigned to the grouped billing and payment code are either missing, negative, or equal to zero but there is a positive rebate amount calculated under § 427.302(a), CMS will:

(i) With respect to NDCs that were not sold or marketed during the applicable calendar quarter and lack manufacturer-reported ASP units for the applicable calendar quarter, NDCs with negative manufacturer-reported ASP units for the applicable calendar quarter, and NDCs with manufacturer-reported ASP units equal to zero for the applicable calendar quarter, apportion a $0 rebate amount to each respective NDC;

(ii) With respect to NDCs that were sold or marketed during the applicable calendar quarter and lack manufacturer-reported ASP units for the applicable calendar quarter, and NDCs that were sold or marketed during the applicable calendar quarter and for which respective NDCs have positive manufacturer-reported units by, apportion rebate amounts as follows:

(A) Solely for purposes of the calculation determined under this paragraph (c)(2)(ii) of this section, assign to NDCs that were sold or marketed during the applicable calendar quarter and lack manufacturer-reported ASP units for the applicable calendar quarter the number of ASP units that is equal to

the lowest positive number of manufacturer reported ASP units for any NDC in the grouped billing and payment code;

(B) Determine the total billing units sold for each NDC assigned to the billing and payment code, by multiplying the number of units reported by a manufacturer in ASP data submissions at the NDC–11 package level by the number of billing units per NDC–11 reporting unit;

(C) With respect to all NDCs of each individual manufacturer assigned to the billing and payment code, sum the total billing units for such NDCs sold during the applicable calendar quarter;

(D) Sum the total billing units sold during the applicable calendar quarter for all NDCs of the Part B rebatable drug assigned to the billing and payment code, including those assigned a ASP unit value as set forth in paragraph (c)(2)(ii)(A) of this section;

(E) Divide the resulting amount from paragraph (c)(2)(ii)(C) of this section by the resulting amount from paragraph (c)(2)(ii)(D) of this section; and

(F) Multiply the resulting amount from paragraph (c)(2)(ii)(E) of this section by the total rebate amount as determined under paragraph (a) of this section.

§ 427.302 Calculation of the per unit Part B rebate.

(a) *Formula for calculating the per unit Part B rebate amount.* CMS will calculate the per unit Part B rebate amount for a Part B rebatable drug and applicable calendar quarter by determining the amount by which the specified amount, as determined under paragraph (b) of this section, exceeds the inflation-adjusted payment amount, as determined under paragraph (g) of this section.

(b) *Identification of the specified amount for the applicable calendar quarter.* For each applicable calendar quarter, subject to paragraph (b)(3) of this section, the specified amount is equal to the amount determined under section 1847A(i)(3)(A)(ii)(I)(aa) or (bb) of the Act, as applicable, for the calendar quarter.

(1) Subject to paragraph (b)(2) of this section, the first applicable calendar quarter for a Part B rebatable drug shall be no earlier than the calendar quarter beginning January 1, 2023 and shall be the later of one of the following:

(i) The first full calendar quarter that is at least the third calendar quarter after the payment amount benchmark quarter identified in paragraphs (c)(1) through (5) of this section.

(ii) The calendar quarter beginning January 1, 2023.

(2) Notwithstanding paragraph (b)(1) of this section, for a Part B rebatable drug that was billed under a NOC code during the calendar quarter beginning July 1, 2021, or the third full calendar quarter after the effective date of the drug's assigned billing and payment code other than a NOC code, whichever is later, the first applicable calendar quarter is the first full calendar quarter that follows the payment amount benchmark quarter identified in paragraphs (c)(1) through (5) of this section.

(3) If all NDCs in the billing and payment code have neither manufacturer-reported ASP nor Wholesale Acquisition Cost (WAC) price data available for the applicable calendar quarter, CMS will use WAC price data from other public sources, if available, to calculate 106 percent of WAC, which will serve as the specified amount.

(c) *Identification of the payment amount benchmark quarter.* For each Part B rebatable drug, CMS will identify the applicable payment amount benchmark quarter as set forth in paragraphs (c)(1) through (3) of this section, as applicable, subject to paragraphs (c)(4) and (5) of this section, using the earliest first marketed date of any NDC ever marketed under any FDA application under which any NDCs that have ever been assigned to the billing and payment code as of the applicable calendar quarter have been marketed, and using the earliest approval or licensure date of any FDA application under which any NDCs that have ever been assigned to the billing and payment code as of the applicable calendar quarter have been marketed:

(1) For a Part B rebatable drug first approved or licensed by the FDA on or before December 1, 2020, and with a first marketed date on or before December 1, 2020, the payment amount

benchmark quarter is the calendar quarter beginning July 1, 2021.

(2) For a Part B rebatable drug first approved or licensed by the FDA after December 1, 2020, the payment amount benchmark quarter is the third full calendar quarter after a drug's first marketed date.

(3) For a Part B rebatable drug first approved or licensed by the FDA on or before December 1, 2020, but with a first marketed date after December 1, 2020, the payment amount benchmark quarter is the third full calendar quarter after a drug's first marketed date.

(4) Notwithstanding paragraph (c)(3) of this section, for a Part B rebatable drug that was billed under a NOC code during the calendar quarter beginning July 1, 2021, or the third full calendar quarter after such drug's first marketed date, whichever is later, the payment amount benchmark quarter is the third full calendar quarter after the Part B rebatable drug is assigned a billing and payment code other than a NOC code.

(5) For a Part B rebatable drug that is a selected drug (as defined in section 1192(c) of the Act) with respect to a price applicability period (as defined in section 1191(b)(2) of the Act), in the case such Part B rebatable drug is no longer considered to be a selected drug, for each applicable quarter beginning after the price applicability period with respect to such drug, the payment amount benchmark quarter is the calendar quarter beginning January 1 of the last year during such price applicability period with respect to such selected drug.

(d) *Identification of the payment amount in the payment amount benchmark quarter.* CMS will identify the payment amount in the payment amount benchmark quarter using the published payment limit for the billing and payment code for the applicable payment amount benchmark quarter identified as set forth in paragraph (c) of this section.

(1) For a Part B rebatable drug, subject to paragraphs (d)(1)(i) and (ii) of this section and except as provided in paragraph (d)(2) of this section, CMS will identify the payment amount in the payment amount benchmark quarter using the published payment limit for the billing and payment code for the applicable payment amount benchmark quarter determined under section 1847A of the Act.

(i) If a published payment limit is not available for the applicable payment amount benchmark quarter, CMS will use the lower of 106 percent of manufacturer-reported ASP or 106 percent of manufacturer-reported WAC.

(ii) If neither a published payment limit nor manufacturer-reported ASP or WAC data are available, CMS will use WAC data from other public sources to calculate 106 percent of WAC, which, solely for the purposes of this section, CMS will consider to be the payment amount for the payment amount benchmark quarter.

(2) For a Part B rebatable drug previously billed under a grouped billing and payment code during the payment amount benchmark quarter and later billed under a unique billing and payment code, CMS will use the grouped billing and payment code payment limit as the payment amount in the payment amount benchmark quarter.

(e) *Identification of the benchmark period CPI–U.* For each Part B rebatable drug, CMS will identify the applicable benchmark period CPI–U at the billing and payment code level as set forth in paragraphs (e)(1) and (2) of this section, subject to paragraphs (e)(3) through (5) of this section:

(1) For a Part B rebatable drug first approved or licensed by the FDA on or before December 1, 2020, and with a first marketed date on or before December 1, 2020, the benchmark period CPI–U is the CPI–U for January 2021.

(2) For a Part B rebatable drug first approved or licensed by the FDA after December 1, 2020, the benchmark period CPI–U is the CPI–U for the first month of the first full calendar quarter after a drug's first marketed date.

(3) Notwithstanding paragraph (e)(2) of this section, for a Part B rebatable drug first approved or licensed by FDA on or before December 1, 2020, and with a first marketed date after December 1, 2020, the benchmark period CPI–U is the CPI–U for the first month of the first full calendar quarter after a drug's first marketed date.

(4) Notwithstanding paragraph (e)(3) of this section, for a Part B rebatable

drug that was billed under a NOC code during the calendar quarter beginning July 1, 2021, or the third full calendar quarter after such drug's first marketed date, whichever is later, the benchmark period CPI–U is the CPI–U for the first month of the first full calendar quarter after the Part B rebatable drug is assigned a billing and payment code other than a NOC code.

(5) Notwithstanding paragraph (e)(4) of this section, for a Part B rebatable drug that is a selected drug (as defined in section 1192(c) of the Act) with respect to a price applicability period (as defined in section 1191(b)(2) of the Act), in the case such Part B rebatable drug is no longer considered to be a selected drug, the benchmark period CPI–U is the CPI–U for the July of the year preceding the last year during such price applicability period.

(f) *Identification of the rebate period CPI–U.* For each Part B rebatable drug by billing and payment code, CMS will identify and use the greater of the benchmark period CPI–U index level or the CPI–U index level for the first month of the calendar quarter that is two calendar quarters before the applicable calendar quarter in which the Part B rebatable drug is furnished.

(g) *Determination of inflation-adjusted payment amount.* For each applicable calendar quarter and for each Part B rebatable drug by billing and payment code, CMS will calculate the inflation-adjusted payment amount by dividing the rebate period CPI–U by the benchmark period CPI–U and then multiplying the quotient by the payment amount in the payment amount benchmark quarter, determined under paragraph (d) of this section.

[89 FR 98578, Dec. 9, 2024, as amended at 90 FR 20808, May 16, 2025]

§ 427.303 Determination of total number of billing units.

(a) *General.* For each Part B rebatable drug, CMS will determine the total number of billing units of the billing and payment code subject to a rebate in the applicable calendar quarter using final action Medicare fee-for-service claims for which Medicare payment was allowed and greater than zero.

(b) *Total billing units.* Using final action claims in the Medicare fee-for-service claims repository, at least 3 months after the end of the applicable calendar quarter, CMS will determine the total number of billing units for a Part B rebatable drug in an applicable calendar quarter by identifying separately payable claim lines for the billing and payment code for dates of service in that applicable calendar quarter and excluding the following billing units in claim lines as applicable:

(1) *Billing units of drugs acquired through the 340B Program.* CMS will exclude billing units acquired under the 340B Program as identified through—

(i) Separately payable units in all professional claim lines for dates of service during 2023 and 2024 that were billed with the ''JG'' or ''TB'' modifiers and separately payable billing units in claim lines for professional claims with dates of service during 2023 and 2024 from suppliers that are associated with covered entities listed by the Health Resources and Services Administration (HRSA) 340B Office of Pharmacy Affairs Information System (OPAIS) as participating in the 340B Program. CMS will use National Provider Identifiers (NPI) and/or Medicare Provider Numbers (MPN), or other fields in the OPAIS database (such as name and address) if NPI or MPN is not available, to identify these suppliers and the claims submitted with such identifiers;

(ii) Separately payable billing units in claim lines for institutional claims that are billed with the ''JG'' or ''TB'' modifiers and units in institutional claims from covered entities that are critical access hospitals and Maryland waiver hospitals with dates of service from January 1, 2023 through December 31, 2023. CMS will use NPIs and MPNs, or other fields in the OPAIS database (such as name and address) if NPI or MPN are not available, to identify these suppliers and the claims submitted with such identifiers;

(iii) Separately payable billing units in claim lines for institutional claims that are billed with the ''JG'' or ''TB'' modifiers for claims with dates of service from January 1, 2024 through December 31, 2024; and

(iv) Separately payable billing units in claim lines billed with the ''TB''

modifier for claims with dates of service on or after January 1, 2025.

(2) *Billing units with a rebate under section 1927 of the Social Security Act.* Subject to paragraph (b)(2)(i) of this section, CMS will exclude billing units from claims with dates of service during a month within an applicable calendar quarter if the units are furnished to a dually eligible Medicare beneficiary who has Medicaid coverage that may provide cost-sharing assistance.

(i) CMS will not exclude billing units from claims when the Medicare beneficiary has Medicaid coverage that does not include cost-sharing assistance, including Specified Low-Income Medicare Beneficiaries (SLMB), Qualified Disabled and Working Individuals (QDWI), and Qualifying Individuals (QI) beneficiaries.

(ii) [Reserved]

(3) *Billing units that are packaged into the payment amount for an item or service and are not separately payable.* CMS will exclude billing units that are packaged into the payment amount for an item or service and are not separately payable.

(4) *Billing units when a drug is no longer a Part B rebatable drug.* In situations where a Part B rebatable drug that is a single source drug becomes a multiple source drug during an applicable calendar quarter, CMS will:

(i) Determine if such drug has become a multiple source drug by reviewing FDA's most recent publication of ''Approved Drug Products with Therapeutic Equivalence Evaluations'' (commonly known as the Orange Book) for a drug that is that is rated as therapeutically equivalent to such drug; and,

(ii) If a therapeutically equivalent drug is identified as set forth in paragraph (b)(4)(i) of this section, determine if the therapeutically equivalent drug was sold or marketed during the applicable calendar quarter; and

(iii) Exclude billing units of such drug furnished on and after the first day of the calendar month in which the therapeutically equivalent drug was first sold or marketed during the applicable calendar quarter.

(5) *Billing units subject to discarded drug refunds.* CMS will exclude billing units of discarded refundable single-dose container or single-use package drugs for which a refund is owed as set forth in § 414.940 of this chapter from the calculation of rebate amounts. For applicable calendar quarters beginning on or after January 1, 2024, these billing units will be excluded as part of the reconciliation process described at § 427.501(d).

§ 427.304 Adjustments for changes to billing and payment codes.

(a) *Changes in billing unit dose description.* If there has been a change to the dose description for a Part B rebatable drug (causing a new billing and payment code to be assigned), CMS will calculate a conversion factor based on the ratio of the billing unit dose description for the current billing and payment code to the billing unit dose description for the prior billing and payment code. CMS will apply the conversion factor to the payment amount in the payment amount benchmark quarter, as set forth in § 427.302(d), before applying the percentage by which the rebate period CPI–U for the calendar quarter exceeds the benchmark period CPI–U.

(b) *Instances when a new billing and payment code is assigned.* If a new billing and payment code is assigned for a Part B rebatable drug, CMS will use the payment amount in the payment amount benchmark quarter, the payment amount benchmark quarter, and the benchmark quarter CPI–U of the prior billing and payment code to calculate the per unit Part B rebate amount under § 427.302.

(c) *Documentation.* CMS will maintain a crosswalk reflecting the changes in billing and payment codes and dose descriptions as applicable.

Subpart E—Reducing the Rebate Amount for Part B Rebatable Drugs in Shortage and When There Is a Severe Supply Chain Disruption

§ 427.400 Definitions.

As used in this subpart, the following definitions apply:

Currently in shortage means that at least one NDC–10 assigned to the billing and payment code of a Part B

rebatable drug with the status ''currently in shortage'' is on a shortage list maintained by the FDA under section 506E of the FD&C Act.

Drug shortage or *shortage* means a period of time when the demand or projected demand for the drug within the United States exceeds the supply of the drug (see section 506C(h)(2) of the FD&C Act).

Natural disaster means any natural catastrophe, including, but not limited to any of the following: hurricane, tornado, storm, high water, wind-driven water, tidal wave, tsunami, earthquake, volcanic eruption, landslide, mudslide, snowstorm, or drought, or regardless of cause, any fire, flood, or explosion.

Other unique or unexpected event means any exogenous, unpredictable event outside of a manufacturer's control, including, but not limited to, a geopolitical disruption, pandemic, or act of terror.

Plasma-derived product means a licensed biological product that is derived from human whole blood or plasma, as indicated on the approved product labeling.

Severe supply chain disruption means a change in production or distribution that is reasonably likely to lead to a significant reduction in the U.S. supply of a Part B rebatable biosimilar biological product by a manufacturer and significantly affects the ability of the manufacturer of the biosimilar biological product to fill orders or meet expected demand for its product in the United States for at least 90 days. This definition does not include interruptions in manufacturing due to matters such as routine maintenance, manufacturing quality issues, or insignificant changes made in the manufacturing process for the drug.

§ 427.401 Reducing the rebate amount for Part B rebatable drugs currently in shortage.

(a) *General.* As required under section 1847A(i)(3)(G)(i) of the Act, CMS will reduce the total rebate amount determined under § 427.301(a), if any is owed, for a Part B rebatable drug that is currently in shortage, as set forth in § 427.400, at any point during the applicable calendar quarter.

(b) *Calculation of the reduced rebate amount.* (1) For each applicable calendar quarter beginning on or after January 1, 2023, the reduced total rebate amount for a Part B rebatable drug currently in shortage will be calculated using the following formula:

Equation 1 to Paragraph (b)(1)

Reduced Total Rebate Amount = the total rebate amount multiplied by (1 *minus* applicable percent reduction) multiplied by (percentage of time drug was currently in shortage during the applicable calendar quarter) added to the total rebate amount multiplied by (1 *minus* percentage of time drug was currently in shortage during the applicable calendar quarter)

(2) For purposes of paragraph (b)(1) of this section, the applicable percent reduction is:

(i) For a Part B rebatable drug that is a plasma-derived product:

(A) 75 percent for the first 4 consecutive applicable calendar quarters such drug is currently in shortage.

(B) 50 percent for the second 4 consecutive applicable calendar quarters such drug is currently in shortage.

(C) 25 percent for each subsequent applicable calendar quarter such drug is currently in shortage.

(ii) For a Part B rebatable drug that is not a plasma-derived product:

(A) 25 percent for the first 4 consecutive applicable calendar quarters such drug is currently in shortage.

(B) 10 percent for the second 4 consecutive applicable calendar quarters such drug is currently in shortage.

(C) 2 percent for each subsequent applicable calendar quarter such drug is currently in shortage.

(iii) Except as provided in paragraph (b)(iv) of this section, CMS will apply the greatest applicable percent reduction as set forth in paragraph (b)(2)(i)(A) or (b)(2)(ii)(A) of this section starting with the first applicable calendar quarter that a Part B drug or biological product is described as currently in shortage regardless of whether the drug or biological product meets the definition of a Part B rebatable drug or whether a rebate amount is owed for that calendar quarter, starting with the calendar quarter that begins January 1, 2023.

(iv) If any applicable calendar quarter for which a rebate reduction determined under § 427.402 has been granted would be the first of the four consecutive applicable calendar quarters described in paragraph (b)(2)(i)(A) or (b)(2)(ii)(A) of this section and the Part B rebatable drug or biological product continues to be currently in shortage after the rebate reduction period described in § 427.402, CMS will treat the quarter following the final quarter in which the rebate reduction determined under § 427.402 applies as the first of the four consecutive applicable calendar quarters so described.

(3) For purposes of paragraph (b)(1) of this section, the percentage of time the drug is currently in shortage during the applicable calendar quarter is equal to the number of days such drug is currently in shortage in an applicable calendar quarter, divided by the total number of days in the applicable calendar quarter.

(c) *Application of reduction.* CMS will apply a reduction of the rebate amount as determined under paragraph (b) of this section to all the NDCs under the relevant billing and payment code.

[89 FR 98578, Dec. 9, 2024, as amended at 90 FR 20808, May 16, 2025]

§ 427.402 Reducing the rebate amount for certain Part B rebatable drugs when there is a severe supply chain disruption.

(a) *General.* As required under section 1847A(i)(3)(G)(ii) of the Act, CMS will reduce the total rebate amount determined under § 427.301(a), if any is owed, for a Part B rebatable biosimilar biological product when CMS determines there is a severe supply chain disruption during the applicable calendar quarter such as that caused by a natural disaster or other unique or unexpected event.

(b) *Calculation of the reduced rebate amount*—(1) *Initial reduction.* If CMS determines the criteria set forth in paragraph (c)(4) of this section are met, then CMS will reduce the total rebate amount determined under § 427.301(a), if any is owed, for a Part B rebatable biosimilar biological product by 75 percent for the applicable calendar quarter in which the event occurred or began, or the following applicable calendar quarter if the request is submitted less than 60 calendar days before the end of an applicable calendar quarter, and the 3 subsequent applicable calendar quarters.

(2) *Extension of reduction.* If CMS determines a severe supply chain disruption continues into a fifth applicable calendar quarter as set forth in paragraph (c)(5) of this section, then CMS will reduce the total rebate amount determined under § 427.301(a), if any is owed, for a Part B rebatable biosimilar biological product by 75 percent for that fifth applicable calendar quarter and an additional 3 consecutive applicable calendar quarters.

(3) *Application of reduction.* If CMS determines there is a severe supply chain disruption for an NDC–11 assigned to a billing and payment code, CMS will apply any reduction of the rebate amount as determined under paragraphs (b)(1) and (2) of this section to all the NDCs under the relevant billing and payment code.

(4) *Limitation on rebate reductions.* CMS will not apply multiple rebate reductions for the same Part B rebatable drug and applicable calendar quarter.

(i) If a manufacturer believes there are multiple events causing severe supply chain disruptions during the same 4 applicable calendar quarters for the same Part B rebatable biosimilar biological product and submits multiple rebate reduction requests for the same product, CMS will grant no more than 1 rebate reduction determined under paragraph (b)(1) or (2) of this section for that product for those consecutive applicable calendar quarters.

(ii) If CMS grants a rebate reduction request under this section, and the Part B rebatable biosimilar biological product subject to the reduction appears as currently in shortage during any of the 4 applicable calendar quarters as the ones for which the severe supply chain disruption reduction request was granted, CMS will reduce the rebate amount as determined under paragraph (b)(1) of this section and will not grant a reduction determined under § 427.401 during those applicable calendar quarters.

(iii) If a Part B rebatable biosimilar biological product that is currently in shortage experiences a severe supply

chain disruption, CMS will reduce the rebate amount as determined under paragraph (b)(1) of this section and will not grant a reduction determined under § 427.401 during those applicable calendar quarters.

(c) *Eligibility for a rebate reduction*—(1) *Eligible drug*. Subject to paragraph (b)(3) of this section, eligibility for a rebate reduction under this section is limited to Part B rebatable biosimilar biological products for which a manufacturer submits a rebate reduction request under this section.

(2) *Timing*. For a natural disaster or other unique or unexpected event occurring on or after August 2, 2024, that the manufacturer believes caused a severe supply chain disruption, the manufacturer must submit the rebate reduction request within 60 calendar days from the first day that the natural disaster or other unique or unexpected event occurred or began in order to receive consideration for a reduction in the rebate amount owed as set forth in paragraph (b)(1) of this section.

(3) *Required elements of a rebate reduction request*. To receive consideration for a reduction in the rebate amount owed determined under paragraph (b)(1) of this section, the manufacturer must submit to CMS information and supporting documentation to substantiate the evaluation criteria set forth in paragraph (c)(4) of this section. Such information and supporting documentation include the following:

(i) Evidence that the severe supply chain disruption directly affects the manufacturer itself, a supplier of an ingredient or packaging, a contract manufacturer, or a method of shipping or distribution that the manufacturer uses to make or distribute the Part B rebatable biosimilar biological product(s), such as a change in the production or distribution of the Part B rebatable biosimilar biological product(s) that is reasonably likely to lead to a significant reduction in the U.S. supply of product and significantly affects the manufacturer's ability to fill orders or meet expected demand for the Part B rebatable biosimilar biological product(s) for at least 90 days;

(ii) Information about when the manufacturer expects supply of the Part B rebatable biosimilar biological product(s) to meet expected demand;

(iii) Evidence that the natural disaster or other unique or unexpected event caused the severe supply chain disruption, including when the natural disaster or other unique or unexpected event occurred or began occurring, and the expected or actual duration of the severe supply chain disruption; and

(iv) Evidence of the manufacturer's physical presence related to manufacturing the Part B rebatable biosimilar biological product(s) in a geographic area where a natural disaster or other unique or unexpected event occurred. If the manufacturer is not physically present in a geographic area where a natural disaster or other unique or unexpected event occurred, but believes there is a severe supply chain disruption caused by a natural disaster or other unique or unexpected event that affects the manufacturer's Part B rebatable biosimilar biological product(s), the information and supporting documentation may include evidence of the impact of the natural disaster or other unique or unexpected event on the supply chain of the Part B rebatable drug or biosimilar, on a supplier of an ingredient or packaging, or method of shipping or distribution that the manufacturer uses.

(4) *Evaluation criteria*. In accordance with paragraph (b)(1) of this section, CMS will grant a reduction in the rebate amount determined under § 427.301(a), if any is owed, if a manufacturer submits to CMS a request in writing for an eligible drug, in accordance with the timing set forth in paragraph (c)(2) of this section, demonstrating that:

(i) A severe supply chain disruption has occurred during the applicable calendar quarter;

(ii) The severe supply chain disruption directly affects the manufacturer itself, a contract manufacturer, a supplier of an ingredient or packaging, or a method of shipping or distribution that the manufacturer uses in a significant capacity to make or distribute the Part B rebatable biosimilar biological product; and

(iii) The severe supply chain disruption was caused by a natural disaster or other unique or unexpected event.

(5) *Rebate reduction extensions.* If CMS determines that a Part B rebatable biosimilar biological product that received a reduction of the rebate amount as determined under paragraph (b)(1) of this section continues to be affected by a severe supply chain disruption, CMS will grant a single extension of the reduction for 4 additional consecutive applicable calendar quarters and reduce the rebate amount calculated at § 427.301(a), if any is owed as determined under paragraph (b)(2) of this section.

(i) To receive consideration for a rebate reduction extension, a manufacturer must submit a request with updated or new information and supporting documentation on why the Part B rebatable biosimilar biological product continues to be affected by the severe supply chain disruption during the fifth through eighth applicable calendar quarters.

(ii) A manufacturer must submit the rebate reduction extension request at least 60 calendar days before the start of the fifth applicable calendar quarter to receive consideration for a reduction in the rebate amount owed, if any, as determined under paragraph (b)(2) of this section.

(6) *Decision to grant or deny a request.* CMS will review rebate reduction requests and rebate reduction extension requests within 60 calendar days of receipt of all documentation, if feasible, beginning with the applicable calendar quarter that begins on October 1, 2024.

(i) CMS will deny a rebate reduction request that does not meet the criteria set forth in paragraph (c)(4) of this section or that is incomplete or untimely based on the requirements set forth in this paragraph (c).

(ii) CMS will deny a rebate reduction extension request that does not meet the criteria set forth in paragraph (c)(5) of this section, that is incomplete or untimely based on the requirements set forth in paragraph (c)(5), or if a reduction determined under paragraph (b)(1) of this section was not granted for such biosimilar biological product.

(iii) CMS' decisions to deny a request are final and will not be subject to an appeals process.

(7) *Public disclosure of information.* CMS will keep confidential, to the extent allowable under law, any requests for a rebate reduction, including supporting documentation. Information provided as part of a request for a rebate reduction that the submitter indicates is a trade secret or confidential commercial or financial information will be protected from disclosure if CMS determines the information meets the requirements set forth under Exemptions 3 and/or 4 in 5 U.S.C. 552.

Subpart F—Reports of Rebate Amounts, Reconciliation, Suggestion of Error, and Payments

§ 427.500 Definitions.

As used in this subpart, *date of receipt* is the calendar day following the day on which a report of a rebate amount (as set forth in §§ 427.501(b) through (d) and 427.502(b) and (c) is made available to the manufacturer of a Part B rebatable drug by CMS.

§ 427.501 Rebate Reports and reconciliation.

(a) *General.* This section applies to Part B rebatable drugs for all applicable calendar quarters except as otherwise set forth in § 427.502 regarding the applicable calendar quarters in calendar years 2023 and 2024.

(b) *Preliminary Rebate Report.* A Preliminary Rebate Report will be provided to each manufacturer of a Part B rebatable drug at least 1 month prior to the issuance of the Rebate Report as set forth in paragraph (c) of this section for an applicable calendar quarter.

(1) The Preliminary Rebate Report for each Part B rebatable drug will include the following information:

(i) The NDC(s) and billing and payment codes identified for the Part B rebatable drug set forth in § 427.20.

(ii) Total number of billing units as determined under § 427.303.

(iii) Payment amount benchmark quarter and payment amount in the payment amount benchmark quarter as determined under § 427.302(c) and (d).

(iv) Applicable calendar quarter specified amount as determined under § 427.302(b).

(v) Applicable benchmark period and rebate period CPI–Us as set forth in § 427.302(e) and (f).

(vi) Inflation-adjusted payment amount as determined under § 427.302(g).

(vii) The amount, if any, by which the specified amount as determined under § 427.302(b) exceeds the inflation-adjusted payment amount as determined under § 427.302(g) for the Part B rebatable drug for the applicable calendar quarter as set forth in § 427.302.

(viii) Any applied reductions as determined under §§ 427.401 and 427.402.

(ix) Rebate amount due as determined under § 427.301(a).

(2) [Reserved]

(c) *Rebate Report.* A Rebate Report will be provided to each manufacturer of a Part B rebatable drug no later than 6 months after the end of each applicable calendar quarter.

(1) The Rebate Report will include the information specified in paragraph (b)(1) of this section, with the inclusion of any revisions to such information resulting from CMS' review of a Suggestion of Error as set forth in § 427.503, if applicable, and any CMS-determined recalculations from paragraph (d)(2) of this section.

(2) The Rebate Report is the invoice of a manufacturer's rebate amount due as determined under § 427.301, if any, for a Part B rebatable drug for an applicable calendar quarter.

(d) *Reconciliation of the rebate amount.* CMS will perform reconciliation of a rebate amount provided in a Rebate Report specified in paragraph (c) of this section for an applicable calendar quarter in the following circumstances:

(1) *Regular reconciliation.* Except as otherwise set forth in § 427.502, CMS will perform one regular reconciliation of the rebate amount within 12 months of the date of receipt of the Rebate Report for each applicable calendar quarter to include revisions to the information used to calculate the rebate amount set forth in paragraph (c)(1) of this section.

(i) *Preliminary reconciliation.* At least 1 month prior to the issuance of a report with the reconciled rebate amount for an applicable calendar quarter as set forth in paragraph (d)(1)(ii) of this section, CMS will conduct a preliminary reconciliation of the rebate amount for an applicable calendar quarter based on the information set forth in paragraphs (b)(1)(i) through (ix) of this section and provide the information set forth in paragraphs (b)(1) and (d)(1)(i)(A) through (F) of this section to the manufacturer of a Part B rebatable drug for the applicable calendar quarter, if applicable:

(A) Updated total number of rebatable units, as determined under § 427.303.

(B) Updated payment amount benchmark quarter and payment amount in the payment amount benchmark quarter, as determined under § 427.302(c) and (d) if any inputs are restated within the reconciliation run-out period.

(C) Applicable calendar quarter specified amount as determined under § 427.302(b), if any inputs are restated within the reconciliation run-out period.

(D) The excess amount by which the specified amount exceeds the inflation-adjusted payment amount as determined under § 427.302, if any inputs are restated within the reconciliation run-out period.

(E) Reconciled total rebate amount as determined under § 427.301(a).

(F) The difference between the total rebate amount due as specified on the Rebate Report set forth in paragraph (c) of this section and the reconciled rebate amount as set forth in this paragraph (d)(1)(i).

(ii) *Report with reconciled rebate amount.* With the inclusion of any additional revisions to such information resulting from CMS' review of a Suggestion of Error as set forth in § 427.503, if applicable, a report with the reconciled rebate amount will be provided to each manufacturer of a Part B rebatable drug within 12 months after the issuance of the Rebate Report described in paragraph (c) of this section.

(2) *CMS identification of error and manufacturer misreporting.* CMS may recalculate a rebate amount and provide the manufacturer of a Part B rebatable drug a report with a reconciled rebate amount when:

(i) CMS identifies an agency error in the information specified in paragraphs (c) and (d)(1) of this section, including reporting system or coding errors, not later than 3 years from the date of receipt by a manufacturer of a reconciled

rebate amount for the applicable calendar quarter; or

(ii) CMS determines at any time that the information used by CMS to calculate the rebate amount was inaccurate due to manufacturer misreporting.

(3) *Impact of reconciliation on rebate amount.* A reconciliation as set forth in this paragraph (d) could result in an increase, decrease, or no change to the rebate amount, as determined under § 427.301, owed by a manufacturer for the applicable calendar quarter for the Part B rebatable drug compared to the amount described in the Rebate Report described in paragraph (c) of this section or an amount described in a previous reconciliation.

(i) A report with a reconciled rebate amount that is an increase to the rebate amount is the invoice for such additional amount due on the manufacturer's rebate amount as determined under § 427.301 for a Part B rebatable drug for an applicable calendar quarter.

(ii) [Reserved]

(4) *Drugs included in a reconciliation.* A drug covered under Part B that does not meet the requirements of a rebatable drug specified in subpart B for an applicable calendar quarter will not be included in a reconciliation under this paragraph (d).

[89 FR 98578, Dec. 9, 2024, as amended at 90 FR 20808, May 16, 2025]

§ 427.502 Rebate Reports for applicable calendar quarters in calendar years 2023 and 2024.

(a) *Transition rule for reporting.* Section 1847A(i)(1)(C) of the Act allows CMS to delay the timeframe for reporting the information and rebate amount described in § 427.501(c) for applicable calendar quarters in calendar years 2023 and 2024 until not later than September 30, 2025.

(b) *Rebate Report information for applicable calendar quarters in calendar years 2023 and 2024.* The Rebate Reports for applicable calendar quarters in calendar years 2023 and 2024 will include the information set forth in § 427.501(b)(1).

(c) *Rebate Report procedures for applicable calendar quarters in calendar years 2023 and 2024.* Rebate amounts for the applicable calendar quarters in calendar year 2023 and 2024 will be reported as follows:

(1) The 4 applicable calendar quarters in calendar year 2023 will be consolidated into a single report and manufacturers will receive a single Preliminary Rebate Report followed by a single Rebate Report.

(i) Discarded drug units for which a refund is owed will be removed from the total number of billing units in the single Preliminary Rebate Report for the applicable calendar quarters in calendar year 2023.

(ii) For this single Preliminary Rebate Report for the applicable calendar quarters in calendar year 2023, the Suggestion of Error period as set forth in § 427.503 will be 30 calendar days.

(iii) No regular reconciliation of the rebate amount as set forth in § 427.501(d)(1) will be conducted for the rebate amount in the single Rebate Report for the applicable calendar quarters in calendar year 2023.

(2) The four applicable calendar quarters in calendar year 2024 will be consolidated into a single report and manufacturers will receive a single Preliminary Rebate Report followed by a single Rebate Report.

(i) For this single Preliminary Rebate Report for the applicable calendar quarters in calendar year 2024, the Suggestion of Error period as set forth in § 427.503 will be 30 calendar days.

(ii) Nine months after issuance of the single Rebate Report, CMS will perform one regular reconciliation for the applicable calendar quarters in calendar year 2024 in order to include revisions to the information used, determined under § 427.501(b)(1), to calculate the rebate amount. Such reconciliation will be as determined under § 427.501(d) inclusive of a preliminary reconciliation and a report with the reconciled rebate amount.

(iii) The Suggestion of Error period for the preliminary reconciliation for the applicable calendar quarters in calendar year 2024 will be 10 calendar days.

§ 427.503 Suggestion of Error.

(a) *General.* The manufacturer of a Part B rebatable drug may submit a

Suggestion of Error about the information in their Preliminary Rebate Report and the report detailing the preliminary reconciliation of the rebate amount to CMS, for its discretionary consideration, if the manufacturer believes that there is a mathematical error or errors to be corrected before the Rebate Report or a subsequent reconciliation of the rebate amount, as applicable, is finalized.

(1) Section 1847A(i)(8) of the Act precludes administrative or judicial review on the determination of units as set forth in § 427.303, the determination of whether a drug is a Part B rebatable drug as set forth in § 427.101, and the calculation of the rebate amount as set forth in § 427.301, inclusive of any reconciled rebate amount.

(2) [Reserved]

(b) *Process of submission.* Subject to the scope and timing requirements specified in paragraphs (a) and (c) of this section, manufacturers may submit the Suggestion of Error and provide supporting documentation (if applicable).

(c) *Timing.* Except as set forth in § 427.502 for applicable calendar quarters in calendar year 2023 and 2024, a manufacturer must submit its Suggestion of Error for the applicable calendar quarter within 10 calendar days from the date of receipt of a Preliminary Rebate Report or a preliminary reconciliation of a rebate amount using the method and process established by CMS in paragraph (b) of this section.

(d) *Notice.* (1) CMS will include any revisions to the calculation of the rebate amount, if determined necessary by CMS based on the Suggestion of Error submitted under this section prior to issuance of the Rebate Report as set forth in § 427.501(c) or § 427.502(c) as well as any report of reconciled rebate amount as set forth in § 427.501(d) or § 427.502(c)(2)(ii).

(2) CMS will notify the manufacturer whether CMS revised its calculation of the rebate amount based on the Suggestion of Error.

§ 427.504 Manufacturer access to Rebate Reports.

(a) *General.* CMS will establish a method and process for a manufacturer of the Part B rebatable drug to:

(1) Access the manufacturer's Rebate Report as set forth in §§ 427.501 and 427.502, including any report of reconciled rebate amount as set forth in §§ 427.501(d) and 427.502(c)(2)(ii);

(2) Submit a Suggestion of Error as set forth in §§ 427.502(c)(1)(ii) and (c)(2)(i) and 427.503; and

(3) Pay a rebate amount as set forth in § 427.505.

(b) [Reserved]

§ 427.505 Deadline and process for payment of rebate amount.

(a) *Rebate amounts owed by a manufacturer.* For a rebate amount owed by a manufacturer, payment is due no later than 11:59 p.m. Pacific Time (PT) on the 30th calendar day after the date of receipt of information regarding the rebate amount on—

(1) A Rebate Report as set forth in § 427.501(c) or § 427.502(c)(1) or (2); or

(2) A report of a reconciled rebate amount as set forth in § 427.501(d) or § 427.502(c)(2)(ii).

(b) *Failure to pay a rebate amount.* Failure to pay a rebate amount due timely and in full may result in an enforcement action as described in subpart G of this part.

(c) *Refund to the manufacturer.* If a reconciled rebate amount for an applicable calendar quarter as set forth in § 427.501(d) or § 427.502(c)(2)(ii) is less than what the manufacturer paid for that applicable calendar quarter, CMS will initiate the process to provide a refund equal to the excess amount paid within 60 days of the date of receipt of the report with such reconciled rebate amount.

Subpart G—Enforcement of Manufacturer Payment of Rebate Amounts

§ 427.600 Civil money penalty notice and appeals procedures.

(a) *General.* CMS may impose a civil money penalty on a manufacturer that fails to pay the rebate amount determined in § 427.301(a) on a Part B rebatable drug as set forth in § 427.101, by the payment deadline as set forth in § 427.505(a) for such drug for such applicable calendar quarter.

(b) *Determination of the civil money penalty amount.* CMS may impose a

civil money penalty for each failure by a manufacturer to provide an inflation rebate for an applicable calendar quarter equal to 125 percent of the rebate amount determined in §427.301(a).

(1) The civil money penalty is in addition to the rebate amount due.

(2) If a reconciled rebate amount as determined in §427.501(d) or §427.502(c)(2)(ii) results in an increase to the rebate amount due, a separate civil money penalty may be imposed for the failure by a manufacturer to provide an inflation rebate for the applicable quarter for the increase to the rebate amount due.

(c) *Notice of imposition of civil money penalties.* If CMS makes a determination to impose a civil money penalty described in paragraph (b) of this section, CMS will send a written notice of its decision to impose a civil money penalty that includes the following:

(1) A description of the basis for the determination.

(2) The basis for the penalty.

(3) The amount of the penalty.

(4) The date the penalty is due.

(5) The manufacturer's right to a hearing as set forth in paragraph (e)(3) of this section.

(6) Information about where to file the request for a hearing.

(d) *Collection.* (1) A manufacturer must pay the civil money penalty in full within 60 calendar days after the date of the notice of imposition of a civil money penalty from CMS under paragraph (c) of this section.

(2) In the event a manufacturer requests a hearing, pursuant to 42 CFR part 423, subpart T, the manufacturer must pay the amount in full within 60 calendar days after the date of a final decision by the Departmental Appeal Board, to uphold, in whole or in part, the civil money penalty.

(3) If the 60th calendar day described in paragraphs (d)(1) and (2) of this section is a weekend or a Federal holiday, then the timeframe is extended until the end of the next business day.

(e) *Appeal procedures for civil money penalties.* Section 1128A(c)(2) of the Act provides that CMS may not collect a civil money penalty until the affected party has had notice and the opportunity for a hearing.

(1) Manufacturers may appeal the following determinations:

(i) A CMS determination that the rebate amount was not paid by the applicable payment deadline as set forth in §427.505.

(ii) The calculation of the amount of the civil money penalty.

(2) If CMS decides to impose a civil money penalty, CMS will provide the manufacturer with notice pursuant to the process set forth in paragraph (c) of this section.

(3) A manufacturer has a right to a hearing following a decision by CMS to impose a civil money penalty following the administrative appeal process and procedures established in 42 CFR part 423, subpart T.

(f) *Other applicable provisions.* The provisions of section 1128A of the Act (except subsections (a) and (b) of section 1128A of the Act) apply to civil money penalties under this section to the same extent that they apply to a civil money penalty or procedures under section 1128A of the Act.

(g) *Bankruptcy.* In the event that a manufacturer declares bankruptcy, as described in title 11 of the United States Code, and as a result of the bankruptcy, fails to pay either the full rebate amount owed or the total sum of civil money penalties imposed, the Government reserves the right to file a proof of claim with the bankruptcy court to recover the unpaid amount of the rebates and civil money penalties owed by the manufacturer.

PART 428—MEDICARE PART D DRUG INFLATION REBATE PROGRAM

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SOURCE: 89 FR 98588, Dec. 9, 2024, unless otherwise noted.

Subpart A—General Provisions

§ 428.10 Basis and scope.

(a) *Basis*. This part implements section 1860D–14B of the Social Security Act (''the Act'').

(b) *Scope*. This part sets forth the requirements of the Medicare Part D Drug Inflation Rebate Program, which requires, for each 12-month applicable period, manufacturers to pay rebates for certain drugs and biological products with prices that increase faster than the rate of inflation.

(c) *Severability*. Were any provision of this part to be held invalid or unenforceable by its terms, or as applied to any person or circumstance, such provisions would be severable from this part and the invalidity or unenforceability would not affect the remainder thereof or any other part of this subchapter or the application of such provision to other persons not similarly situated or to other, dissimilar circumstances.

§ 428.20 Definitions.

As used in this part, the following definitions apply:

Annual manufacturer price (AnMP) means the amount determined under § 428.202(b).

Applicable period means a 12-month period beginning with October 1 of a year (beginning with October 1, 2022).

Applicable period Consumer Price Index for All Urban Consumers (CPI–U) means, with respect to an applicable period, the CPI–U for the first month of such applicable period (that is, October).

Applicable threshold means the amount determined under § 428.101(b)(2).

Average manufacturer price (AMP) means the average price paid to the manufacturer for the drug by wholesalers for drugs distributed to retail community pharmacies and retail community pharmacies that purchase drugs directly from the manufacturer, determined under § 447.504 of this chapter.

Benchmark period CPI–U means the CPI–U identified as set forth in § 428.202(e).

Benchmark period manufacturer price means the amount determined under § 428.202(d).

Covered Part D Drug has the meaning set forth in section 1860D–2(e) of the Act and § 423.100 of this chapter.

CPI–U means the monthly Consumer Price Index for All Urban Consumers (United States city average) index level for all items from the Bureau of Labor Statistics.

First marketed date means the date that a manufacturer is required to report for a Part D rebatable drug as its

''market date'' under section 1927(b)(3)(A)(v) of the Act.

Inflation-adjusted payment amount means the amount determined under §428.202(f).

Manufacturer has the meaning set forth in section 1927(k)(5) of the Act.

National Drug Code (NDC) means the unique identifying prescription drug product number that is listed with FDA identifying the product.

Part D rebatable drug means, subject to the exclusion set forth in §428.101(b), a drug or biological that is a covered Part D drug that, as of the first day of the applicable period, is:

(1) A drug approved under a New Drug Application (NDA) under section 505(c) of the Federal Food, Drug, and Cosmetic (FD&C) Act;

(2) A generic drug approved under an Abbreviated New Drug Application (ANDA) under section 505(j) of the FD&C Act (''section 505(j) ANDA''), in the case where:

(i) The reference listed drug approved under an NDA under section 505(c) of the FD&C Act, including any authorized generic drug as defined in section 505(t)(3) of the FD&C Act, is not being marketed, as identified in the Food and Drug Administration's (FDA) NDC Directory;

(ii) There is no other drug approved under section 505(j) of the FD&C Act that is rated as therapeutically equivalent in FDA's most recent publication of ''Approved Drug Products with Therapeutic Equivalence Evaluations'' (commonly known as the Orange Book), and that is being marketed, as identified in FDA's NDC Directory;

(iii) The manufacturer is not a ''first applicant'' during the ''180-day exclusivity period,'' as those terms are defined in section 505(j)(5)(B)(iv) of the FD&C Act; and

(iv) The manufacturer is not a ''first approved applicant'' for a competitive generic therapy, as that term is defined in section 505(j)(5)(B)(v) of the FD&C Act; or

(3) A biological licensed under section 351 of the Public Health Service (PHS) Act, including a biosimilar.

Payment amount benchmark period means the period identified as set forth in §428.202(c).

Subsequently approved drug means a Part D rebatable drug first approved or licensed by the FDA after October 1, 2021.

Unit means, with respect to a Part D rebatable drug, the lowest dispensable amount (such as a capsule or tablet, milligram of molecules, or grams) of the Part D rebatable drug, as reported under section 1927 of the Act.

Subpart B—Determination of Part D Rebatable Drugs

§428.100 Definitions.

As used in this subpart, the following definitions apply:

Individual who uses such a drug or biological means a unique Medicare Part D beneficiary who was dispensed the Part D drug or biological that was covered by their Part D plan sponsor during the applicable period, identified using Prescription Drug Event (PDE) data with dates of service during the applicable period and with gross covered prescription drug costs greater than zero.

Gross covered prescription drug costs has the meaning set forth in §423.308 of this chapter.

§428.101 Identification of Part D rebatable drugs.

(a) *Determination of Part D rebatable drugs.* (1) For each applicable period, CMS will use PDE data to identify all covered Part D drugs.

(2) CMS will match the covered Part D drugs identified in the PDE data with application numbers using FDA sources to determine whether each covered Part D drug is a drug or biological approved under an NDA under section 505(c) of the FD&C Act, approved under an ANDA under section 505(j) of the FD&C Act, or licensed under a Biologics License Application (BLA) under section 351 of the PHS Act, as of the first day of the applicable period.

(3) For a covered Part D drug identified in the PDE that is approved under an ANDA under section 505(j) of the FD&C Act, CMS will determine whether such drug meets the criteria in section 1860D–14B(g)(1)(C)(ii) of the Act as of the first day of the applicable period as follows:

(i) To determine whether the reference listed drug or an authorized generic of the reference listed drug is being marketed, as required under section 1860D–14B(g)(1)(C)(ii)(I) of the Act, CMS will use FDA's NDC Directory, including historical information from NDC Directory files such as discontinued, delisted, and expired listings, provided by the FDA or published on the FDA website.

(ii) To determine whether another drug has been approved under an ANDA that is therapeutically equivalent to the Part D rebatable drug identified as set forth in this paragraph (a)(3), CMS will use FDA's Orange Book. To determine if this therapeutically equivalent drug is being marketed, as required under section 1860D–14B(g)(1)(C)(ii)(II) of the Act, CMS will use FDA's NDC Directory, including historical information from NDC Directory files, such as discontinued, delisted, and expired listings, provided by the FDA or published on the FDA website.

(iii) To determine whether the manufacturer of the drug identified as set forth in this paragraph (a)(3) is a first applicant during the 180-day exclusivity period, or whether the manufacturer of this drug is a first approved applicant for a competitive generic drug therapy, CMS will refer to publicly available FDA sources such as the Orange Book and may consult with FDA for technical assistance as needed.

(b) *Drugs and biologicals with average annual total cost below the applicable threshold.* For each applicable period, CMS will identify drugs and biologicals with average annual total costs under Part D for such applicable period, per individual who uses such drug or biological, that are below the applicable threshold in accordance with the steps described in this paragraph (b). Such drugs and biologicals are not considered Part D rebatable drugs and will be excluded from the identification of Part D rebatable drugs set forth in paragraph (a) of this section.

(1) *Average annual total cost.* For each drug or biological that is identified as set forth in paragraph (a) of this section, CMS will calculate average annual total costs under Part D per individual who uses such drug or biological by dividing the gross covered prescription drug costs for the drug or biological by the number of individuals who use such drug or biological in the applicable period. When calculating the gross covered prescription drug costs for the drug or biological, CMS will exclude PDE records indicating the drug or biological was billed as a compound.

(2) *Applicable threshold.* CMS will calculate the applicable threshold for an applicable period as follows:

(i) For the applicable period beginning October 1, 2022, the applicable threshold is equal to $100.

(ii) For the applicable period beginning October 1, 2023, the applicable threshold is equal to $100 increased by the percentage increase in CPI–U for the 12-month period beginning October 1, 2023.

(iii) For subsequent applicable periods, the applicable threshold is equal to the applicable threshold for the prior applicable period increased by the percentage increase in the CPI–U for the 12-month period beginning with October of the previous period.

(iv) If the resulting amount determined under paragraph (b)(2)(ii) or (iii) of this section is not a multiple of $10, CMS will round that amount to the nearest multiple of $10.

Subpart C—Determination of the Rebate Amount for Part D Rebatable Drugs

§ 428.200 Definitions.

As used in this subpart, the following definitions apply:

340B Program is the program under section 340B of the PHS Act.

Line extension has the meaning set forth in § 447.502 of this chapter.

New formulation has the meaning set forth in § 447.502 of this chapter.

Oral solid dosage form has the meaning set forth in § 447.502 of this chapter.

§ 428.201 Calculation of the total rebate amount to be paid by manufacturers.

(a) *Total rebate.* (1) Subject to paragraph (b) of this section, the total rebate amount to be paid by a manufacturer for a Part D rebatable drug, identified as set forth in § 428.101, for an applicable period is equal to:

(i) The product of the per unit Part D rebate amount of such drug, as determined under § 428.202(a), and the total number of units dispensed of such drug under Part D, as determined under § 428.203; or

(ii) In the case of a Part D rebatable drug that is a line extension of a Part D rebatable drug that is an oral solid dosage form, the amount determined under § 428.204.

(2) The rebate amount may be reduced in accordance with subpart D of this part or adjusted in accordance with subpart E of this part.

(b) *Drugs and biologicals excluded from Part D rebate calculations.* CMS will exclude from the Part D drug inflation rebate calculations described in this subpart—

(1) Drugs and biologicals that meet the definition of a Part D rebatable drug but whose manufacturers do not have an agreement in effect with the HHS Secretary under section 1927 of the Act at any point during the applicable period, as determined by CMS through consultation with Medicaid Drug Rebate Program staff and review of the Medicaid Drug Programs system.

(2) Drugs and biologicals that meet the definition of a Part D rebatable drug but, for the entire duration of the applicable period, are excluded from the definition of covered outpatient drugs as defined in section 1927(k)(2)–(4) of the Act and § 447.502 of this chapter, as determined by CMS through consultation with Medicaid Drug Rebate Program staff and review of the Medicaid Drug Programs system.

§ 428.202 Calculation of the per unit Part D rebate amount.

(a) *Formula for calculating the per unit Part D rebate amount.* CMS will calculate the per unit Part D rebate amount for a Part D rebatable drug and applicable period by determining the amount by which the AnMP for the Part D rebatable drug, as calculated in accordance with paragraph (b) of this section, exceeds the inflation-adjusted payment amount, as calculated in accordance with paragraph (f) of this section.

(b) *Calculation of the AnMP for the applicable period.* Subject to paragraph (g) of this section, CMS will calculate the AnMP for a Part D rebatable drug using the AMP reported by a manufacturer under sections 1927(b)(3)(A)(i)(I) and (ii) of the Act for each calendar quarter of the applicable period and units reported by a manufacturer under section 1927(b)(3)(A)(iv) of the Act for each month of the applicable period.

(1) CMS will calculate the AnMP for a Part D rebatable drug as the sum of the following:

(i) The product of—

(A) The AMP for the Part D rebatable drug reported for the calendar quarter beginning October of the applicable period; and

(B) The sum of the monthly units reported for the calendar quarter beginning October of the applicable period divided by the sum of the monthly units reported for the 4 calendar quarters in the applicable period.

(ii) The product of—

(A) The AMP for the Part D rebatable drug reported for the calendar quarter beginning January of the applicable period; and

(B) The sum of the monthly units reported for the calendar quarter beginning January of the applicable period divided by the sum of the monthly units reported for the 4 calendar quarters in the applicable period.

(iii) The product of—

(A) The AMP for the Part D rebatable drug reported for the calendar quarter beginning April of the applicable period; and

(B) The sum of the monthly units reported for the calendar quarter beginning April of the applicable period divided by the sum of the monthly units reported for the 4 calendar quarters in the applicable period.

(iv) The product of—

(A) The AMP for the Part D rebatable drug reported for the calendar quarter beginning July of the applicable period; and

(B) The sum of the monthly units reported for the calendar quarter beginning July of the applicable period divided by the sum of the monthly units reported for the 4 calendar quarters in the applicable period.

(2) The first applicable period for a Part D rebatable drug will be the earliest applicable period that follows the

payment amount benchmark period identified as set forth in paragraphs (c)(1) through (4) of this section.

(c) *Identification of the payment amount benchmark period.* As applicable under this paragraph, CMS will use information reported by a manufacturer under section 1927(b)(3) of the Act, including without limitation the date of FDA approval or licensure and the first marketed date, to identify the payment amount benchmark period as set forth in paragraphs (c)(1) and (2) of this section, subject to paragraphs (c)(3) through (5) of this section:

(1) For a Part D rebatable drug first approved or licensed by the FDA on or before October 1, 2021, the payment amount benchmark period is the period beginning on January 1, 2021, and ending on September 30, 2021;

(2) For a subsequently approved drug, the payment amount benchmark period is the first calendar year beginning after the drug's first marketed date;

(3) Notwithstanding paragraph (c)(1) of this section, for a Part D rebatable drug first approved or licensed by the FDA on or before October 1, 2021, for which there are no quarters during the period beginning on January 1, 2021, and ending on September 30, 2021, for which AMP has been reported under section 1927(b)(3) of the Act for the NDC–9, including information as set forth in paragraph (d)(3), the payment amount benchmark period is the first calendar year no earlier than calendar year 2021 in which such NDC–9 has at least 1 quarter of AMP reported;

(4) Notwithstanding paragraph (c)(2) of this section, for a subsequently approved drug for which there are no quarters during the first calendar year beginning after the drug's first marketed date for which AMP has been reported under section 1927(b)(3) of the Act for the NDC–9, including information as set forth in paragraph (d)(3) of this section, the payment amount benchmark period is the first calendar year in which such NDC–9 has at least 1 quarter of AMP reported; and

(5) Notwithstanding paragraphs (c)(1) through (4) of this section, for a Part D rebatable drug that is a selected drug (as defined in section 1192(c) of the Act) with respect to a price applicability period (as defined in section 1191(b)(2) of the Act), in the case such Part D rebatable drug is no longer considered to be a selected drug, for each applicable period beginning after the price applicability period with respect to such drug, the payment amount benchmark period is the last calendar year of such price applicability period with respect to such selected drug.

(d) *Calculation of benchmark period manufacturer price.* Subject to paragraphs (d)(3) and (g) of this section, CMS will calculate the benchmark period manufacturer price for a Part D rebatable drug using the AMP reported by a manufacturer under sections 1927(b)(3)(A)(i)(I) and (ii) of the Act for each calendar quarter of the payment amount benchmark period and the monthly units reported by a manufacturer under section 1927(b)(3)(A)(iv) of the Act during the payment amount benchmark period.

(1) For a Part D rebatable drug with a payment amount benchmark period identified as set forth in paragraph (c)(1) of this section, CMS will calculate the benchmark period manufacturer price as the sum of the following:

(i) The product of—

(A) The AMP reported for the calendar quarter beginning January 2021; and

(B) The sum of the monthly units reported for the calendar quarter beginning January 2021 divided by the sum of the monthly units reported for the 3 quarters of the payment amount benchmark period.

(ii) The product of—

(A) The AMP reported for the calendar quarter beginning April 2021; and

(B) The sum of the monthly units reported for the calendar quarter beginning April 2021 divided by the sum of the monthly units reported for the 3 quarters of the payment amount benchmark period.

(iii) The product of—

(A) The AMP reported for the calendar quarter beginning July 2021; and

(B) The sum of the monthly units reported for the calendar quarter beginning July 2021 divided by the sum of the units reported for the 3 quarters of the payment amount benchmark period.

(2) For a Part D rebatable drug with a payment amount benchmark period

identified under paragraphs (c)(2) through (5) of this section, CMS will calculate the benchmark period manufacturer price as the sum of the following:

(i) The product of—

(A) The AMP reported for the calendar quarter beginning January of the payment amount benchmark period; and

(B) The sum of the monthly units reported for the calendar quarter beginning January of the payment amount benchmark period divided by the sum of the monthly units reported for the 4 quarters of the payment amount benchmark period.

(ii) The product of—

(A) The AMP reported for the calendar quarter beginning April of the payment amount benchmark period; and

(B) The sum of the monthly units reported for the calendar quarter beginning April of the payment amount benchmark period divided by the sum of the monthly units reported for the 4 quarters of the payment amount benchmark period.

(iii) The product of—

(A) The AMP reported for the calendar quarter beginning July of the payment amount benchmark period; and

(B) The sum of the monthly units reported for the calendar quarter beginning July of the payment amount benchmark period divided by the sum of the monthly units reported for the 4 quarters of the payment amount benchmark period.

(iv) The product of—

(A) The AMP reported for the calendar quarter beginning in October of the payment amount benchmark period; and

(B) The sum of the monthly units reported for the calendar quarter beginning October of the payment amount benchmark period divided by the sum of the monthly units reported for the 4 quarters of the payment amount benchmark period.

(3) To the extent that a new NDC–9 of a Part D rebatable drug is reported under section 1927 of the Act and AMP has not been reported for such NDC–9 under section 1927(b)(3)(A)(i)(I) or (ii) of the Act during the period set forth in paragraph (c)(1) or (2) of this section, as applicable, CMS will identify the payment amount benchmark period and calculate the benchmark period manufacturer price for such NDC–9 using other information reported by a manufacturer under section 1927(b)(3) of the Act for the Part D rebatable drug, as available, such as the base date AMP if such base date AMP is reported for a calendar quarter that overlaps with the period set forth in paragraph (c)(1) or (2) of this section. Base date AMP has the meaning set forth in § 447.509(a)(7)(ii)(B) of this title.

(e) *Identification of the benchmark period CPI–U.* For each Part D rebatable drug, CMS will identify the benchmark period CPI–U as set forth in paragraphs (e)(1) and (2) of this section, subject to paragraphs (e)(3) through (5) of this section:

(1) For a Part D rebatable drug first approved or licensed by the FDA on or before October 1, 2021, the benchmark period CPI–U is the CPI–U for January 2021.

(2) For a subsequently approved drug, the benchmark period CPI–U is the CPI–U for January of the first calendar year beginning after a drug's first marketed date.

(3) Notwithstanding paragraph (e)(1) of this section, for a Part D rebatable drug first approved or licensed by the FDA on or before October 1, 2021, for which there are no quarters during the period beginning on January 1, 2021, and ending on September 30, 2021, for which AMP has been reported under section 1927(b)(3) of the Act for the NDC–9, including information as set forth in paragraph (d)(3) of this section, the benchmark period CPI–U is the CPI–U for January of the payment amount benchmark period identified under paragraph (c)(3) of this section.

(4) Notwithstanding paragraph (e)(2) of this section, for a subsequently approved drug for which there are no quarters during the first calendar year beginning after the drug's first marketed date for which AMP has been reported under section 1927(b)(3) of the Act for the NDC–9, including information as set forth in paragraph (d)(3) of this section, the benchmark period CPI–U is the CPI–U for January of the payment amount benchmark period

identified as set forth in paragraph (c)(4) of this section.

(5) Notwithstanding paragraphs (e)(1) through (4) of this section, for a drug that is a selected drug (as defined in section 1192(c) of the Act) with respect to a price applicability period (as defined in section 1191(b)(2) of the Act), in the case such Part D rebatable drug is no longer considered to be a selected drug, the benchmark period CPI–U is the CPI–U for January of the last calendar year of such price applicability period.

(f) *Calculation of inflation-adjusted payment amount.* For an applicable period for each Part D rebatable drug, CMS will calculate the inflation-adjusted payment amount by dividing the applicable period CPI–U by the benchmark period CPI–U and then multiplying the quotient by the benchmark period manufacturer price.

(g) *Situations in which manufacturers do not report units under section 1927(b)(3)(A)(iv) of the Act.* For the purpose of calculating the AnMP as determined under paragraph (b) of this section and the benchmark period manufacturer price as determined under paragraph (d) of this section—

(1) If there is 1 or more quarter(s) in the payment amount benchmark period or applicable period for which a manufacturer has not reported units under section 1927(b)(3)(A)(iv) of the Act but has reported AMP under sections 1927(b)(3)(A)(i)(I) and (ii) of the Act, CMS will calculate the benchmark period manufacturer price or AnMP, as applicable, using data only from quarter(s) with units. Quarter(s) in the payment amount benchmark period or applicable period for which a manufacturer has not reported units under section 1927(b)(3)(A)(iv) of the Act will be excluded from the calculation.

(2) If there are no quarters of the payment amount benchmark period or applicable period for which a manufacturer has reported units under section 1927(b)(3)(A)(iv) of the Act, but the manufacturer has reported AMP under sections 1927(b)(3)(A)(i)(I) and (ii) of the Act for at least 1 quarter of such period or, with respect to paragraph (d)(3), there exists other information reported by a manufacturer under section 1927(b)(3) of the Act for the Part D rebatable drug to identify the payment amount benchmark period, CMS will use the AMP or other information as applicable as set forth in paragraph (d)(3) reported for 1 quarter to calculate the benchmark period manufacturer price or AnMP, respectively. If AMP is reported for more than 1 quarter, CMS will use the average of the AMP over the calendar quarters of the payment amount benchmark period or applicable period for which AMP is reported to calculate the benchmark period manufacturer price or AnMP, respectively.

[89 FR 98588, Dec. 9, 2024, as amended at 90 FR 20808, May 16, 2025]

§ 428.203 Determination of the total number of units dispensed under Part D.

(a) *General.* For each Part D rebatable drug, CMS will determine the total number of units as follows:

(1) *Use of PDE data to determine total units dispensed.* To determine the total number of units of each Part D rebatable drug dispensed under Part D and covered by Part D plan sponsors during an applicable period, CMS will use the quantity dispensed reported on the PDE record for each Part D rebatable drug with gross covered prescription drug costs greater than zero.

(2) *Crosswalk to AMP units.* CMS will crosswalk the information from the PDE record to database(s) that includes the unit type (for example, each, capsule) for the Part D rebatable drug, matching on the NDC of the Part D rebatable drug. If the unit type obtained from such database does not match the AMP unit type reported by a manufacturer to the Medicaid Drug Programs system, CMS will convert the total units reported on the PDE to the AMP units reported.

(b) *Removal of certain units.* CMS will exclude certain units from the total number of units dispensed of a Part D rebatable drug, with respect to an applicable period, as follows:

(1) *Removal of units when a generic drug is no longer a Part D rebatable drug.* To determine whether a generic drug that meets the definition of a Part D rebatable drug on the first day of an applicable period ceases to meet such

definition later in the applicable period, CMS will—

(i) Review FDA's NDC Directory, including historical information from NDC Directory files such as discontinued, delisted, and expired listings provided by the FDA or published on the FDA website to determine whether the reference listed drug or an authorized generic of the reference listed drug is being marketed;

(ii) Review the most recent version of the downloadable FDA Orange Book to determine whether another drug has been approved under a section 505(j) ANDA that is therapeutically equivalent to such generic drug. If CMS determines that FDA has approved such a therapeutically equivalent drug under a section 505(j) ANDA, CMS will then: use the FDA's NDC Directory, including historical information from NDC Directory files such as discontinued, delisted, and expired listings provided by the FDA or published on the FDA website to determine the marketing status of such therapeutically equivalent drug and whether, during the applicable period, the therapeutically equivalent drug was marketed; and

(iii) Exclude from the total number of units determined under paragraph (a) of this section any units dispensed on or after the first day of the calendar month that a generic drug no longer meets the definition of a Part D rebatable drug.

(2) *Exclusion of units acquired through the 340B Program.* (i) For the applicable period beginning October 1, 2025, and subsequent applicable periods, CMS will exclude from the total number of units determined under paragraph (a) of this section units for which a manufacturer provided a discount under the 340B Program (''340B units'') as follows:

(A) For the applicable period beginning October 1, 2025, 340B units will be excluded from the total number of units dispensed for claims with a date of service on or after January 1, 2026.

(B) For the applicable period beginning October 1, 2026, and applicable periods thereafter, 340B units will be excluded from the total number of units dispensed.

(ii) To determine the total number of such units for which a manufacturer provided a discount under the 340B Program, CMS will use data reflecting the total number of units of a Part D rebatable drug for which a discount was provided under the 340B Program and that were dispensed during the applicable period.

(3) *Exclusion of compounded drug units.* CMS will exclude units from the total number of units dispensed of a Part D rebatable drug when those units are associated with a Part D rebatable drug that has been billed as compounded.

§ 428.204 Treatment of new formulations of Part D rebatable drugs.

In the case of a Part D rebatable drug that is a line extension of a Part D rebatable drug that is an oral solid dosage form, the rebate amount for an applicable period is equal to the amount determined under § 428.201(a)(1)(i) for such new drug or, if greater, the alternative total rebate amount. CMS will determine the alternative total rebate amount for such new formulations according to the following:

(a) *Identification* of the *initial drug.* The initial drug that CMS will use to calculate the inflation rebate amount ratio is the initial drug identified in accordance with § 447.509(a)(4)(iii)(B) of this chapter for the last quarter of the applicable period or, if an initial drug was not identified in the last quarter, the initial drug identified for a quarter most recently in that applicable period.

(b) *Calculation of the inflation rebate amount ratio.* The inflation rebate amount ratio is equal to the per unit Part D rebate amount for the initial drug, as determined under § 428.202(a), divided by the AnMP for that initial drug for the applicable period.

(c) *Calculation of the alternative total rebate amount.* The alternative total rebate amount is equal to the product of all of the following:

(1) The AnMP for the applicable period, as determined under § 428.202(b), of the Part D rebatable drug that is a line extension of a Part D rebatable drug that is an oral solid dosage form.

(2) The inflation rebate amount ratio as determined under paragraph (b) of this section.

(3) The total number of units dispensed under Part D identified as set forth in § 428.203.

[89 FR 98588, Dec. 9, 2024, as amended at 90 FR 20808, May 16, 2025]

Subpart D—Reducing the Rebate Amount for Part D Rebatable Drugs in Shortage and When There Is a Severe Supply Chain Disruption or Likely Shortage

§ 428.300 Definitions.

As used in this subpart, the following definitions apply:

Biosimilar has the meaning set forth in section 351(i) of the PHS Act.

Currently in shortage means that at least one NDC–10 of a Part D rebatable drug with the status ''currently in shortage'' is on a shortage list maintained by the FDA under section 506E of the FD&C Act.

Drug shortage or *shortage* means a period of time when the demand or projected demand for the drug within the United States exceeds the supply of the drug (see section 506C(h)(2) of the FD&C Act).

Generic Part D rebatable drug means a generic drug approved under an ANDA under section 505(j) of the FD&C Act that meets the sole source criteria specified in § 428.101(a)(3).

Likely to be in shortage means that a generic Part D rebatable drug is likely to be described as currently in shortage during a subsequent applicable period without such rebate reduction.

Natural disaster means any natural catastrophe, including, but not limited to any of the following: hurricane, tornado, storm, high water, wind-driven water, tidal wave, tsunami, earthquake, volcanic eruption, landslide, mudslide, snowstorm, or drought, or regardless of cause, any fire, flood, or explosion.

Other unique or unexpected event means any exogenous, unpredictable event outside of a manufacturer's control, including, but not limited to, a geopolitical disruption, pandemic, or act of terror.

Plasma-derived product means a licensed biological product that is derived from human whole blood or plasma, as indicated on the approved product labeling.

Severe supply chain disruption means a change in production or distribution that is reasonably likely to lead to a significant reduction in the U.S. supply of a generic Part D rebatable drug or biosimilar by a manufacturer and significantly affects the ability of the manufacturer of the generic drug or biosimilar to fill orders or meet expected demand for its product in the United States for at least 90 days. This definition does not include interruptions in manufacturing due to matters such as routine maintenance, manufacturing quality issues, or insignificant changes made in the manufacturing process for the drug.

§ 428.301 Reducing the rebate amount for Part D rebatable drugs currently in shortage.

(a) *General.* As required under section 1860D–14B(b)(1)(C)(i) of the Act, CMS will reduce the total rebate amount determined under § 428.201(a), if any is owed, for a Part D rebatable drug that is currently in shortage, as set forth in § 428.300, at any point during the applicable period.

(b) *Calculation of the reduced rebate amount.* (1) For each applicable period beginning on or after October 1, 2022, the reduced total rebate amount for a Part D rebatable drug currently in shortage will be calculated using the following formula:

Equation 1 to Paragraph (b)(1)

Reduced *Total* Rebate Amount = the total rebate amount *multiplied by* (1 *minus* applicable percent reduction) *multiplied by* (percentage of time drug was currently in shortage during the applicable period) *added to* the total rebate amount *multiplied by* (1 *minus* percentage of time drug was currently in shortage during the applicable period)

(2) For purposes of paragraph (b)(1) of this section, the applicable percent reduction is:

(i) For a Part D rebatable drug that is a generic drug or plasma-derived product:

(A) 75 percent for the first applicable period such drug is currently in shortage.

(B) 50 percent for the second applicable period such drug is currently in shortage.

(C) 25 percent for each subsequent period such drug is currently in shortage.

(ii) For a Part D rebatable drug that is not a generic drug or plasma-derived product:

(A) 25 percent for the first applicable period such drug is currently in shortage.

(B) 10 percent for the second applicable period such drug is currently in shortage.

(C) 2 percent for each subsequent applicable period such drug is currently in shortage.

(iii) Except as provided in paragraph (b)(iv) of this section, CMS will apply the greatest applicable percent reduction as set forth in paragraph (b)(2)(i)(A) or (b)(2)(ii)(A) of this section starting with the first applicable period that a Part D drug or biological is described as currently in shortage, regardless of whether the drug or biological meets the definition of a Part D rebatable drug or whether a rebate amount is owed for that applicable period, starting with the applicable period that begins October 1, 2022.

(iv) If an applicable period for which a rebate reduction determined under § 428.302 or 428.303 has been granted would be the first applicable period described in paragraph (b)(2)(i)(A) or (b)(2)(ii)(A) of this section and the Part D rebatable drug or biosimilar continues to be in shortage after the rebate reduction period described din § 428.302 or 428.303, as applicable, CMS will treat the applicable period following the applicable period in which the rebate reduction determined under § 428.302 or 428.303 applies as the first applicable period so described.

(3) For purposes of paragraph (b)(1) of this section, the percentage of time the drug is currently in shortage during the applicable period is equal to the number of days such drug is currently in shortage in an applicable period, divided by the total number of days in the applicable period.

(c) *Application of reduction.* CMS will apply a reduction of the rebate amount as determined under paragraph (b) of this section to the Part D rebatable drug at the NDC–9 level.

[89 FR 98588, Dec. 9, 2024, as amended at 90 FR 20808, May 16, 2025]

§ 428.302 Reducing the rebate amount for certain Part D rebatable drugs when there is a severe supply chain disruption.

(a) *General.* As required under section 1860D–14B(b)(1)(C)(ii) of the Act, CMS will reduce the total rebate amount determined under § 428.201(a), if any is owed, for a generic Part D rebatable drug or biosimilar when CMS determines there is a severe supply chain disruption during the applicable period such as that caused by a natural disaster or other unique or unexpected event.

(b) *Calculation of the reduced rebate amount*—(1) *Initial reduction.* If CMS determines the criteria set forth in paragraph (c)(4) of this section are met, then CMS will reduce the total rebate amount determined under § 428.201(a), if any is owed, for a generic Part D rebatable drug or biosimilar by 75 percent for the applicable period in which the event occurred or began or, the following applicable period if the request is submitted less than 60 calendar days before the end of an applicable period.

(2) *Extension of reduction.* If CMS determines a severe supply chain disruption continues into a second consecutive applicable period as set forth in paragraph (c)(5) of this section, then CMS will reduce the total rebate amount determined under § 428.201(a), if any is owed, for a generic Part D rebatable drug or biosimilar by 75 percent for that second applicable period.

(3) *Application of reduction.* If CMS determines there is a severe supply chain disruption for an NDC–11, CMS will apply any reduction of the rebate amount as determined under paragraphs (b)(1) and (2) of this section to a Part D rebatable drug at the NDC–9 level.

(4) *Limitation on rebate reductions.* CMS will not apply multiple rebate reductions for the same Part D rebatable drug and applicable period.

(i) If a manufacturer believes there are multiple events causing severe supply chain disruptions during the same applicable period for the same generic

Part D rebatable drug or biosimilar and submits multiple rebate reduction requests for the same drug or biosimilar, CMS will grant no more than 1 rebate reduction determined under paragraph (b)(1) or (2) of this section for that product for the applicable period.

(ii) If CMS grants a rebate reduction request under this section and the generic Part D rebatable drug or biosimilar subject to the reduction appears as currently in shortage during the same applicable period as the one for which the severe supply chain disruption reduction request was granted, CMS will reduce the rebate amount as determined under paragraph (b)(1) of this section and will not grant a reduction as set forth in § 428.301 during that applicable period.

(iii) If a generic Part D rebatable drug or biosimilar that is currently in shortage experiences a severe supply chain disruption, CMS will reduce the rebate amount as determined under paragraph (b)(1) of this section, and will not grant a reduction as set forth in § 428.301 during that applicable period.

(c) *Eligibility for a rebate reduction*—(1) *Eligible drug.* Subject to paragraph (b)(3) of this section, eligibility for a rebate reduction under this section is limited to generic Part D rebatable drugs and biosimilars for which a manufacturer submits a rebate reduction request under this section.

(2) *Timing.* For a natural disaster or other unique or unexpected event occurring on or after August 2, 2024 that the manufacturer believes caused a severe supply chain disruption, the manufacturer must submit the rebate reduction request within 60 calendar days from the first day that the natural disaster or other unique or unexpected event occurred or began to receive consideration for a reduction in the rebate amount owed determined under paragraph (b)(1) of this section.

(3) *Required elements of a rebate reduction request.* To receive consideration for a reduction in the rebate amount owed as determined under paragraph (b)(1) of this section, the manufacturer must submit to CMS information and supporting documentation to substantiate the evaluation criteria set forth in paragraph (c)(4) of this section. Such information and supporting documentation include the following:

(i) Evidence that the severe supply chain disruption directly affects the manufacturer itself, a supplier of an ingredient or packaging, a contract manufacturer, or a method of shipping or distribution that the manufacturer uses to make or distribute the generic Part D rebatable drug(s) or biosimilar(s), such as a change in the production or distribution of the generic Part D rebatable drug(s) or biosimilar(s) that is reasonably likely to lead to a significant reduction in the U.S. supply of product and significantly affects the manufacturer's ability to fill orders or meet expected demand for the generic Part D rebatable drug(s) or biosimilar(s) for at least 90 days;

(ii) Information about when the manufacturer expects supply of the generic Part D rebatable drug(s) or biosimilar(s) to meet expected demand;

(iii) Evidence that the natural disaster or other unique or unexpected event caused the severe supply chain disruption, including when the natural disaster or other unique or unexpected event occurred or began occurring, and the expected or actual duration of the severe supply chain disruption; and

(iv) Evidence of the manufacturer's physical presence related to manufacturing the generic Part D rebatable drug(s) or biosimilar(s) in a geographic area where a natural disaster or other unique or unexpected event occurred. If the manufacturer is not physically present in a geographic area where a natural disaster or other unique or unexpected event occurred, but believes there is a severe supply chain disruption caused by a natural disaster or other unique or unexpected event that affects the manufacturer's generic Part D rebatable drug(s) or biosimilar(s), the information and supporting documentation may include evidence of the impact of the natural disaster or other unique or unexpected event on the supply chain of the generic Part D rebatable drug or biosimilar, on a supplier of an ingredient or packaging, or method of shipping or distribution that the manufacturer uses.

(4) *Evaluation criteria.* In accordance with paragraph (b)(1) of this section, CMS will grant a reduction in the total rebate amount determined under § 428.201, if any is owed, if a manufacturer submits to CMS a request in writing for an eligible drug, in accordance with the timing set forth in paragraph (c)(2) of this section, demonstrating that:

(i) A severe supply chain disruption has occurred during the applicable period;

(ii) The severe supply chain disruption directly affects the manufacturer itself, a contract manufacturer, a supplier of an ingredient or packaging, or a method of shipping or distribution that the manufacturer uses in a significant capacity to make or distribute the generic Part D rebatable drug or biosimilar; and

(iii) The severe supply chain disruption was caused by a natural disaster or other unique or unexpected event.

(5) *Rebate reduction extensions.* If CMS determines that a generic Part D rebatable drug or biosimilar that received a reduction of the rebate amount as determined under paragraph (b)(1) of this section continues to be affected by the severe supply chain disruption, CMS will grant a single extension of the reduction for 1 additional consecutive applicable period and reduce the total rebate amount determined under § 428.201, if any is owed, as set forth in paragraph (b)(2) of this section.

(i) To receive consideration for a rebate reduction extension, a manufacturer must submit a request with updated or new information and supporting documentation on why the generic Part D rebatable drug or biosimilar continues to be affected by the severe supply chain disruption during the second applicable period.

(ii) A manufacturer must submit the rebate reduction extension request at least 60 calendar days before the start of the second consecutive applicable period to receive consideration for a reduction in the rebate amount owed, if any, determined under paragraph (b)(2) of this section, except for when the initial request is made less than 60 calendar days before the end of an applicable period such that the initial rebate reduction is applied to the next applicable period rather than the applicable period in which the event that caused the severe supply chain disruption occurred or began. In these cases, the rebate reduction extension request must be submitted at least 60 calendar days prior to the end of the applicable period in which the initial reduction determined under paragraph (b)(1) of this section is applied.

(6) *Decision to grant or deny a request.* CMS will review rebate reduction requests and rebate reduction extension requests within 60 calendar days of receipt of all documentation, if feasible, beginning with the applicable period that begins on October 1, 2024.

(i) CMS will deny a rebate reduction request that does not meet the criteria set forth in paragraph (c)(4) of this section or that is incomplete or untimely based on the requirements set forth in this paragraph (c).

(ii) CMS will deny a rebate reduction extension request that does not meet the criteria set forth in paragraph (c)(5) of this section, that is incomplete or untimely based on the requirements set forth in paragraph (c)(5) of this section, or if a reduction determined under paragraph (b)(1) of this section was not granted for such generic Part D rebatable drug or biosimilar.

(iii) CMS' decisions to deny a request are final and will not be subject to an appeals process.

(7) *Public disclosure of information.* CMS will keep confidential, to the extent allowable under law, any requests for a rebate reduction, including supporting documentation. Information provided as part of a request for a rebate reduction request that the submitter indicates is a trade secret or confidential commercial or financial information will be protected from disclosure if CMS determines the information meets the requirements set forth under Exemption 3 or Exemption 4 in 5 U.S.C. 552.

§ 428.303 Reducing the rebate amount for generic Part D rebatable drugs likely to be in shortage.

(a) *General.* As required under section 1860D–14B(b)(1)(C)(iii) of the Act, CMS will reduce the total rebate amount determined under § 428.201, if any is owed,

for a generic Part D rebatable drug when CMS determines that the generic Part D rebatable drug is likely to be in shortage, as set forth in § 428.300.

(b) *Calculation of the reduced rebate amount*—(1) *Initial reduction.* If CMS determines the criteria set forth in paragraph (c)(4) of this section are met, then CMS will reduce the total rebate amount owed by the manufacturer for a generic Part D rebatable drug by 75 percent for the applicable period in which the request was submitted or the following applicable period, depending on the timing of the submission of the request.

(2) *Extension of reduction.* If CMS determines the generic Part D rebatable drug is likely to be in shortage in a second applicable period as set forth in paragraph (c)(5) of this section, then CMS will reduce the total rebate amount owed by the manufacturer for a generic Part D rebatable drug by 75 percent for a second consecutive applicable period.

(3) *Application of reduction.* If CMS determines that an NDC–11 is likely to be in shortage, CMS will apply any reduction of the rebate amount as determined under paragraphs (b)(1) and (2) of this section to the generic Part D rebatable drug at the NDC–9 level.

(4) *Limitation on rebate reductions.* If CMS grants a rebate reduction request under this section, and the generic Part D rebatable drug subject to the reduction is currently in shortage during the same applicable period as the one for which the request was granted, CMS will reduce the rebate amount as determined under paragraph (b)(1) of this section and will not grant a reduction determined under § 428.301 during that applicable period.

(c) *Eligibility for a rebate reduction*—(1) *Eligible drug.* Subject to paragraph (b)(3) of this section, eligibility for a rebate reduction under this section is limited to generic Part D rebatable drugs for which a manufacturer submits a rebate reduction request under this section.

(2) *Timing.* The manufacturer must submit the rebate reduction request before the start of the next applicable period in which the manufacturer believes the generic Part D rebatable drug is likely to be in shortage to receive consideration for a reduction in the rebate amount owed determined under paragraph (b)(1) of this section.

(3) *Required elements of a rebate reduction request.* To receive consideration for a reduction in the rebate amount owed determined under paragraph (b)(1) of this section, the manufacturer must submit to CMS information and supporting documentation to substantiate the evaluation criteria set forth in paragraph (c)(4) of this section. Such information and supporting documentation include the following:

(i) Evidence that demonstrates a generic Part D rebatable drug is likely to be in shortage, including anticipated cause(s) of the shortage and information about why the manufacturer believes the generic Part D rebatable drug is likely to be in shortage; and

(ii) Evidence of the anticipated start date and duration of the potential drug shortage, the actions the manufacturer is taking to avoid the potential drug shortage, and how the reduction of the rebate amount would reduce the likelihood of the drug appearing on an FDA shortage list.

(4) *Evaluation criteria.* In accordance with paragraph (b)(1) of this section, CMS will grant a reduction in the rebate amount owed if a manufacturer submits to CMS a request in writing for an eligible drug, in accordance with the timing set forth in paragraph (c)(2) of this section, demonstrating that:

(i) The generic Part D rebatable drug is likely to be in shortage;

(ii) The manufacturer is taking actions to avoid the potential drug shortage; and

(iii) The reduction of the rebate amount would reduce the likelihood of the drug appearing on an FDA shortage list.

(5) *Rebate reduction extensions.* If CMS determines that a generic Part D rebatable drug that received a reduction of the rebate amount as determined under paragraph (b)(1) of this section continues to be affected by the potential drug shortage, CMS will grant a single extension of the reduction for 1 additional consecutive applicable period and reduce the total rebate amount determined under § 428.201, if any is owed, as determined under paragraph (b)(2) of this section.

(i) To receive consideration for a rebate reduction extension, a manufacturer must submit a request with updated or new information and supporting documentation on why the generic Part D rebatable drug continues to be affected by the potential drug shortage during the second applicable period.

(ii) A manufacturer must submit the rebate reduction extension request at least 60 calendar days before the start of the second consecutive applicable period in which the manufacturer believes the generic Part D rebatable drug is likely to be in shortage to receive consideration for a reduction in the rebate amount owed, if any, in accordance with paragraph (b)(2) of this section.

(6) *Decision to grant or deny a request.* CMS will review rebate reduction requests and rebate reduction extension requests within 60 calendar days of receipt of all documentation, if feasible, beginning with the applicable period that begins on October 1, 2024.

(i) CMS will deny a rebate reduction request that does not meet the criteria set forth in paragraph (c)(4) of this section or that is incomplete or untimely based on the requirements set forth in this paragraph (c).

(ii) CMS will deny a rebate reduction extension request that does not meet the criteria set forth in paragraph (c)(5) of this section, that is incomplete or untimely based on the requirements set forth in paragraph (c)(5) of this section, or if a reduction determined under paragraph (b)(1) of this section was not granted for such generic Part D rebatable drug.

(iii) CMS' decisions to deny a request are final and will not be subject to an appeals process.

(7) *Public disclosure of information.* CMS will keep confidential, to the extent allowable under law, any requests for a rebate reduction, including supporting documentation. Information provided as part of a request for a rebate reduction that the submitter indicates is a trade secret or confidential commercial or financial information will be protected from disclosure if CMS determines the information meets the requirements set forth under Exemption 3 or Exemption 4 in 5 U.S.C. 552.

Subpart E—Reports of Rebate Amounts, Reconciliation, Suggestion of Error, and Payments

§ 428.400 Definitions.

For the purposes of this subpart, *date of receipt* is the calendar day following the day in which a report of a rebate amount (as set forth in §§ 428.401(b), (c), and (d) and 428.402(b) and (c)) is made available to the manufacturer of a Part D rebatable drug by CMS.

§ 428.401 Rebate Reports and reconciliation.

(a) *General.* This section applies to Part D rebatable drugs for all applicable periods except as otherwise set forth in § 428.402 for the applicable periods beginning October 1, 2022, and October 1, 2023.

(b) *Preliminary Rebate Report.* A Preliminary Rebate Report will be provided to each manufacturer of a Part D rebatable drug at least 1 month prior to the issuance of the Rebate Report as set forth in paragraph (c) of this section for an applicable period.

(1) The Preliminary Rebate Report for each Part D rebatable drug will include the following information:

(i) The NDC(s) identified for the Part D rebatable drug as set forth in § 428.20;

(ii) The total number of units dispensed under Part D for the Part D rebatable drug for the applicable period as determined under § 428.203;

(iii) The payment amount benchmark period and benchmark period manufacturer price as set forth in §§ 428.202(c) and (d);

(iv) The AnMP for the Part D rebatable drug for the applicable period as determined under § 428.202(b);

(v) The amount, if any, of the excess AnMP for the Part D rebatable drug for the applicable period as set forth in § 428.202(a);

(vi) The benchmark period and applicable period CPI-Us as set forth in §§ 428.202(e) and 428.20, respectively;

(vii) The inflation-adjusted payment amount as set forth in § 428.202(f);

(viii) Any applied reductions determined under §§ 428.301, 428.302, and 428.303; and

(ix) The rebate amount due as set forth in § 428.201(a).

(2) If the Part D rebatable drug is a line extension, the Preliminary Rebate Report will also include the following information as set forth in § 428.204:

(i) The NDC for the initial drug;

(ii) The inflation rebate amount ratio for the initial drug; and

(iii) The alternative total rebate amount.

(c) *Rebate Report.* A Rebate Report will be provided to each manufacturer of a Part D rebatable drug no later than 9 months after the end of each applicable period.

(1) The Rebate Report will include the information described in paragraphs (b)(1) and (2) of this section, if applicable, with the inclusion of any revisions to such information resulting from CMS' review of a Suggestion of Error as set forth in § 428.403, if applicable, and any CMS-determined recalculations from paragraph (d)(2) of this section.

(2) The Rebate Report is the invoice of a manufacturer's rebate amount due as determined in § 428.201(a), if any, for a Part D rebatable drug for an applicable period.

(d) *Reconciliation of the rebate amount.* CMS will perform reconciliation of the rebate amount provided in a Rebate Report as determined in paragraph (c) of this section for an applicable period in the following circumstances:

(1) *Regular reconciliation.* Except as otherwise described in § 428.402, CMS will perform a reconciliation of the rebate amount within 12 months of the date of receipt of the Rebate Report for an applicable period and a second reconciliation approximately 24 months thereafter to include revisions to the information used to calculate the rebate amount as set forth in paragraph (c)(1) of this section.

(i) *Preliminary reconciliation.* At least 1 month prior to the issuance of a report with the reconciled rebate amount for an applicable period as set forth in paragraph (d)(1)(ii) of this section, CMS will conduct a preliminary reconciliation of the rebate amount for an applicable period based on the information specified in paragraphs (d)(1)(i)(A) through (G) of this section, and CMS will provide the information specified in paragraphs (d)(1)(i)(A) through (G) to the manufacturer of a Part D rebatable drug for the applicable period, if applicable:

(A) Updated total number of rebatable units, including updates submitted by a prescription drug plan (PDP) or Medicare Advantage Prescription Drug (MA–PD) plan sponsor and updates to 340B units (as applicable to the dates of service and applicable periods set forth in § 428.203(b)(2)(i)(A) and (B)), or units otherwise excluded as determined under § 428.203(b);

(B) The inflation-adjusted payment amount as determined under § 428.202(f) if any inputs are restated or newly reported within the reconciliation run-out period;

(C) Updated payment amount benchmark period and benchmark period manufacturer price as set forth in § 428.202(c) and (d) if any inputs are restated or newly reported;

(D) The excess amount by which the AnMP exceeds the inflation-adjusted payment amount for the applicable period as determined under § 428.202(a), using the most recent AMP (if any inputs are restated or newly reported within the reconciliation run-out period);

(E) Updated data on line extension calculations, including the initial drug identified as set forth in § 447.509(a)(4)(iii)(B) of this chapter, the inflation rebate amount ratio, and the alternative total rebate amount as determined under § 428.204 if any inputs are restated or newly reported within the reconciliation run-out period;

(F) The reconciled rebate amount as determined under § 428.201(a); and

(G) The difference between the total rebate amount due as specified on the Rebate Report set forth in paragraph (c) of this section and the reconciled rebate amount as set forth in this paragraph (d)(1)(i).

(ii) *Report with a reconciled rebate amount.* With the inclusion of any additional revisions to such information resulting from CMS' review of a Suggestion of Error as set forth in § 428.403, if applicable, a report with the reconciled rebate amount will be provided to each

manufacturer of a Part D rebatable drug within 12 months and 36 months after the issuance of the Rebate Report set forth in paragraph (c) of this section.

(2) *CMS identification of an error or manufacturer misreporting.* CMS may recalculate a rebate amount and provide the manufacturer of a Part D rebatable drug a report with a reconciled rebate amount when:

(i) CMS identifies an error in the information specified in paragraphs (c) and (d)(1) of this section, including reporting system or coding errors, not later than 5 years from the date of receipt by a manufacturer of a reconciled rebate amount for the applicable period; or

(ii) CMS determines at any time that the information used by CMS to calculate the rebate amount was inaccurate due to manufacturer misreporting.

(3) *Impact of reconciliation on rebate amount.* A reconciliation as determined under this paragraph (d) could result in an increase, decrease, or no change to the rebate amount as determined under § 428.201(a) owed by a manufacturer for the applicable period for the Part D rebatable drug compared to the amount described in the Rebate Report set forth in paragraph (c) of this section or an amount described in a previous reconciliation.

(i) A report with a reconciled rebate amount that is an increase to the rebate amount is the invoice for such additional amount due on the manufacturer's rebate amount as set forth in § 428.201 for a Part D rebatable drug for an applicable period.

(ii) [Reserved]

(4) *Drugs included in a reconciliation.* A drug covered under Part D that does not meet the requirements of a rebatable drug set forth in § 428.101 for an applicable period will not be included in a reconciliation as determined under this paragraph (d).

§ 428.402 Rebate Reports for applicable periods beginning October 1, 2022, and October 1, 2023.

(a) *Transition rule for reporting.* Section 1860D–14B(a)(3) of the Act allows CMS to delay the timeframe for reporting the information and rebate amount set forth in § 428.401 for the applicable periods beginning October 1, 2022, and October 1, 2023, until not later than December 31, 2025.

(b) *Rebate Report information for applicable periods beginning October 1, 2022, and October 1, 2023.* The Rebate Reports for the applicable periods beginning October 1, 2022, and October 1, 2023, will include the information set forth in § 428.401(b)(1).

(c) *Rebate Report procedures for applicable periods beginning October 1, 2022, and October 1, 2023.* Rebate amounts for the applicable periods beginning October 1, 2022, and October 1, 2023, will be reported as follows:

(1) The Rebate Report for the applicable period beginning October 1, 2022, will be issued no later than December 31, 2025. The Preliminary Rebate Report for such applicable period will be issued at least 1 month prior to the Rebate Report.

(i) For this single Preliminary Rebate Report for the applicable period, the Suggestion of Error period as set forth in § 428.403 will be 30 calendar days.

(ii) The rebate amount will be reconciled 21 months after the Rebate Report set forth in paragraph (c)(1) of this section is issued to include the information set forth in § 428.401(d)(1)(i)(A) through (G).

(iii) The Suggestion of Error period for the reconciliation set forth in paragraph (c)(1)(ii) of this section will be 10 calendar days.

(2) The Rebate Report for the applicable period beginning October 1, 2023, will be issued no later than December 31, 2025. The Preliminary Rebate Report for such applicable period will be issued at least 1 month prior to the Rebate Report.

(i) For this single Preliminary Rebate Report for the applicable period, the Suggestion of Error period as set forth in § 428.403 will be 30 calendar days.

(ii) The rebate amount will be reconciled 9 months after the Rebate Report and 33 months after the Rebate Report specified in paragraph (b)(2) of this section is issued to include the information determined under § 428.401(d)(1)(i)(A) through (G).

§ 428.403 Suggestion of Error.

(a) *General.* Manufacturers of Part D rebatable drugs may submit a Suggestion of Error about the information in their Preliminary Rebate Report and the report detailing the preliminary reconciliation of the rebate amount to CMS, for its discretionary consideration, if the manufacturer believes that there is a mathematical error or errors to be corrected before the Rebate Report or a subsequent reconciliation, as applicable, is finalized.

(1) Section 1860D–14B(f) of the Act precludes administrative or judicial review on the determination of units as set forth in § 428.203, the determination of whether a drug is a Part D rebatable drug as set forth in § 428.101, and the calculation of the rebate amount as set forth in § 428.201(a) inclusive of any reconciled rebate amount.

(2) [Reserved]

(b) *Process of submission.* Subject to the scope and timing requirements specified in paragraphs (a) and (c) of this section, manufacturers may submit the Suggestion of Error and provide supporting documentation (if applicable).

(c) *Timing.* Except as set forth in § 428.402 for the applicable periods beginning on October 1, 2022, and October 1, 2023, a manufacturer must submit its Suggestion of Error for the applicable period within 10 calendar days from the date of receipt of a Preliminary Rebate Report or a preliminary reconciliation of a rebate amount using the method and process set forth by CMS in paragraph (b) of this section.

(d) *Notice.* (1) CMS will include any revisions to the calculation of the rebate amount, if determined necessary by CMS based on the Suggestion of Error submitted under this section prior to issuance of the Rebate Report as set forth in § 428.401(c) or § 428.402(c) as well as any report of a reconciled rebate amount as set forth in § 428.401(d) or § 428.402(c)(1)(ii) and (c)(2)(ii).

(2) CMS will notify the manufacturer whether CMS revised its calculation of the rebate amount based on the Suggestion of Error.

§ 428.404 Manufacturer access to Rebate Reports.

(a) *General.* CMS will establish a method and process for a manufacturer of the Part D rebatable drug to:

(1) Access the Rebate Report as set forth in §§ 428.401 and 428.402, including any report of a reconciled rebate amount as set forth in §§ 428.401 and 428.402;

(2) Submit a Suggestion of Error as set forth in §§ 428.402(c) and 428.403; and

(3) Pay a rebate amount as set forth in § 428.405.

(b) [Reserved]

§ 428.405 Deadline and process for payment of rebate amount.

(a) *Rebate amounts owed by a manufacturer.* For payment of a rebate amount owed by a manufacturer:

(1) Upon receipt of a rebate amount, payment is due no later than 11:59 p.m. Pacific Time (PT) on the 30 calendar days after the date of receipt of information regarding the rebate amount on—

(i) A Rebate Report as set forth in § 428.401(c) or § 428.402; or

(ii) A report of a reconciled rebate amount as set forth in § 428.401(d) or § 428.402.

(2) Failure to pay a rebate amount due timely and in full may result in an enforcement action as described in subpart F of this part.

(b) *Refund to the manufacturer.* If a reconciled rebate amount for an applicable period as set forth in § 428.401(d) or § 428.402 is less than what the manufacturer paid for that applicable period, CMS will initiate the process to provide a refund equal to the excess amount paid within 60 days of the date of receipt of the report with such reconciled rebate amount.

Subpart F—Enforcement of Manufacturer Payment of Rebate Amounts

§ 428.500 Civil money penalty notice and appeals procedures.

(a) *General.* CMS may impose a civil money penalty on a manufacturer that fails to pay the rebate amount set forth in § 428.201(a) on a Part D rebatable drug set forth in § 428.20, by the payment deadline as set forth in

section § 428.405(a) for such drug for such applicable period.

(b) *Determination of the civil money penalty amount.* CMS may impose a civil money penalty for each failure by a manufacturer to provide an applicable inflation rebate equal to 125 percent of the rebate amount determined in § 428.201(a).

(1) The civil money penalty is in addition to the rebate amount due.

(2) If a reconciled rebate amount as determined in § 428.401(d) or § 428.402(c)(1)(ii) or (c)(2)(ii) results in an increase to the rebate amount due, a separate civil money penalty may be imposed for the failure by a manufacturer to provide an inflation rebate for the applicable period for the increase to the rebate amount due.

(c) *Notice of imposition of civil money penalties.* If CMS makes a determination to impose a civil money penalty set forth in paragraph (b) of this section, CMS will send a written notice of its decision to impose a civil money penalty that includes the following:

(1) A description of the basis for the determination.

(2) The basis for the penalty.

(3) The amount of the penalty.

(4) The date the penalty is due.

(5) The manufacturer's right to a hearing as set forth in paragraph (e) of this section.

(6) Information about where to file the request for a hearing.

(d) *Collection.* (1) A manufacturer must pay the civil money penalty in full within 60 calendar days after the date of the notice of imposition of a civil money penalty from CMS as set forth in paragraph (c) of this section.

(2) In the event a manufacturer requests a hearing, pursuant to 42 CFR part 423, subpart T, the manufacturer must pay the amount in full within 60 calendar days after the date of a final decision by the Departmental Appeal Board, to uphold, in whole or in part, the civil money penalty.

(3) If the 60th calendar day described in paragraphs (d)(1) and (2) of this section is a weekend or a Federal holiday, then the timeframe is extended until the end of the next business day.

(e) *Appeal procedures for civil money penalties.* Section 1128A(c)(2) of the Act provides that CMS may not collect a civil money penalty until the affected party has had notice and the opportunity for a hearing.

(1) Manufacturers may appeal the following determinations:

(i) A CMS determination that the rebate amount was not paid by the applicable payment deadline as set forth in § 428.405.

(ii) The calculation of the amount of the civil money penalty.

(2) If CMS decides to impose a civil money penalty, CMS will provide the manufacturer with notice pursuant to the process set forth in paragraph (c) of this section.

(3) A manufacturer has a right to a hearing following a decision by CMS to impose a civil money penalty following the administrative appeal process and procedures established in 42 CFR part 423, subpart T.

(f) *Other applicable provisions.* The provisions of section 1128A of the Act (except subsections (a) and (b) of section 1128A of the Act) apply to civil money penalties under this section to the same extent that they apply to a civil money penalty or procedures under section 1128A of the Act.

(g) *Bankruptcy.* In the event that a manufacturer declares bankruptcy, as described in title 11 of the United States Code, and as a result of the bankruptcy, fails to pay either the full rebate amount owed or the total sum of civil money penalties imposed, the government reserves the right to file a proof of claim with the bankruptcy court to recover the unpaid amount of the rebates and civil money penalties owed by the manufacturer.

PART 429 [RESERVED]

FINDING AIDS

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For changes to this volume of the CFR prior to this listing, consult the annual edition of the monthly List of CFR Sections Affected (LSA). The LSA is available at *www.govinfo.gov*. For changes to this volume of the CFR prior to 2001, see the ''List of CFR Sections Affected, 1949–1963, 1964–1972, 1973–1985, and 1986–2000'' published in 11 separate volumes. The ''List of CFR Sections Affected 1986–2000'' is available at *www.govinfo.gov*.

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423.182 (b)(3)(ii)(A) and (B) revised 6118
423.184 (g)(1)(ii)(A) revised 6118
423.186 (i)(6) amended 6118
423.265 (b)(2) revised 6118
423.286 (d)(4)(ii) revised 6118
423.503 (b)(1)(i) and (ii) added 6118
(a)(3) revised 6118
423.504 (b)(4)(vi)(G)(*4*) through (*7*) added 6118
423.505 (b)(22) revised 6119
423.514 (a)(5) redesignated as (a)(6); new (a)(5) added 6119
423.551 (g)(2) revised 6119
423.560 Amended 6119
423.566 (c)(2) revised 6119
423.568 (i) through (m) added 6119
(j)(2), (3), and (k) amended 29528
423.570 (f) added 6120
423.578 (a)(6)(iii) revised; (b)(4) amended 6120
423.582 (d) amended; (e) through (h) added 6120
423.584 (f) added 6120
423.590 (i) and (j) added 6120
423.600 (b) revised; (f) through (k) added 6120

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423.760 (b)(3) and (4) redesignated as (b)(4) and (5); new (b)(3) added 6121
Regulation at 81 FR 61562 continued to 9-6-22 50263
423.2006 (c)(1) and (2) redesignated as (c)(2) and (3); new (c)(1) added 6121
423.2014 (a)(1)(ii) amended 6121
423.2036 (c) and (d) amended 6121
423.2260 Revised 6121
423.2261 Added 6122
423.2262 Revised 6122
423.2263 Added 6123
423.2264 Revised 6124
423.2265 Added 6125
423.2266 Added 6125
423.2267 Added 6126
(e)(13)(ii)(H) redesignated as (e)(13)(ii)(G) 29528
423.2268 Removed 6129
423.2274 Revised 6129
423.2305 Amended 6131
424 Technical correction 5020, 14690
424.205 (b)(5) and (6) redesignated as (b)(6) and (7); new (b)(5) added 65682
424.502 Amended 65682
424.520 (d) revised 62419
424.521 Heading and (a) revised 62419
424.522 Added 62419
424.525 Heading and (a)(1) revised; (a)(2), (3), and (b) amended; (e) added 62419
(a)(2), (3), and (b) correctly amended 72532
424.526 Added 62420
424.530 (a)(2) introductory text and (11)(i) revised 65682
424.535 (a)(2) introductory text, (8)(ii), (13)(i), and (e) revised 65682
424.540 (a)(2), (b)(1), and (c) revised; (a)(4) through (8), (d) and (e) added 62420
424.545 (b) amended 65683
424.546 Added 65683
424.550 (b)(2)(i) revised 62421
425 Technical correction 5020, 14690, 58019
425.116 (c) revised 65683
425.204 (b), (c)(6), (f)(4)(ii)(A), (B), (iii) introductory text, and (A) revised; (f)(4)(v) added 65683
425.312 (a)(2)(ii) revised; (iii) added 65684

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425.400 (c)(1)(v) introductory text, (2)(i) introductory text, (A)(2), and (ii) revised; (c)(1)(vi) added 65684
425.512 (a)(4) redesignated as (a)(5); new (a)(4) added; (a)(2), (3), new (5), (b)(2)(i), (ii), (3)(i), and (ii) revised 65685
425.600 (a)(4)(i)(B)(*2*)(*iv*) redesignated as (a)(4)(i)(B)(*2*)(*v*); new (a)(4)(i)(B)(*2*)(*iv*) added; (a)(4)(i)(B)(*3*) amended 45521
429 Technical correction 58019

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414 Policy statement 2051, 42096, 48609
414 Technical correction 36409
414.68 (j) added 25427
414.210 (g)(2)(iii) correctly amended 199
414.502 Amended; interim 70225
414.504 (a)(1) amended; interim 70225
414.507 (d) introductory text and (5) revised; (d)(8) added; (f) removed; (g) and (h) redesignated as new (f) and (g); interim 70225
414.523 Added; interim 70225
414.626 (d)(1) introductory text and (e)(2) introductory text amended; interim 70226
414.707 (a)(2)(iii) amended; interim 70226
414.902 Amended; interim 70226
414.904 (e)(1) amended; interim 70226
414.940 Added; interim 70226
414.1305 Amended; interim 70227
414.1318 (a)(1), (b), and (c)(2) revised; (a)(3) and (4) added; interim 70227
414.1340 (a)(4) and (b)(4) added; interim 70227
414.1365 (b)(2)(iii), (d)(3)(i)(B)(*1*), (*2*), (ii)(A), and (B) added; (d)(3)(i)(A)(*1*) revised; interim 70227
414.1380 (b)(1)(i)(A)(*3*) and (C) correctly amended 7747

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414.1380 (b)(1)(ii)(D) added; (b)(2)(iv)(E), (4)(ii)(B), (C), (c)(2)(i)(A)(*4*)(*i*), (*iii*), (3) introductory text, (e)(2) introductory text, (ii), (4), (5)(i), (ii), (6)(iv), (v), (vi)(A), and (B) revised; interim 70228

414.1400 (b)(4)(i)(B), (iii)(A)(*3*), (e)(1)(i)(B), (2) introductory text, (3), and (f)(1) revised; (e)(1)(i)(E) and (5) added; interim 70229

414.1405 (b)(9) revised; interim 70229

414.1415 (b)(3), (c)(3)(i)(A), and (7) revised; (b)(4) added; interim 70229

414.1420 (c)(3)(ii), (d)(3)(i), and (8) revised; (c)(4) added; interim 70230

414.1430 (a)(2)(iii), (4)(iii), (b)(3)(i)(A), (B), (4)(i)(A), and (B) revised; (a)(3)(ii) amended; (a)(3)(iii), (iv), and (4)(iv) added; interim 70230

414.1440 (e)(2) revised; interim 70230

414.1450 (c)(8) amended; interim 70230

415.140 Transferred to Subpart C; (a) amended; interim 70230

416 Technical correction 2058

416.166 (d)(1) revised 72291

416.172 (h) added 72291

416.174 (a) revised 72291

417.472 Regulation at 85 FR 19289 confirmed 27893

418.306 (c) revised 45702

419 Technical correction 2058

419 Heading revised 72291

419.43 (j) added 72291

419.46 (f)(3)(iv) revised; (f)(3)(v) added 72291

419.47 Added 72291

419.83 (a)(3) and (b) revised 72292

419.90—419.94 (Subpart J) Added 72292

422.2 Amended 27893

422.100 (f)(1) heading, (2) heading, (3) heading, and (7) through (9) added; (f)(4) through (6) and (j) revised 22423

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422.100 (f)(4) and (5)(iii) amended; (m)(1) introductory text, (2) introductory text, (3), (4), and (5)(i) revised; (m)(2)(ii)(B) removed; (m)(2)(ii)(A) redesignated as (m)(2)(ii); (m)(6) added 27893

422.101 (d)(2) and (3) revised 22427

422.101 (d)(4) amended; (f)(1)(i) revised 27894

422.107 Heading, (c)(6), and (d) revised; (e) redesignated as (i); new (e) and (f) through (h) added 27894

422.113 (b)(2)(v) revised; (b)(2)(vi) added 22428

422.116 (a)(1)(ii) revised; (d)(7) added 27895

422.152 Regulation at 85 FR 19290 confirmed 27893

422.164 (i) removed 27895

422.166 Regulation at 85 FR 19230 and 54872 confirmed 27893

422.166 (a)(2)(i) revised; (i)(12) added; (j)(1)(v) and (2) removed 27895

422.252 Regulation at 85 FR 19290 confirmed 27893

422.252 Amended 27895

422.502 (b)(1) introductory text and (i) revised 27896

422.503 (b)(5)(i) and (ii) revised 27896

422.504 (m) revised 27896

422.530 (c)(4) revised 27896

422.561 Amended 27897

422.629 (d) and (l)(1) revised; (k)(4)(ii) amended; (l)(4) added 27897

422.631 (d)(3) added 27897

422.633 Heading, (e)(1), and (f)(3)(i) introductory text revised 27897

422.634 (d) revised 27898

422.2260 Amended 27898

422.2265 (b)(13) and (14) added 27898

422.2267 (e)(30) through (38) redesignated as (e)(32) through (40); new (e)(30), new (31), and (41) added 27898

422.2274 Heading revised; (g) added 27899

422.2460 (a), (b) introductory text, and (d) revised; (e) added 27899

422.2490 (b)(2) redesignated as (b)(2)(i); (b)(2)(ii) added 27899

423.30 (a)(1)(i) revised 66510

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423.100 Amended; eff. in part 1-1-24 27899
423.160 (a)(5)(ii) and (iii) revised; interim 70231
423.182 Regulation at 85 FR 19291 confirmed 27893
423.184 (i) removed 27899
423.186 Regulation at 85 FR 19291 and 54872 confirmed 27893
423.186 (a)(2)(i) and (i)(9) revised; (j)(1)(iv) removed 27899
423.503 Heading, (b)(1) introductory text, and (i) revised 27900
423.505 (n) revised 27900
423.2260 Amended 27901
423.2265 (b)(14) and (15) added 27901
423.2267 (e)(32) through (37) redesignated as (e)(34) through (39); new (e)(32), new (33), (40) and (41) added 27901
423.2274 Heading revised; (g) added 27901
423.2305 Amended; eff. 1-1-24 27902
423.2460 (a), (b) introductory text, and (d) revised; (e) added 27902
424.57 (b)(6) added; interim 70231
424.502 Amended; interim 70231
424.518 (a)(1)(xviii) removed; (b)(1)(xiv), (c)(1)(v), (vi), and (4) added; introductory text and (c)(1) introductory text revised; interim 70231
424.518 (a)(1)(viii) revised 72293
424.530 (a)(2), (3) introductory text, and (c) revised; (a)(3)(iii) added; interim 70231
424.535 (a)(2), (3)(i), (12)(ii), and (e) revised; (a)(3)(iv) added; interim 70232
424.575 Added 72293
425.20 Amended; interim 70232
425.100 (b)(1) revised; (d) added; interim 70232
425.204 (g) introductory text amended; interim 70232
425.224 (a)(4) amended; interim 70232
425.302 (a)(3)(iv) added; interim 70232
425.308 (b)(8) added; interim 70232
425.310 Revised; interim 70233
425.312 (a)(2) revised; interim 70233
425.316 (e) added; interim 70233
425.400 (c)(1)(vi) introductory text revised; (c)(1)(vii) added; interim 70233
425.402 (f) added; interim 70234

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425.512 (b) redesignated as (c); (a)(4)(iii), (5)(iii), (6), and new (b) added; (a)(4)(i)(A) and new (c)(2) introductory text amended; (a)(4)(ii), (5)(i), (ii), and new (c)(3) revised; interim 70234
425.600 (a)(4)(i)(B) heading and (e) introductory text revised; (a)(4)(i)(B)(*2*)(*ii*), (*2*)(*iv*), (ii), (d) introductory text, (f)(4)(ii), and (iii) amended; (a)(4)(i)(B)(*2*)(*vi*), (*vii*), (C), (g), and (h) added; interim 70235
425.601 Heading, (a)(1)(i), and (c)(2)(i) revised; (d) introductory text, (1)(iv), (2), (f)(5)(ii), and (iv) amended; (d)(3) removed; interim 70237
425.605 (a) introductory text, (1)(i), (ii), (2) introductory text, (5)(i), (6), (b)(3), (c)(2), (d)(1)(i)(A)(*2*) heading, (B)(*1*), (ii)(A)(*2*) heading, (B)(*1*) (iii)(A)(*2*) heading, (B)(*1*), (iv)(A)(*2*) heading, (B)(*1*), (v)(A)(*2*) heading, and (B)(*1*) revised; (b)(2)(ii)(E), (d)(1)(i)(A)(*3*), (*4*), (ii)(A)(*3*), (iii)(A) (*3*) and (*4*) (iv)(A)(*3*), (*4*), (v)(A)(*3*), (*4*), and (h) added; (d)(1) introductory text, (iii)(D)(*2*), (iv)(D)(*2*), (v)(D)(*2*), and (2) amended; interim 70237
425.610 (a) introductory text and (g) amended; (a)(2)(i), (ii), (3) introductory text, (6)(i), (d)(2) heading, and (f)(2) heading revised; (d)(3), (4), (f)(3), and (4) added; interim 70240
425.611 (c)(2)(i), (ii)(A), (B), and (v) amended; (c)(2)(iii) and (4) revised; interim 70241
425.612 (a)(1)(i)(A) introductory text revised; (a)(1)(i)(A)(*1*) amended; interim 70242
425.630 Added; interim 70242
425.650 Added; interim 70243
425.652 Added; interim 70244
425.654 Added; interim 70246
425.656 Added; interim 70246
425.658 Added; interim 70248
425.660 Added; interim 70248
425.702 (c)(2)(iii) added; interim 70249
425.704 (b) introductory text revised; (b)(3) added; interim 70249

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425.800 (a)(4) amended; interim.....70249

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414 Notification.....49309
414.53 Added.....79530
414.84 (b)(1) through (5) removed; (b)(6), (7), (c), and (d) redesignated as (b)(1), (2), (d), and (e); (a) amended; (b) introductory text, (1) heading, (i), new (2) heading, (i), new (d)(1), and new (e) revised; (b)(1)(iii) and new (c) added.....79530
414.94 Removed.....79531
414.210 (g)(2)(ii) introductory text, (iii) introductory text, (9)(iii), and (vi) amended; (g)(9)(v) revised.....77875
414.402 Amended.....77875
414.408 (g)(5) added.....77875
414.412 (b)(2) revised.....77876
414.502 Amended.....79531
414.504 (a)(1) amended.....79531
414.507 (d) introductory text and (6) revised; (d)(9) added.....79531
414.610 (c)(1)(ii) introductory text and (5)(ii) amended.....79531
414.902 Amended.....79531
414.904 (e)(4) and (j) revised.....79532
414.940 Correction: Second (e) redesignated as (f).....15920
414.940 (a)(1)(iii), (e), and (f) redesignated as (a)(1)(iv), (f), and (g); new (a)(1)(iii) and new (e) added; (a)(3), (b)(1), (2), (c), and (d) revised.....79532
414.1305 Amended.....79533
414.1320 (h) introductory text revised; (i) added.....79534
414.1325 (a)(1), (c) introductory text, and (d) revised.....79534
414.1335 (a) introductory text, (1), (3) heading, and (i) revised; (a)(4) added.....79534
414.1340 (a) introductory text, (2), (3), (4), (b) introductory text, (4), and (d) revised; (b)(2)(i), (ii), (3)(i), (ii) and (e) added.....79534
414.1350 (c)(4) through (6) revised; (c)(7) added.....79535
414.1360 (a) introductory text revised.....79535

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414.1365 (e)(2)(ii) introductory text and (3) revised; (e)(4)(i) and (ii) added.....79535
414.1375 (b)(2)(ii)(C) revised; (b)(2)(ii)(D) added.....79535
414.1380 Correction: (e)(6)(v)(A) and (B) added.....15921
414.1380 (a)(1)(i), (ii), (b)(1)(v)(A), (2)(iv)(A) through (C), (E), (3)(i), and (c)(2)(i)(A)(*4*)(*iii*) revised; (c)(2)(iv) added; (c)(3)(v) and (vi) amended.....79535
414.1385 (a), (1), (3), and (6) amended; (a)(2) and (5) revised.....79536
414.1400 (a)(1)(iii), (2)(i), (ii)(A), (3), (b)(1)(ii), (2), (3)(v)(E)(*1*), (*2*), (4)(i)(B), (e)(1) introductory text, (ii), (3), (4), and (f) revised; (b)(1)(iii), (3)(ix) through (xvii), (4)(i)(C), (iv)(O), (P), (e)(1)(i)(F), (2)(iv), and (v) added.....79536
414.1405 (b)(9)(iii) added.....79538
414.1415 (a) revised.....79538
414.1420 (b) revised.....79539
414.1430 (a)(1)(iv), (2)(iv), (3)(iv), (4)(iv), (b)(1)(i)(A), (B), (i)(A), (B), (3)(i)(A), (B), (4)(i)(A), and (B) revised; (a)(1)(v), (2)(v), (3)(v), and (4)(v) added.....79539
414.1450 (a)(1)(i) and (ii) added; (b)(1) revised.....79539
414.1600—414.1690 (Subpart Q) Added.....77876
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415.140 (a) amended.....79539
416 Technical correction.....297
416.51 (c) removed.....36510
416.171 (a)(2)(iii), (iv), (vi), (vii), (viii)(B), and (C) revised.....82179
416.172 (d) revised.....82179
416.305 (b)(1) revised.....82179
416.310 (c)(1)(i) and (d)(1) revised.....82179
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418.60 (d) removed.....36510
418.56 (a)(1)(iii) revised.....79539
418.114 (b)(9) and (10) added.....79539
418.204 (d) removed.....51199
418.309 (a)(1) and (2) amended.....51199
418.312 (j) added.....51199
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419.20 (b)(5) added 82180
419.21 (c) revised 82180
419.22 (w) and (x) added 82180
419.32 (b)(1)(iv)(B)(*11*) revised; (b)(1)(iv)(B)(*12*) added 77193
419.41 (d) through (g) added 82180
419.46 Heading, (b), (c), (d)(2), (e)(1), (g)(1), and (i)(2) revised 82180
419.92 (d) added 59335
419.92 (e) and (f) added 82181
419.93 (a)(2) revised 82181
419.95 Added 82181
422 Authority citation revised 79539
422.62 (b)(18) removed; (b)(26) redesignated as (b)(27); new (b)(26) added 22328
422.62 Correction: (b)(18) revised 50044
422.100 (n) added 22328
422.101 (b)(2) and (c) revised; (b)(6) added 22328
422.109 Heading revised; (e) and (f) added 22329
422.111 (b)(3)(i) and (e) revised 22329
422.112 (a)(1)(iii) and (b)(8) added; (a)(1)(i) and (3) amended; (a)(6)(i), (8), and (b)(3) revised 22330
422.113 (b)(1)(i) introductory text revised 22330
422.116 (a)(1)(i), (d)(2) Table 1, and (e)(3)(i)(C) Table 2 amended; (b)(1)(xxviii), (xxix), (d)(5)(xiii), and (xxiv) added 22330
422.137 Added 22331
422.138 Added 22331
422.152 (a)(5) added 22332
422.162 (a) amended; (b)(1) and (3)(iv)(A)(*1*) revised 22332
422.164 (e)(1)(iii) added 22332
422.166 (f)(3) added; (a)(2)(i), (c)(1), (d)(1), (e)(1)(iii), (iv), (f)(1) introductory text, (2)(i) introductory text, (g)(1), (i)(3)(iv), (9)(i), and (10)(i) revised 22332
422.166 Correction: Amended 37175
422.202 (b)(1)(i) revised 22334
422.300 Revised 6665
422.310 (e) revised 6665
422.310 (f)(3)(iv) added 79539
422.311 (a) revised 6665
422.503 (e)(1) and (2) revised 22334
422.504 (a)(19) added 22334
422.510 (a)(4)(xvi) added 22334
422.514 (d)(1) revised; (g) added 22334

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422.566 (d) revised 22334
422.590 (b)(1) revised 22334
422.629 (k)(3) revised 22335
422.2261 (a)(2) revised; (a)(3) removed 22335
422.2262 (a)(1)(ii) revised; (a)(1)(xix) added 22335
422.2263 (b)(8) through (10) added 22335
422.2264 (c)(1)(ii)(C) removed; (c)(1)(ii)(D) and (E) redesignated as new (c)(1)(ii)(C) and (D); (a)(2)(i)(A) and (B) added; (b)(2), new (c)(1)(ii)(D), (2)(i), (3)(i), (iii)(A), and (B) revised 22335
422.2265 (b)(4) revised 22336
422.2267 (a)(3) redesignated as (a)(5); new (a)(3), (4), and (e)(4)(viii) added; (e)(4) introductory text, (5)(ii)(A) introductory text, (10) introductory text, (12), (30)(vi), and (41) revised 22336
422.2267 Correction: (a)(3), (e)(41) introductory text, and (i) amended 34780
422.2272 (e) added 22337
422.2274 (c)(12) added; (g)(2)(ii) revised 22337
423.4 Amended 22337
423.38 (c)(16) revised; (c)(34) redesignated as (c)(35); new (c)(34) added 22337
423.154 (c) revised 22337
423.160 (a)(5)(ii) through (iv) redesignated as (a)(5)(i) through (iii); (a)(5) introductory text and new (ii) revised; (a)(5)(i) removed 79540
423.182 (a) amended; (b)(1) and (3)(ii)(A)(*1*) revised 22337
423.184 (e)(1)(iii) added 22338
423.186 (a)(2)(i), (c)(1), (d)(1), (e)(1)(iii), (iv), (f)(1) introductory text, (2)(i) introductory text, (g)(1), (i)(7)(i), and (8)(i) revised; (f)(3) added 22338
423.186 Correction: Amended 37175
423.265 (b)(2) and (3) redesignated as new (b)(3) and (4); new (b)(2) and new (4) heading added 22339
423.308 Amended 22340
423.505 (b)(22) revised 22340

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423.773 (b)(1) and (d) introductory text revised; (b)(2)(ii) amended; (b)(2)(iii) added 22340
423.780 (d) introductory text revised 22340
423.2261 (a)(2) revised; (a)(3) removed 22340
423.2262 (a)(1)(ii) revised; (a)(1)(xviii) added 22340
423.2263 (b)(8) through (10) added 22340
423.2264 (a)(2)(i)(A) and (B) added; (c)(1)(ii)(C) removed; (c)(1)(ii)(D) and (E) redesignated as new (c)(1)(ii)(C) and (D); (b)(2), new (c)(1)(ii)(D), (2)(i), (3)(i), (iii)(A), and (B) revised 22340
423.2264 Correction: (c)(3)(i)(A) amended 34780
423.2267 (a)(3) redesignated as (a)(5); new (a)(3), (4), (e)(4)(viii), and (42) through (44) added; (e)(4) introductory text, (13) introductory text, (32)(vi), and (41) revised 22341
423.2267 Correction: (e)(41) introductory text and (i) amended 34780
423.2272 (e) added 22341
423.2274 (c)(12) added; (g)(2)(ii) revised 22342
423.2500—423.2536 (Subpart Y) Added 22342
423.2536 Correction: (c) introductory text amended 34780
423.2600—423.2615 (Subpart Z) Heading revised 22344
424 Technical correction 297
424.24 (b) and (e)(1)(i) revised; (d) added 82182
424.205 (a) amended; (c), (10)(iii), and new (f)(5)(iii) removed; (d) through (i) redesignated as (c) through (h); new (f)(5)(iv) and (v) redesignated as (f)(5)(iii) and (iv); (b)(1), new (c)(1), new (14), new (f)(2)(i), new (5)(iii), and (g)(1)(i)(C) revised 79540
424.210 (b)(2) and (d)(1) revised 79540
424.502 Amended 77877, 79540, 80168
424.507 (b) introductory text and (1) introductory text revised; (b)(3) added 51199
424.516 (d)(1)(iii) and (e)(1) revised 79541

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424.516 (g) added 80168
424.518 (b)(1)(iv) and (x) through (xiv) removed; (b)(1)(v) through (viii) and (xii) redesignated as (b)(1)(iv) through (vii) and (viii); new (b)(1)(viii), (ix), and (c)(1)(vi) revised; (c)(1)(vii) and (viii) added 77877
424.527 Added 77877
424.530 (f) introductory text amended; (f)(3) added 77878
424.530 (a)(1) revised; (a)(16), (17), and (18) added 79541
424.535 (a)(1) introductory text, (17) introductory text, (e), and (g) revised; (a)(17)(i) through (vi) redesignated as (a)(17)(i)(A) through (F); (a)(15), (17)(ii), and (23) added 79541
424.540 (a)(1) amended 77878
424.541 Added 79542
424.542 Added 77878
424.550 (b)(1) introductory text revised; (b)(1)(i) and (2)(i) through (iv) amended 77878
424.555 (b) revised 79543
425.20 Amended 79543
425.106 (c)(5) revised 79544
425.204 (c)(3)(ii) amended, (c)(3)(iii) revised 79544
425.302 (a)(3)(iii) revised 79544
425.308 (b)(9) added 79544
425.316 (e)(2) introductory text and (i) revised 79544
425.400 (a)(2)(ii), (c)(1)(vii) introductory, (2)(i) introductory text, and (ii) revised; (a)(3)(i) amended; (c)(1)(viii) added 79544
425.402 (b)(1) and (c) introductory text revised; (b)(5) added; (e)(2)(ii)(A) amended 79545
425.506 (f) introductory text revised 79546
425.507 Added 79546
425.512 (b)(2) and (3) redesignated as (b)(3) and (4); (a)(2), (5)(i)(A)(*2*), (iii)(A), (B), new (b)(3)(ii)(B), new (iv)(A), new (4)(i), and (c)(3) revised; (a)(5)(i) introductory text, (b)(1), new (3)(iii), new (iv)(B), new (v), and (4) introductory text amended; (a)(7) and new (b)(2) added 79546
425.600 (f)(4)(ii) amended 79547

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425.601 (a) introductory text amended 79547
425.611 (c)(2)(iii) amended 79548
425.630 (b)(2), (3), (e)(3), (f) introductory text, and (g)(4) revised; (h)(1)(i) and (ii) amended; (h)(1)(iii) and (i) added 79548
425.650 (a) amended 79548
425.652 (a) introductory text, (9)(iv), and (v) amended; (a)(5)(v)(A), (8), (9) introductory text, (ii), and (b)(2)(iv)(A) revised; (a)(9)(vi) and (b)(2)(ii)(C) added 79548
425.654 (a)(1)(i) revised 79549
425.655 Added 79549
425.656 (b)(3) revised; (d) and (e) redesignated as (e) and (f); (c)(2), new (e)(5)(ii), new (iv), and new (f) introductory text amended; (d) added 79550
425.658 (b)(3)(i) amended; (c) revised; (d) and (e) added 79551
425.659 Added 79551
425.702 (c)(2)(ii) introductory text amended; (c)(1)(ii)(A)(*3*) revised; (c)(1)(iii) added 79551

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414 Technical correction 6019
414 Notification 41324, 58071
414.84 (a) amended; (b)(1) introductory text, (2) introductory text, and (d) revised; (c)(4) added; (e) removed 98558
414.502 Amended 98559
414.504 (a)(1) amended 98559
414.507 (d) introductory text, (7), and (8) revised; (d)(10) and (11) added 98559
414.605 Amended 98559
414.902 Amended 98559
414.904 (e)(6) added; (i) revised 98559
414.1001 (a) revised; (b) removed; (c) and (d) redesignated as new (b) and (c); new (b)(2) amended 98560
414.1305 Amended 54716
414.1325 (a)(1)(i) through (iii) and (f) added 98560
414.1330 (c) added 98561
414.1335 (a) introductory text revised; (b) added 98561

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414.1340 (a)(4), (b)(4), (d) introductory text, and (1) revised 98561
414.1350 (e) added 98561
414.1355 (d) added 98561
414.1365 (b)(2)(i), (c)(3)(i), (ii), (4)(i)(A), (d)(3)(i)(A) introductory text, (*1*), (ii) introductory text, (A), and (iii) revised 98562
414.1367 (c)(1) introductory text revised; (c)(1)(iii) added 98562
414.1375 (b) introductory text revised 54717
414.1380 (b)(1)(ii) introductory text, (iv)(B), (vii) introductory text, (2) introductory text, and (3) introductory text revised; (b)(1)(ii)(E), (F), (iv)(C), (vii)(C), (2)(i)(A), (B), (v)(B), (c)(2)(i)(A)(*10*), and (C)(*12*) added 98562
414.1405 Correction: (b)(9)(iii) amended 9784
414.1405 (b)(10) added; (g) revised 98564
414.1430 (a)(1)(v), (2)(v), (3)(v), (4)(v), (b)(1)(i)(A), (B), (2)(i)(A), (B), (3)(i)(A), (B), (4)(i)(A), and (B) revised; (a)(1)(vi), (2)(vi), (3)(vi), and (4)(vi) added 98564
414.1450 (a)(1)(i) revised; (b)(1) amended 98564
416 Technical correction 9002
416.164 (a)(4) and (b)(6) revised 94588
416.171 (b)(1) revised 94588
416.174 Revised 94588
416.320 (b) revised 94589
417.460 (c)(3), (e)(2), and (4) revised; (e)(7) added 30812
417.472 (l) added 30812
417.911 Amended; eff. 10-1-25; interim 80069
418 Technical correction 79764
418.22 (c)(1)(i) revised 64272
418.24 (a) and (b)(3) revised; (e) through (h) redesignated as (f) through (i); new (e) added 64272
418.25 (a) and (b) introductory text revised 64272
418.102 Introductory text, (b) introductory text and (c) revised 64272
418.114 (b)(9) revised 64272
418.309 (a)(1) and (2) amended 64272
418.312 (b)(1) revised 64272
419 Technical correction 9002
419.2 (b)(15) revised 94589

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419.41 (h) through (j) added 94589
419.43 (k) added 94590
419.46 (i)(2) revised; (j) added 94590
419.47 Heading and (a) introductory text revised 94590
419.82 (d)(1)(iii) revised 94591
422 Authority citation revised 30812, 63826
422.2 Amended 30812
422.4 (a)(1)(iv)(A) and (B) added 30814
422.52 (b)(2) and (f) revised; (g) added 30814
422.60 (a)(1) revised; (a)(3), (h), and (i) added 30814
422.62 (a)(1)(i), (4), (b)(2), and (18) introductory text revised; (b)(18)(i) through (iii) redesignated as (b)(18)(ii) through (iv); new (b)(18)(i) added 30815
422.66 (b)(3)(v) and (6) added 30815
422.68 (g) added 30815
422.74 (c), (d)(1)(i)(B)(*1*), (v), (2)(iii), (iv), (4)(i), (iv), and (e)(1) revised; (d)(8) redesignated as (d)(9); (b)(2)(vi), (d)(2)(vii), (4)(ii)(A), (iii)(F), new (8), and (10) added 30816
422.74 Correction: (d)(4)(i) revised 63826
422.100 (o) added 30817
422.101 (f)(2)(iv) and (3)(iv) added; (f)(3)(iii) revised 30817
422.101 Correction: (f)(3)(iv)(B)(3) amended 79451
422.102 (f)(1)(i)(A)(*2*), (3), and (4) revised; (f)(5) added 30818
422.102 Correction: (f)(4) added 63826
422.111 (h)(1)(iv)(B) revised; (l) added 30818
422.114 (a)(3)(ii) revised 30819
422.116 (b)(2)(xiv), (d)(5)(xv), (f)(2)(iv), and (3) added; (d)(2) Table 1 and (f)(1) introductory text amended; (f)(1) revised 30819
422.116 Correction: (f)(1) revised 63827
422.119 (b)(1)(ii) amended; (b)(1)(iii), (c)(1), (4)(ii)(C), (e)(2), (f), and (h) revised; (b)(1)(iv) and (v) added 8974
422.121 Added 8974
422.122 Added 8976
422.125 Added 30820
422.137 (c)(5), (d)(6), and (7) added 30820

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422.164 (d)(1)(v) and (g)(1)(iii) revised; (h)(3) added 30820
422.166 (e)(2) and (f)(2)(i)(B) revised; (f)(3)(viii)(A) and (B) added 30821
422.254 (a)(5) added 30822
422.260 (c)(1)(i), (2)(v), (vii), and (d) revised; (c)(3)(iii) added 30822
422.310 (f)(1)(vi) and (vii) revised; (f)(3)(v) added 30822
422.311 (a), (c)(5)(ii)(B), (iii), (6)(i)(A), (iv)(B), (7)(ix), (8)(iii), and (iv) through (vi) revised; (c)(5)(ii)(C) removed; (c)(5)(iv), (6)(v), (8)(vii), and (9) added 30822
422.326 (c) revised 98565
422.500 (b) amended 30823
422.502 (a)(1) heading, (2) heading, and (3) added; (b)(1)(i)(A), (B), and (C) revised; (b)(1)(i)(E)(*2*)(*A*) and (*B*) removed 30824
422.503 (b)(8) added 30824
422.504 (a)(15) revised; (a)(20) and (21) added 30824
422.510 (e) added 30824
422.514 (d)(1) introductory text, (ii), (2) introductory text, and (ii) revised; (e)(1)(i), (iii), and (iv) amended; (e)(1)(v) and (h) added 30824
422.514 Correction: (h)(2) amended 79451
422.516 (a) introductory text and (2) revised 30825
422.528 Added 30825
422.529 Added 30825
422.530 (c)(4)(iii) added 30826
422.550 (d) revised 30826
422.568 (b)(1) revised; (b)(2) redesignated as (b)(3); new (b)(2) added; new (b)(3) amended 8976
422.570 (d)(1) amended 8977
422.582 (b) revised 30827
422.584 (b) introductory text revised; (b)(3) and (4) added 30827
422.626 (a)(2) revised; (a)(3) removed 30827
422.631 (d)(2)(i)(B), (iv)(B)(*1*), and (*2*)(*i*) revised 8977
422.633 (d)(1) revised 30827
422.760 (b)(3) revised 30827
422.2267 (e)(31) and (34) revised; (e)(42) added 30827
422.2267 Correction: (e)(34) revised 63827

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422.2274 (a) amended; (c)(5), (13), (d)(1)(ii), (2) introductory text, (3) introductory text, (e)(1), and (2) revised; (g)(4) added 30829
422.2274 Correction: (c)(13) added 63827
423 Technical correction 72999
423.4 Amended 30829
423.32 (h) through (j) added 30830
423.36 (b)(4) and (d) through (f) added 30830
423.38 (c)(4)(i), (7), and (23) introductory text revised; (c)(23)(i) through (iii) and (35) redesignated as (c)(23)(ii) through (iv) and (36); new (c)(23)(i) and new (35) added 30830
423.40 (f) added 30831
423.44 (d)(2)(iv) through (vii) redesignated as (d)(2)(v) through (viii); (b)(1)(iii), new (d)(2)(iv), and (9) added; (d)(1) introductory text, (iii)(A), (v), (vi), (2)(iii), new (v), (5)(i), and (ii) revised 30831
423.44 Correction: (d)(2)(iii) through (viii) revised 63827
423.100 Amended 30832
423.100 Correction: Amended 63828
423.104 (d)(2)(iv)(A)(6) amended 30833
423.120 (b)(3)(i)(B), (5), and (6) revised; (e) and (f) added 30833
423.128 (d)(1)(v)(B), (2)(iii), and (e)(6) revised 30834
423.129 Added 30834
423.150 (a) amended 30834
423.153 Heading, (d)(1)(vii)(B)(*1*)(*i*), (*2*), (2)(i)(C), (5)(i), (ii), and (f)(8)(i)(A) revised; (d) heading removed; (d)(1) introductory text, (2) introductory text, (3), (4), (6), and (8)(i) introductory text amended; (f)(8)(ii) redesignated as (f)(8)(iii); (d)(2)(iii), (iv), and new (f)(8)(ii) added 30834
423.153 Correction: Heading revised; (a), (d)(1)(vi), (vii) introductory text, and (6) amended; (d) heading added; (g)(1) through (iii) redesignated as (g)(1)(i) through (iii) 79452
423.160 Revised 51263
423.160 (a)(5) introductory text revised 98565
423.165 (b)(2) amended 30835

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423.184 (d)(1)(v) revised; (h)(3) added 30835
423.186 (e)(2) and (f)(2)(i)(B) revised; (f)(3)(viii)(A) and (B) added 30835
423.265 (b)(5) added 30836
423.293 (a)(4) amended 30836
423.294 Added 30836
423.308 Amended 30837
423.346 (a) introductory text revised; (a)(2) amended; (e) through (g) added 30837
423.346 Correction: (e)(2) amended 79452
423.360 (c) revised 98565
423.501 Amended 30837
423.501 Correction: Amended 63828
423.503 (a)(1) heading, (2) heading, (3) heading, and (4) added; (b)(1)(i)(A) and (C) revised 30837
423.505 (b)(22) revised; (i)(6) added 30838
423.507 (a)(3) revised 30838
423.508 (e) revised 30838
423.509 (f) added 30838
423.514 (a) introductory text and (2) revised 30838
423.521 Added 30838
423.522 Added 30839
423.522 Correction: (c) and (d) removed; (e) and (f) redesignated as new (c) and new (d) 63828
423.530 Added 30839
423.551 (e) revised 30840
423.562 (a)(1)(v) revised 30841
423.578 (d) revised 30841
423.582 (b) revised 30841
423.584 (b) introductory text revised; (b)(3) and (4) added 30841
423.584 Correction: (b) introductory text and (4) amended 63828
423.600 (a) revised 30841
423.760 (b)(3) revised 30841
423.2267 (e)(33) revised 30842
423.2274 (c)(13) and (g)(4) added; (c)(5), (d)(1)(ii), (2) introductory text, (3) introductory text, (e)(1), and (2) revised; (a) amended 30842
424 Technical correction 6019, 9002, 104064
424.24 (c) heading, (1)(i), and (3)(ii) revised; (c)(5) added 98565
424.205 (c)(10), (f)(1)(ii), (2)(i), and (5) revised 98565
424.527 (a)(4) added 88485

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424.541 Correction: (a)(2)(ii)(B)(*3*) through (*5*) removed; (a)(3) through (5) added 9784
425.100 (e) added 98566
425.110 (b)(2) revised 98566
425.202 (a)(3) revised 98566
425.204 (f)(1) and (3) introductory text revised; (f)(3)(iv), (4)(iv)(A), (5), (6)(ii) introductory text, (iii), (iv)(A), and (C) amended 98566
425.208 (b)(6) added 54717
425.218 (b)(3) revised 54717
425.224 (a)(3) revised 98566
425.304 (d) added 98566
425.305 (a)(1) revised 54717
425.308 (b)(10) added 98566
425.312 (a)(2)(iii) and (v)(A) revised 98566
425.315 (a)(4) revised; (b) added 98567
425.316 (f) added 98567
425.400 (c)(1)(viii) introductory text revised; (c)(1)(ix) added 98567
425.402 (e)(2)(ii) introductory text revised; (e)(2)(iii) added 98568
425.508 (b) revised; (c) added 98568
425.510 Heading and (b) revised 98568
425.512 (a)(2)(iii), (5)(i) introductory text, (A) introductory text, (B), (ii), (iii)(B), (7), and (b) revised; (a)(2)(iv), (5)(i)(C), (iii)(C), and (c)(3)(iv) added; (c)(3) introductory text and (iii) amended 98568
425.601 (a)(9) introductory text revised; (a)(9)(iii) and (iv) added 98570
425.605 (a)(1)(ii)(C) revised 98571
425.610 (a)(2)(ii)(C) revised 98571
425.630 (g)(3), (h)(1)(ii), and (iii) amended; (g)(5) redesignated as (g)(7); new (g)(5), (6), and (h)(1)(iv) added 98571
425.640 Added 98571
425.650 (a) amended 98574
425.652 (a)(8) and (9) revised 98574
425.655 (d)(2) revised 98576
425.658 (d) revised 98576
425.662 Added 98576
425.670 Added; eff. 10-15-24 79171
425.672 Added 98576
425.674 Added 98577
427 Added 98578
428 Added 98588

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417 Technical correction 22649
417.486 (a)(1) and (2) amended; (a)(3) added 15909
418 Technical correction 42709
418.22 (a)(4)(ii) and (b)(4) revised 37430
418.25 (a) and (b) introductory text revised 37431
418.312 (j)(2) revised 37431
422 Technical correction 22649
422.2 Amended 15909
422.101 (f)(1) revised 15909
422.102 (f)(1)(iii) added 15910
422.111 (m) added; eff. 11-17-25 45151
422.116 (a)(1) through (4) redesignated as (a)(2) through (5); new (a)(1) added; new (a)(2)(i) and (b)(2)(xiv)(A) amended 15910
422.138 (c) revised 15910
422.562 (c)(2) revised 15910
422.566 (b)(3) revised 15910
422.568 (b)(1) introductory text, (d) introductory text, and (f) revised 15910
422.572 (f) revised 15911
422.616 (a) revised; (e) added 15911
422.631 (a) and (d)(1)(i) and (ii) revised 15911
422.2267 (e)(30)(vi) and (vii) amended; (e)(30)(viii) added 15911
422.2420 (b)(4)(i)(D) added 15911
423 Technical correction 22649
423.100 Amended 15911
423.120 (g) and (h) added 15912
423.137 Added 15912
423.325 Added 15919
423.505 (q) added 15919
423.2265 (b)(16) added 15920
423.2267 (e)(32)(vi) and (vii) amended; (e)(32)(viii) and (45) through (51) added 15920
423.2420 (b)(4)(i)(D) added 15920
423.2536 (c) through (k) redesignated as (d) through (l); new (c) added; new (i)(1) and (4) revised 15920
427.302 Correction: Heading and (c) introductory text revised 20808
427.401 Correction: (b)(2)(iv) amended 20808

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427.501 Correction: (d)(1)(i) introductory text revised	20808
428.202 Correction: Heading and (a) revised	20808
428.204 Correction: Introductory text amended; (b) revised	20808
428.301 Correction: (b)(2)(iv) amended	20808